The International Comparative Legal Guide to: Product Liability 2005

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This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Eight general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability law and regulation in 34 jurisdictions.

All chapters are written by leading product liability lawyers and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers, for all their assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.co.uk.

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Introduction

The key piece of European product liability legislation is the Product Liability Directive, 85/374/EEC (the “Directive”), which lays down common rules governing liability for defective products in the European Union (“EU”). Although the strict liability regime imposed by the Directive has general support amongst Member States, its scope has proved controversial, almost since its inception. In particular, the so-called “development risks defence”, which gives the producer of a defective product a defence if he can establish that the defect was not discoverable when the product was supplied, has been the subject of intense scrutiny and discussion. Consumer groups and some Member States argue that the defence effectively re-introduces fault based liability by the ‘back door’ into legislation that was intended to impose strict liability, and there has been pressure over the years to abolish it.

Proposals for reform of product liability legislation in the EU have focussed on the defence and are discussed in more detail below. To set matters in context we outline first the key provisions of the Directive and the broader product liability regime in Europe.

The Product Liability Directive

The Directive imposes strict liability on a producer of defective products for damage caused by the defect. The burden of proof rests on the injured person to prove the defect, damage, and a causal relationship between these two. However, it is not necessary to establish negligence on the part of the producer or importer and, therefore, it was anticipated that the Directive would enable persons injured by products to obtain compensation more readily than had been the case with fault-based liability systems throughout the EU. A product is defective when it does not provide the safety that the general public is entitled to expect taking account of a range of factors including the product’s presentation, the time when it was put into circulation, and its expected use.

The Directive applies to almost all consumer products. Following the BSE crisis it was extended to include unprocessed agricultural products.

Although the Directive imposes a common set of rules it contains two important derogations:

- the development risks defence, which gives the producer a defence if he can establish that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered. Member States can opt out of this requirement and impose strict liability irrespective of whether the defect could be discovered; and
- the Directive gives Member States the option of setting a maximum limit of not less than ECU 70 million on a producer’s total liability for damage resulting from death or personal injury caused by identical items with the same defect.

All EU Member States, including the 10 accession Member States, have now adopted the Directive in their national legislation. The table below identifies those Member States that have adopted the development risks defence and imposed an upper limit on producer liability.

<table>
<thead>
<tr>
<th>Member State</th>
<th>Development Risk Defence included</th>
<th>Financial ceiling on producer’s liability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Belgium</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>The Czech Republic</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Denmark</td>
<td>Yes, but pre-existing law, which remains in force, imposes liability for development and production risks in relation to pharmaceutical products.</td>
<td>Yes</td>
</tr>
<tr>
<td>Finland</td>
<td>Yes, but with exclusions (defence not available for products derived from the human body).</td>
<td>No</td>
</tr>
<tr>
<td>France</td>
<td>Yes, but with exclusions (defence not available for products derived from the human body).</td>
<td>No</td>
</tr>
<tr>
<td>Greece</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hungary</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Ireland</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Italy</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
The Scope of the Development Risks Defence

Much uncertainty remains about the scope of the Directive and, in particular, the development risks defence. Few cases have been decided by national courts applying the Directive and case law on the development risks defence is particularly limited. The European Court of Justice (“ECJ”) has only considered the defence once, in a case against the UK Government regarding its implementation of the Directive. The court discounted the knowledge of intermediaries (health professionals) about the risks to health that it was said rendered the product defective, deciding that the correct test was the expectation of consumers.

There is potential for divergence between Member States in the way national courts interpret the Directive in answering these, and other questions. It is to be hoped that these matters will be addressed in a reference to the European Court in the near future, as more cases are pursued under the Directive.

Scope of Article 11

One area of uncertainty may soon be clarified. In November 2003 the English courts referred to the European Court of Justice certain questions regarding the interpretation of Article 11 of the Directive in the case of Master Declan O’Byrne v Aventis Pasteur MSD and Aventis Pasteur SA.

The Claimant alleged that he became brain damaged as a result of receiving the HiB vaccine. He mistakenly brought proceedings against Aventis Pasteur MSD, believing it to be the producer of the vaccine; in fact the producer was Aventis Pasteur SA, APMSD’s then French parent company. The Claimant commenced a second action against Aventis Pasteur SA (by then no longer the immediate parent of APMSD) after the 10 year “long stop” period had expired; he also applied to substitute the French company as the Defendant in similar circumstances and whether national courts have a discretion to allow the substitution of a Defendant or the commencement of an additional set of proceedings against the same Defendant when that period has expired.

The European Court of Justice (“ECJ”) has been asked to rule on the application of the 10 year long stop period in these circumstances and whether national courts have a discretion to allow the substitution of a Defendant or the commencement of an additional set of proceedings against the same Defendant when that period has expired. (In a previous decision the English Court of Appeal permitted the substitution of a Defendant in similar circumstances where the Claimant made a mistake as to the name of the correct Defendant, but not its identity - he always intended to sue...

The ECJ has also been asked to provide guidance on when in the supply chain a product is “put into circulation”; is it when (on the facts of the O’Byrne case) it leaves the French manufacturer, when it arrives at the English subsidiary, when it leaves the English subsidiary, or when it reaches the national health body that will supply it to a patient? The oral hearing took place in April 2005 and the Advocate-General will deliver his opinion in June 2005. A decision of the Court is not expected until late 2005 at the earliest.

**Minimal or Maximal Requirements - Can Member States Provide Greater Consumer Protection?**

A widely held misconception was that the Directive laid down minimum requirements, and it was therefore open to Member States to adopt the Directive in such a way as to provide greater protection to consumers. The position has recently been clarified in a series of decisions handed down by the ECJ (Case C-52/00, Commission of the European Community v French Republic, Case C-134/00, Commission of the European Community v The Hellenic Republic (Greece); Case C-183/00, Maria Victoria Gonzalez Sanchez v Medicina Asturiana SA), which confirmed that Member States could not impose a more rigorous scheme of liability than that laid down in the Directive. Derogations were permitted only where these were specified and narrowly defined in the Directive itself.

Two of the cases, brought by the Commission against France and Greece seeking declarations that both countries had incorrectly transposed the Directive into national law, raised similar issues. Both the French and Greek Governments had declined to implement the lower threshold of EUR 500 for damage to property claims imposed by Article 9(b) of the Directive. Both sets of implementing legislation permitted recovery in respect of all damage to private and public property, whatever the value. In addition, the French Government sought to add a further condition to the development risks defence stating that a producer was only able to rely on the defence if he could prove that he had taken appropriate steps to monitor post-marketing use of his product. The French implementing legislation also made the supplier of a defective product liable on the same basis as the producer in all cases, not just in circumstances where the supplier was unable to identify the producer or the person from whom he bought the defective product in response to a request from the injured party.

The ECJ ruled against the French and Greek Governments on all issues finding that the Directive was intended to establish “a harmonised system of civil liability on the part of producers in respect of damage caused by defective products”. The purpose of the Directive was to “ensure undistorted competition between traders, to facilitate the free movement of goods and to avoid differences in levels of consumer protection”.

**The Product Liability Regime in EU Member States**

Although the Directive’s requirements are applied strictly, in practice the product liability regimes available in different EU Member States vary widely. The reason for this is that the Directive supplements, but does not replace, existing product liability laws in force at the time the Directive was made. Most countries have fault based and contractual laws, and some also have so called “special liability systems” applicable to particular product sectors. For example, under German law a special scheme applies to pharmaceutical products, which imposes strict liability for development and production risks. As a result, it is common for claims under a number of different laws to be brought in parallel. In addition, the courts in some Member States interpret fault based liability widely with the result that there is little practical difference between rights under the Directive and under other liability systems.

The scope of these provisions was considered by the ECJ in the Sanchez case, which is referred to above. Ms Sanchez claimed to have been infected with Hepatitis C virus after receiving a blood transfusion from a medical establishment belonging to Medicina Asturiana. She sought compensation under both the Spanish law implementing the Directive (Law No. 22/94) and the previous Spanish legislation (Law No. 26/84) which imposed a system of strict liability enabling consumers to obtain compensation for damage caused by the use of a defective product or service. The Spanish court ruled that consumers rights under the earlier law, No. 26/84, were more extensive than those arising under Law No. 22/94, implementing the Directive, but sought guidance from the ECJ on whether the Directive operated to curtail consumers rights under the pre-existing law.

The ECJ decided that although other, different, systems of product liability (such as fault based or contractual laws) could remain in force, the Directive could not be interpreted to give Member States the possibility of maintaining a general system of strict product liability different from that provided for in the Directive. It ruled that:

“a system of producer liability founded on the same basis as that put in place by the Directive and not limited to a given sector of production does not come within any of the systems of liability referred to in Article 13 of the Directive. That provision cannot therefore be relied on in such a case in order to justify the maintenance in force of national provisions affording greater protection than those of the Directive.”

It decided that a “special liability system” was a specific scheme limited to a given sector of production that was in existence at the time when the Directive was notified. The Court therefore concluded that Ms Sanchez was not entitled to recover compensation under the earlier Spanish law.

**Amendment of the Directive to Relax the Rules on Supplier Liability**

The ECJ’s decisions in the three cases outlined above have resulted in controversy, most particularly in France, but also in other Member States that had introduced into their national legislation provisions that arguably went beyond the
scope of the Directive. In particular, Denmark implemented laws including provisions relating to supplier liability similar to those imposed by the French Government. As a result, towards the end of 2002, the Danish presidency of the EU announced that it would present an “EU initiative designed to ensure a continued level of consumer protection in the field of product liability”. The initiative was intended to address the issue of supplier liability.

On 19 December 2002 the Council of Ministers adopted a resolution seeking amendment of the Directive to impose supplier liability. The resolution provides that the Council considers there is a need to assess whether the Directive: “should be modified in such a way as to allow for national rules on liability of suppliers based on the same grounds as the liability system in the Directive concerning liability of producers”.

Although the resolution provides an indication of some Member States’ ongoing concerns regarding the scope of the Directive, and the need to provide consumers with adequate protection from defective products, no legislative steps are presently being undertaken to amend the Directive to implement the resolution and to introduce supplier liability. It remains to be seen whether the issue of supplier liability will be pursued in future.

Reform of the Directive

Reform of the Directive has focussed on the development risks defence, which has proved controversial since the inception of the Directive. Indeed, when the Directive was originally drawn up in 1985 the matter was dealt with provisionally on the basis that the Commission would report on the operation of the defence and the financial ceiling on producer’s liability 10 years after the Directive was notified. The first report was presented in 1995 and concluded that the Directive had increased awareness of, and emphasis on, product safety. However, at that stage very few cases had been brought in Member States and experience of the operation of the Directive was limited. The Commission therefore considered that it was not appropriate to amend the Directive.

In the aftermath of the BSE crisis, the Commission sought to extend the scope of the Directive to include unprocessed primary agricultural products and this amendment was eventually enacted in Directive 99/34. During the course of consultation on the Directive, various parties, including the European Parliament, called for substantial revisions and it was agreed that a fuller debate should be conducted in the form of a Green Paper which would pave the way for the second report on the application of the Directive. The Green Paper was published in July 1999 and sought to obtain information on how the Directive had worked in practice and to what extent it should be modified.

Following an extensive consultation period, the Commission published its second report on 31 January 2001. Overall the Commission concluded that it remained the case that there was insufficient information to draw firm conclusions, and it would therefore be premature to make changes to the Directive. In summary, the situation prevailing was as follows:

- There was limited experience in relation to application of the Directive. This was due to two main factors - the late transposition of the Directive in some Member States and the possibility of pursuing other remedies under alternative laws e.g fault liability.

- Based on the limited information available, no major problems were identified with the application of the Directive.

- Member States supported the maintenance of a cost effective framework preserving the balance between the interests of consumers and producers. The Commission indicated that any changes to the Directive should be grounded on an objective factual basis.

Further Actions

However, in the light of the limited information available, the Commission stated that it intended to take a number of follow-up actions and we outline the current position regarding those actions.

- Expert group - the Commission has set up an expert group on product liability involving national experts nominated by the Governments of the Member States. It is intended that the expert group will gather information on the product liability regimes in all Member States, including information on the legal application of the Directive, recent case law and changes in national legislation impacting on product liability (including issues concerning access to justice).

- Injury data - the Commission intends to update existing systems of injury data collection so that it is possible to identify and collate information on injuries caused by defective products and services. The previous system, EHLASS (European Home and Leisure Accident Surveillance System), did not identify injuries caused by defective products.

- Practical effect study - a report on the practical operation of the systems of law under which product liability claims may be brought in each Member State was published in March 2003. These systems include the Directive and “national” systems of law such as those of contract and tort, which are permitted to operate alongside the Directive by virtue of Article 13. The Study also considered the extent to which there is a need for further harmonisation of product liability laws in the EU, or to make any reforms of the Directive. The principal findings of the study are outlined below.

- Economic impact study - a further study to assess the economic impact on the internal market of the possible removal of the development risks defence was undertaken by Fondazione Rosselli, an independent Italian research institute, in 2003/4. The study was intended to assess the current impact on the internal market of the defence, to determine if its application has led to problems in practice for persons injured as a result of using defective products, to assess if there is a real economic need for the further protection of injured persons (taking account of a range of factors, including existing social security systems) and to evaluate whether the introduction of a stricter system of product liability would impact on the operation of the internal market. Its conclusions are outlined below.
**Conclusions of the Practical Effects Study**

The practical effects study found that there had been an increase in the number of product liability claims brought in the EU in the last 10 years and in the success of those claims. Although the Directive had contributed to that increase it was only one of a number of factors (such as the greater awareness by consumers of their rights, improved access to information, increased media activity, the wider availability of legal assistance and a change in judicial attitudes) which had prompted the increase.

In terms of the need for reform, the study’s authors (Lovells) concluded that overall the evidence did not point to the need for fundamental reform of the Directive. There was broad acceptance of the Directive in all Member States and although the respondents to the study had indicated issues of concern there was no consistent evidence from either consumers or producers of the need for reform of specific measures. Consumers identified three main issues for possible reform: the abolition of the development risks defence and the 10 year long-stop and the reversal of the burden of proof (so that the burden of proving defect, damage and causation rests on the producer). The study found that the development risks defence is, in practice, construed so narrowly that it is of little practical value to defendants. Indeed, it has only been relied upon successfully in one case in the Netherlands (the Sanquin Foundation case). The study therefore concluded that there was presently no justification for re-consideration of the defence. As many Member States had only recently implemented the Directive, the study concluded that it was possibly still too early to assess if there was a need for reform of the 10 year long-stop period which extinguishes a claimant’s right to bring proceedings. It also found that the evidence in relation to the burden of proof was evenly balanced.

The study also considered whether there was a need for further harmonisation of the Directive, by abolishing Article 13, so that the Directive becomes consumers’ sole remedy in respect of product liability claims. The report found there was no significant support for the abolition of Article 13 as it was generally accepted that this would be detrimental to consumers because they would lose their right to choose the most advantageous means of seeking compensation under the available liability schemes in each Member State.

The study also found that although further harmonisation was possible there were differences of approach to the interpretation of the Directive by national courts. However, greater consistency might arise as a result of developing experience of the Directive. The Commission did not consider that the differences of interpretation were currently so great as to justify its intervention to clarify the position.

**Conclusions of the Economic Impact Study**

The economic impact study specifically considered the impact of the development risks defence on the functioning of the EU’s internal market. It concluded that there remained a strong case for retaining the defence as it was “a significant factor in achieving the Directive’s balance between the need to preserve incentives to innovation and consumer’s interests.” In particular, Fondazione Rosselli found that the defence:

- protects incentives to innovate - it ensures that R&D resources are not diverted to meeting insurance costs;
- helps to prevent excessive litigation and is a key factor in ensuring that product liability costs remain stable; and
- without the defence companies in high-tech/high risk sectors would find it very difficult to obtain insurance to cover developmental risks - some risks would be uninsurable.

Overall, the report concluded that without the defence some producers would have little incentive to innovate, which would ultimately be detrimental to consumers. However, while the report acknowledged that there remained a strong case for retaining the defence, the authors also suggested that consumer protection could be strengthened by the introduction of other measures including mandatory EU wide compensation funds, funded both by public authorities and by industry. They indicated, in particular, that industry specific compensation funds could be set up in respect of ‘high risk’ product sectors including pharmaceuticals and vaccines, blood and blood products, food and chemicals. The operation of such funds was left for further discussion, but one possibility suggested by the report was that the funds could provide compensation for development risks.

If the defence is retained the authors suggested some secondary reforms:

- the application of the defence should be harmonised so that it is applied uniformly by all Member States and all industry sectors - this would involve repealing the ‘opt out’ provided to Member States;
- the Commission should produce guidance on the scope and application of the defence so that it is applied uniformly in all Member States; and
- there should be closer linkage between the Directive and laws relating to product safety (including the General Product Safety Directive).

It remains to be seen whether the European Commission will adopt Fondazione Rosselli’s recommendations. There are a number of difficulties with their proposal that centralised EU-wide compensation funds should be set up. In particular, it remains unclear how such funds would be financed. Fondazione Rosselli acknowledged that requiring industry alone to finance such funds would act as a disincentive to innovation. However, it remains unclear if any public funds will be made available by government bodies. Similarly, there are likely to be difficulties in setting the premium or contribution to be made by producers at a fair level, which properly reflects the type and extent of the risks/injuries that may be associated with use of the producer’s product. Unless the compensation scheme is transparent and objectively ‘fair’ it is unlikely to be workable.

**Conclusion**

The debate between EU institutions, Member States, manufacturers and consumers regarding the purpose and scope of the Directive continues. The two studies on the operation of the Directive are likely to influence the future shape of product liability legislation. The practical effects study suggests that the Directive is accepted in all Member States and the evidence does not currently suggest there is a
need for fundamental reform. The economic impact study conducted by Fondazione Rosselli suggests that there remains a strong case for retaining the development risks defence. However, the future of the defence remains under discussion and it is unclear whether manufacturers or consumers will gain the upper hand in the continuing debate. It remains to be seen whether it is feasible to harmonise throughout the EU all aspects of the law relevant to product liability, given the fundamental differences that remain in the substantive and procedural laws of Member States. Significantly, the practical effects study suggests that the abolition of Article 13 of the Directive does not currently attract much support amongst Member States. However, there is certainly scope for further amendment of the Directive.

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Ian Dodds-Smith is a Partner and Head of Arnold & Porter's European Product Liability Practice Group and Co-Head of its Food, Drug and Medical Devices Practice Group. He is a specialist in product liability and has particular expertise in relation to product liability in the pharmaceutical sector. He has conducted the defence of very many product liability cases for companies, both in relation to marketed products and products under research. He has defended very many multi-claimant group actions involving pharmaceuticals, devices and other products that have frequently involved co-ordinating activity throughout the UK and the EU. Mr Dodds-Smith currently serves as Consultant Editor of the Regulatory Affairs Journal and is a Fellow of the Royal Society of Medicine. He has written widely on product liability issues including as co-author of the chapter on product liability for medicinal products in the Butterworths textbook on Medical Negligence.
Chapter 2

Avoiding/Minimising the Risk of Punitive Damages

Shook, Hardy & Bacon LLP

I. Introduction


The modern concept of punitive damages is aimed at punishing a defendant. Id. at 1686. The standards for imposition of punitive damages have also changed through the years. Traditionally, courts only imposed punitive damages for “intentional” conduct. See Schwartz, et al., 82 Oregon L. Rev. at 36-37. Since the 1960s, however, with the emergence of mass products liability litigation, courts have showed a willingness to award punitive damages for conduct that is less than intentional, e.g., conduct described as “willful and wanton,” or “with a reckless disregard for the safety of consumers.” See id.

Historically, punitive damages were awarded infrequently. See Schwartz et al., 82 Oregon L.R. at 33. In recent years, however, the size and frequency of punitive damage awards has grown exponentially. See id. at 34. Indeed, whereas multi-million dollar verdicts were once unheard of in the United States, several verdicts in the past five years have exceeded $1 billion. See id. at 36-37. For example, in October 2002, a Kansas City, Missouri jury awarded $2.2 billion in punitive damages to a cancer patient whose pharmacist diluted drugs to boost profits. See id. at 37. In 2000, a Florida jury awarded a class of Florida smokers $145 billion in punitive damages against various tobacco companies. The award was subsequently struck down and is now pending on appeal to the Florida Supreme Court. See Engle v. Liggett Group, Inc., 873 So.2d 1222 (Fla. 2004). In 2003, an Alabama jury entered a verdict in a fraud case against Exxon assessing $11.8 billion in punitive damages, which the trial court remitted to $3.5 billion. See Alabama v. Exxon, No. 99-2368, slip op. at 1.

Not only has the amount of punitive damage awards “skyrocketed” in the past few decades (see Haslip, 499 U.S. at 18), the inconsistency among these awards has wreaked havoc on the civil justice system. First, it is difficult to predict whether punitive damages will be submitted for a jury’s consideration because there is no “bright-line” rule for determining what evidence is necessary to sustain a claim for punitive damages. As a result, much is left to the court’s discretion. Likewise, if a punitive damage claim is submitted to the jury, “[t]he difficulty of predicting whether punitive damages will be awarded by [the] jury in any particular case and the marked trend toward astronomically large amounts when they are awarded, have seriously distorted settlement and litigation processes and have led to wildly inconsistent outcomes in similar cases.” Tort Reform Record, available online at the American Tort Reform Association website, www.atra.org.

Responding to the growing concern that punitive damages were “run[n]ing wild,” (Haslip, 199 U.S. at 18), the United States Supreme Court has given substantial attention to the topic during the past ten years. See State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 417 (2003) (stressing a concern about the “imprecise manner in which punitive damages systems are administered); see also Cooper Indus., Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001); BMW of N. Am. Inc. v. Gore, 517 U.S. 559 (1996), Honda Motor Co. v. Oberg, 512 U.S. 415 (1994); TXO Prod. Corp. v. Alliance Res. Corp., 509 U.S. 443 (1993); Haslip, 499 U.S. 1 (1991). According to a prominent commentator, “[t]he Supreme Court’s jurisprudence since the late 1980’s demonstrates the Court’s concern that punitive damage awards should not be assessed without constraints on jury discretion.” Schwartz et al., 82 Oregon L.R. at 38.

The most significant recent decisions are BMW of North America, Inc. v. Gore, 517 U.S. 559 (1996) (“BMW v. Gore”) and State Farm Mutual Automobile Insurance Co. v. Campbell, 123 S. Ct. 1513 (2003) (“State Farm”). In both cases, the Supreme Court attempted to reign in punitive awards by setting some guidelines for courts and juries to follow. In BMW v. Gore, the Supreme Court set forth three “guideposts” to be used in determining whether to award punitive damages and, if so, in what amount. In State Farm v. Campbell, the Court expounded further on the Gore guideposts.

This article discusses the Supreme Court’s opinions in BMW v. Gore, State Farm v. Campbell and their progeny and offers practical guidance for defence counsel who are involved in...
cases that may result in a punitive damage award. Further, this article explores the yet unanswered questions concerning punitive damages.

II. BMW of North America v. Gore

In BMW v. Gore, 517 U.S. 559 (1996), plaintiff alleged that BMW committed fraud by failing to disclose minor cosmetic repairs to cars that were being sold as new. Id. at 563. The flawed paint job on plaintiff’s new BMW sedan was so minor that he never noticed it. The repair was brought to his attention months later when he brought the car to a detailer for cleaning. Plaintiff sued BMW seeking compensatory and punitive damages on the theory that BMW’s failure to disclose the re-painting constituted “gross, oppressive or malicious” fraud under Alabama law.

At trial, an Alabama jury awarded plaintiff $4,000 as compensatory damages. Id. at 565. The jury also awarded $4 million in punitive damages, which it apparently calculated by multiplying Dr. Gore’s damage estimate ($4,000) by 1,000, i.e., the number of cars BMW allegedly sold throughout the country under its nondisclosure policy. Id. at 564.

On appeal to the Alabama Supreme Court, BMW contended that its out-of-state conduct was permissible under the law of other states and, therefore, could not serve as a basis for a punitive damages award. Id. at 565. The Alabama Supreme Court agreed, holding that the jury should not have been permitted to consider sales by BMW outside of Alabama. Id. at 566. The court then reduced the punitive damages amount to $2 million, reasoning that this amount was “constitutionally reasonable.” Id.

In an 6-3 decision, the United States Supreme Court overturned the Alabama Supreme Court, holding that even the reduced punitive award was “grossly excessive” in violation of due process. The Court began its analysis by noting that “[t]he Due Process Clause of the Fourteenth Amendment [to the United States’ Constitution] prohibits a violation of due process. The Court began its analysis by noting that “[t]he Due Process Clause of the Fourteenth Amendment [to the United States’ Constitution] prohibits a violation of due process. The Court began its analysis by noting that “[t]he Due Process Clause of the Fourteenth Amendment [to the United States’ Constitution] prohibits a violation of due process. The Court began its analysis by noting that “[t]he Due Process Clause of the Fourteenth Amendment [to the United States’ Constitution] prohibits a violation of due process. The Court began its analysis by noting that “[t]he Due Process Clause of the Fourteenth Amendment [to the United States’ Constitution] prohibits a violation of due process.

A. The first Gore guidepost: the degree of reprehensibility of the defendant’s conduct

According to the Supreme Court, the first guidepost is “the most important indicium of reasonableness” of a punitive award. State Farm, 538 U.S. at 419. The Court held that it “should be presumed that a plaintiff has been made whole for his injuries by compensatory damages.” Thus, punitive damages are justified only if “the defendant’s culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence.” Id. The reprehensibility of a defendant’s conduct should be determined by considering whether (1) the harm caused was physical or economic; (2) the conduct evinced “an indifference to or a reckless disregard of the health or safety of others;” (3) the target/victim of the alleged conduct was financially vulnerable; (4) the conduct was repeated or isolated; and (5) the harm was the result of “intentional malice, trickery, or deceit.” Id. at 419.

Applying these factors, the Court concluded that “a more
modest punishment for this reprehensible conduct could have satisfied the State’s legitimate objectives, and the Utah courts should have gone no further.” \textit{Id.} at 419. The Court was troubled that the award was based on State Farm’s nationwide policies, rather than its conduct toward Mr. Campbell, noting that the case had been used “as a platform to expose, and punish, the perceived deficiencies of State Farm’s operations throughout the country.” \textit{Id.} This was improper, because a state “cannot punish a defendant for conduct that may have been lawful where it occurred…. Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State’s jurisdiction.” \textit{Id.} at 420. In rejecting plaintiff’s argument that evidence of lawful out-of-state conduct was relevant to demonstrate State Farm’s motive against its insured, the Court held that “[i]lawful out-of-state conduct may be probative when it demonstrates the deliberateness and culpability of the defendants’ action in the State where it is tortious, but that conduct must have a nexus to the specific harm suffered by plaintiff.” \textit{Id.} Accordingly, the jury must be instructed that “it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred.” \textit{Id.} at 421.

Perhaps even more significant to the United States Supreme Court was the fact that the jury awarded punitive damages to punish conduct that “bore no relation” to plaintiff’s harm. \textit{Id.} at 422. The Court specifically rejected this as a basis for a punitive award. \textit{Id.} “A defendant’s dissimilar acts, independent from the acts upon which liability was premised, may not serve as a basis for punitive damages.” \textit{Id.} “A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business.” \textit{Id.} Thus, “[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties’ hypothetical claims against a defendant under the guise of a reprehensibility analysis…. Punishment on these bases creates the possibility of multiple punitive damages awards for the same conduct.” \textit{Id.}

\section{B. The second Gore guidepost: the disparity between the actual or potential harm suffered by plaintiff and the punitive damages award}

Although the Court refused to “identify concrete constitutional limits on the ratio between harm, or potential harm, to the plaintiff and the punitive damages award” (\textit{id.} at 424), it did set forth some parameters. Specifically, “few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process.” \textit{Id.} at 425. Moreover, “[s]ingle digit multipliers are more likely to comport with due process, while still achieving the State’s goal of deterrence and retribution.” \textit{Id.}

In support of its holding, the Court cited the following: (1) the 4-to-1 ratio cited in \textit{Gore}; (2) its earlier decision in \textit{Pacific Mutual Life Insurance Company v. Haslip}, 499 U.S. 1, 23-24 (1991), wherein the Court held that a ratio of more than 4-to-1 “might be close to the line of constitutional impropriety,” and (3) a long history of “sanctions of double, treble, or quadruple damages to deter and punish.” The concept of a single-digit ratio was “not binding,” rather “instructive” and “must be based upon the facts and circumstances of the defendant’s conduct and the harm to the plaintiff.” Greater ratios “may comport with due process where a particularly egregious act has resulted in only a small amount of economic damages.” And a lesser ratio, “perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee” when substantial compensatory damages are awarded.” \textit{Id.} at 425-26.

Turning to the facts before it, the Court held that there is a presumption against a 145-to-1 ratio. \textit{Id.} The award was further found to be excessive because, (1) the compensatory award was substantial; (2) the harm was economic, not physical, and (3) the compensatory award was likely based on a punitive element. \textit{Id.} at 425-26. The Court specifically rejected the Utah Supreme Court’s rationale that State Farm would be “punished in only the rare case.” \textit{Id.} at 426. Such rationale “had little to do with the actual harm sustained” by plaintiff. \textit{Id.} Moreover, the “wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award.” \textit{Id.} at 427.

\section{C. The third Gore guidepost: the difference between the punitive damages awarded by the jury and the civil penalties authorised or imposed in comparable cases}

The Court began its brief analysis of this guidepost by noting that, in the past, it had looked to criminal penalties that could be imposed. \textit{Id.} at 428. The Court stated that, although criminal penalties continue to have some relevance regarding the seriousness with which a State views the wrongful action, such penalties have “less utility” in determining the amount of a punitive award. \textit{Id.} Indeed, “great care” should be taken to prevent juries from assessing criminal penalties in civil trials, which lack the “heightened protection” of a criminal trial. \textit{Id.} For this reason, “the remote possibility of a criminal sanction does not automatically sustain a punitive damages award.” \textit{Id.}

Applied to the facts of the case, the Court determined that the most relevant civil penalty under Utah law was a $10,000 fine for fraud, “an amount dwarfed by the $145 million punitive damages award.” \textit{Id.} at 428. Finally, the Court rejected the Utah Supreme Court’s speculation about potential civil penalties such as State Farm’s loss of license or disgorgement of profits because such penalties were based upon evidence of out-of-state and dissimilar conduct. \textit{Id.}

\section{IV. Post-State Farm Cases}

\textit{Gore} and \textit{State Farm} provided needed guidance to lower courts; however, the Supreme Court left many unanswered questions. For example, neither \textit{Gore} nor \textit{State Farm} involved product liability. Accordingly, courts have not uniformly applied \textit{State Farm} in the personal injury context. Other questions also remain. According to one commentator, the District Court for the Northern District of Alabama in a product liability action “deliberately waited for the State Farm holding before deciding a case on its docket, but was disappointed with the outcome, stating that it was ‘not sure that the wait was worth it.’” The Alabama court admitted that it was not sure it understood all of the lessons of \textit{State Farm} and lamented that the case it was currently deciding was so factually and procedurally

Since it was handed down two years ago, 324 cases have referenced State Farm. The debate over the interpretation continues in state and federal courts throughout the United States. Some courts have strictly applied the *State Farm* factors, while other courts have rendered *State Farm* virtually meaningless by “distinguishing” cases on their particular facts. Three significant areas that remain unsettled among lower courts are discussed below.

A. Lower Courts Have Varying Interpretations Of The Ratio Guideline

There is great variance among lower courts regarding how to apply the ratio guideline enunciated in State Farm. Some courts strictly apply the ratio guideline by adhering to the admonition that ratios greater than 9:1 should be viewed with caution and by insisting that even single-digit ratios must be scrutinised. Other courts find creative ways to get around the single-digit ratio guideline and/or disregard the ratio guideline as a mere “suggestion” rather than a requirement. Defence trends and plaintiff trends are identified below.

1. Defence Trends

(a) Single-Digit Ratios Are Not Per Se Constitutional

In *Bunton v. Bentley*, 153 S.W.3d 50 (Tex. Dec. 19, 2004), a defamation case, the jury entered a verdict awarding the plaintiff $150,000 for past and future loss of reputation, $7 million for mental anguish and $1 million in punitive damages. *Id.* at 52. The court of appeals reduced the mental anguish award to $150,000 but did not reduce the punitive damages award noting that the defendant did not “complain on appeal of the award of exemplary damages” and “the ratio between the actual damage award, after remittitur, and the award of exemplary damages falls within the parameters set by the United States Supreme Court.” *Id.* The Texas Supreme Court affirmed the remittitur of compensatory damages but remanded to the court of appeals for evaluation of whether the punitive damages needed to be adjusted based on the remittitur. *Id.* at 54.

The Texas Supreme Court gave specific instructions to the court of appeals regarding how to conduct the *State Farm* analysis. The court stressed that each of the *Gore/State Farm* guideposts must be reviewed in order to make a determination about the excessiveness of the punitive damages award. *Id.* “These Factors are intertwined … and cannot be viewed in isolation; specifically, a reviewing court cannot conclude that a particular ratio is consistent with due process unless that court examines the ratio in light of the other factors and in light of the actual harm to the plaintiff.” *Id.* Recognising that the court of appeals had noted that the 3-1 ratio in the case was in line with ratios in other cases, the Texas Supreme Court stressed that “the analysis cannot end there” and instructed the court of appeals to apply the *Gore/State Farm* guideposts “with care to ensure both reasonableness and proportionality.” *Id.* In so ruling, the Texas Supreme Court became one of the first courts to definitively address the trend of “rubberstamping” single-digit ratios. See Fey, Laura Clark et al., *The Supreme Court Raised Its Voice: Are the Lower Courts Getting the Message?* 56 Baylor L. Rev. 807, 840 (2004). *Bunton* provides strong authority for the proposition that courts cannot merely rubberstamp a single-digit ratio and must instead conduct a full due process review of each award of punitive damages.

(b) When Compensatory Damages Are High, A Lower Ratio Is Appropriate

In *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594 (8th Cir. Jan 7, 2005), the Eighth Circuit ordered a remittitur of a $15 million punitive damages award that was supported by $4 million in compensatory damages. *Id.* at 603. Although the punitive damages award presented only a single-digit ratio, the court determined that, given the substantial compensatory damages, due process required a ratio closer to 1:1 and remitted the award from $15 million to $5 million. The court ordered the remittitur despite finding that the defendant’s conduct was highly reprehensible and “shown to relate directly to the harm suffered.” *Id.*

*Boerner* is significant because it demonstrates a faithful application of the Supreme Court’s instruction that lesser ratios are appropriate when compensatory damages are substantial. The Eighth Circuit started with the proposition that when compensatory damages are high, “caution is required.” *Id.* The court then noted that the factors that could justify a higher ratio, “such as the presence of an ‘injury that is hard to detect’ or a ‘particularly egregious act [that] has resulted in only a small amount of economic damages’” were absent. *Id.* *Boerner* gives defendants an additional tool for arguing that a 1:1 ratio is appropriate in cases involving substantial compensatory damages.

Like *Boerner*, *Roth v. Farner-Bocken Co.*, 667 N.W.2d 651 (S.D. July 16, 2003) stands for the proposition that a lower ratio may be appropriate when compensatory damages are high and/or when compensatory damages contain a punitive element. Plaintiff in *Roth* anticipated that he was going to be fired by his employer. Accordingly, he secretly recorded a conversation in which he was terminated and left this tape with an attorney he consulted about filing an age discrimination action. The attorney decided not to take the case and returned the tape and other material to the plaintiff. Due to a clerical error, the attorney mailed these materials to the plaintiff’s former work address; and the plaintiff’s former employer discovered the contents of the package. Plaintiff eventually found the materials in his employment file during the course of discovery in his age discrimination case and filed a suit for breach of privacy.

The jury awarded $25,000 in compensatory damages and $500,000 in punitive damages. The South Dakota Supreme Court remanded the case for a new trial on punitive damages, finding that the punitive award should have been at or near the amount of compensatory damages.

This case is significant because the court held that when compensatory damages contain a punitive element, an award at or near the amount of compensatory damages is warranted. Specifically, in this case, plaintiff’s damages “consisted of emotional distress, including feelings of anger, betrayal and devastation.” *Id.* at 669. “Accordingly, not only was [plaintiff] completely compensated for his economic injuries by the large compensatory damages award, but we find also that the compensatory damages in
this case contained a punitive element.” *Id.* Thus, “where there was a substantial compensatory damage award containing a punitive element which fully compensated [plaintiff] for the harm caused, we find ‘a punitive damages award at or near the amount of compensatory damages’ is justified.” *Id.* (quoting *State Farm*, 123 S. Ct. at 1526). Based in part on the foregoing analysis, the court held that the 20:1 ratio between punitive damages and compensatory damages could not stand.

2. *Plaintiff Trends*

   (a) The Ratio Guideline Is A Mere “Suggestion”
   Some lower courts read the *State Farm* single-digit ratio guideline as a suggestion rather than a requirement. *Mathias v. Accor Economy Lodging, Inc.*, 347 F.3d 672 (7th Cir. Oct. 21, 2003) is an example. In an opinion written by Judge Richard A. Posner, the United States Court of Appeals for the Seventh Circuit affirmed a judgment reflecting an award of $5,000 in compensatory damages and $186,000 in punitive damages for injuries resulting from bedbug bites occurring at defendant’s hotel.

   Defendant argued that, under *State Farm*, four times the compensatory damages (i.e., $20,000) was the maximum the jury could have constitutionally awarded each plaintiff in punitive damages. *Id.* at 674. The Seventh Circuit disagreed, initially noting that the Supreme Court did not “lay down a 4-to-1 or single-digit ratio rule - it said merely that ‘there is a presumption against an award that has a 145-to-1 ratio.’” *Id.* at 676. The court went on to ignore many of the basic tenants enunciated in *State Farm*.

   The court relied on some of the following facts in holding that the punitive award, which was 37.2 times greater than the compensatory award, was not excessive: (1) unlike in *State Farm*, where plaintiff was awarded $1 million in compensatory damages, in the present case, although “defendant’s behaviour was outrageous... the compensable harm done was slight and at the same time difficult to quantify because a large element of it was emotional.”; (2) defendant “may well have profited from its misconduct because by concealing the infestation it was able to keep renting rooms;” (3) defendant might have “postponed the instituting of litigation to rectify the hotel’s misconduct” by telling guests the bugs were ticks instead of bedbugs; and (4) “[T]he award of punitive damages in this case thus serves the additional purpose of limiting the defendant’s ability to profit from its fraud by escaping detection and (private) prosecution. If a tortfeasor is ‘caught’ only half the time it commits torts, then when he is caught he should be punished twice as heavily in order to make up for the times he gets away.” *Id.* at 677.

   *Simon v. San Paolo U.S. Holdings Co., Inc.*, 2003 WL 22847318 (Cal. Ct. App. Dec. 2, 2003), review granted, 86 P.3d 881 (2004), is another example of the pro-plaintiff trend involving hard-to-measure damages, tend to allow greater compensatory damages. Courts in these, and other cases involving a violation of constitutional rights. These cases tend to involve smaller, harder to define and quantify, compensatory damages. *Dunn v. Village of Put in Bay, Ohio*, 2004 WL 169788 (N.D. Ohio Jan. 26, 2004) is a Section 1983 excessive force case involving a police officer’s use of pepper spray. In *Dunn*, the District of Ohio upheld a punitive damages award of $23,422 based on a compensatory damages award of $1,577. The court determined that the use of pepper spray to apprehend a “non threatening suspect … for an act of alleged vandalism was egregiously reprehensible and showed ‘callous indifference’ to the plaintiff’s Fourth Amendment rights. *Id.* at *2.* The court recognised that the 15-1 ratio of punitive damages to compensatory damages raised due process concerns but determined that case fell within the Supreme Court’s allowance for higher ratios in cases where “a particularly egregious act has resulted in only a small amount of economic damages.” *Id.*

   *Dunn* is an excellent example of how courts tend to deal with cases involving a violation of constitutional rights. These cases tend to involve smaller, harder to define and quantify, compensatory damages. Courts in these, and other cases involving hard-to-measure damages, tend to allow greater than single-digit ratios. *See* Fey, et al., 56 Baylor L. Rev at 840.

(b) Ratio Guidelines May Not Apply When Compensatory Damages Are Minimal

   *Id*.

2. Some Lower Courts’ Interpretation of “Potential Harm” Allows Significant Room For Large Punitive Damage Awards

   A pro-plaintiff trend among lower courts is to use the United States Supreme Court’s language regarding “potential harm” to justify an otherwise unconstitutional award. For example, in *In re Exxon Valdez*, 296 F. Supp. 2d 1071 (D. Ala. 2004), the District of Alaska reconsidered a jury’s $5 billion punitive damages award based on a $513 million compensatory damages award. The case had been remanded from the Ninth Circuit with instructions to enter a remittitur. While the district court reduced the punitive damages award from $5 billion to $4.5 billion, the case demonstrates how a court can disregard the spirit of *Gore* and *State Farm* to uphold a large punitive damages award.

   The district court relied heavily on the expansive concept of...
potential harm when analysing the Gore/State Farm guideposts. With regard to reprehensibility, rather than focusing on the actual harm caused by the accident (which was substantial in its own right) the court considered the harm that could have resulted had the ship sunk, had the entire cargo of oil spilled or had the oil slick ignited. Id. at 1094-95. Accordingly, the district court did not consider applying State Farm's 1-1 ratio exception for high compensatory damages but instead justified a higher punitive damages award by dividing the compensatory damages by the number of plaintiffs in the case and using this “relatively small” compensatory damage award to justify a higher ratio.

Another example of a court using “potential harm” to justify a high punitive damage award is Williams v. Philip Morris Inc., 92 P.3d 126, (Or. Ct. App. 2004). Williams was remanded to the Oregon Court of Appeals by the United States Supreme Court for further consideration in light of State Farm. Upon remand, the Oregon Court of Appeals reaffirmed its decision reinstating a $79.5 million punitive damages award against a tobacco company based on compensatory damages of $521,485. In doing so, the Oregon Court of Appeals recognised that there was “a presumption of constitutional invalidity arising from the jury’s award of punitive damages in this case, if there is, in fact a 96-1 ratio.” Id. at 144. The court then stated that, in addition to the harm to the plaintiff, it was appropriate for the court to consider the potential harm that would have been caused if the defendant’s wrongful plan had succeeded. Id. Thus, the court held that it was appropriate to consider not only the compensatory damages in the ratio analysis but also the potential harm to other Oregon smokers: “[T]he jury, in assessing the amount of punitive damages was entitled to draw reasonable inferences as to the number of smokers in Oregon who had been defrauded during the past decades.” Id. at 145. Applying this rule, the court speculated that if 100 other smokers had been defrauded by the defendant’s conduct and suffered comparable harm, it would bring the ratio well within “State Farm’s 4-to-1 boundary.” Id.

Like Exxon Valdez, Williams demonstrates that when courts consider potential harm (vs. actual harm), the ratio guidepost becomes virtually meaningless, which results in large punitive damage awards.

C. There Is Confusion Among Lower Courts Regarding The Role Of The Wealth Of The Defendant

In State Farm, the Supreme Court sent mixed messages regarding what role defendants’ wealth should play in assessing punitive damages. See Fey et al., 56 Baylor L. Rev. at 848. In one respect, the Supreme Court suggested that wealth was not relevant to determining whether a punitive damages award is constitutional. Indeed, the Court specifically indicated that a consideration of defendant’s wealth “bear[s] no relation to the award’s reasonableness or proportionality to the harm” and that “[t]he wealth of a defendant cannot justify an otherwise unconstitutional punitive damage award.” State Farm, 538 U.S. at 427. The Court followed this language, however, with language from Justice Breyer’s concurring opinion in Gore which suggested the consideration of a defendant’s wealth was neither unlawful nor inappropriate. See id. at 427-28 (wealth “provides an open-ended basis for inflating awards when the defendant is wealthy…That does not make its use unlawful or inappropriate; it simply means that this factor cannot make up for a failure of other factors.”) (citing Gore, 517 U.S. at 591 (Breyer, J., concurring).

Add to the confusion the fact that many state and federal courts have long accepted wealth as an appropriate factor. See Fey et al., 56 Baylor L. Rev. at 849. For these reasons, lower courts have not reach a consensus regarding whether a defendant’s wealth should be considered and, if so, to what extent. Some courts have questioned whether wealth can play any role in setting the amount of punitive damages. See, e.g., Hayes v. Wal-Mart Stores, Inc., 294 F. Supp. 2d 1249, 1251 (E.D. Okla. 2003) (“[T]he use of a defendant’s net worth may be in doubt.”); McClain v. Metabolife Int’l Inc., 259 F. Supp. 2d 1225, 1229 (N.D. Ala. 2003) (“[T]his court is not sure whether the financial impact on a defendant is a thing to be considered.”); see also Romo v. Ford Motor Co., 6 Cal. Rptr. 3d 793, 801 (Cal. Ct. App. 2003) (noting that State Farm shifted the focus away from “the defendant’s wealth or general incorrigibility”).

By contrast, a majority of lower state and federal courts continue to find that a defendant’s wealth is relevant. See, e.g., Lowry’s Reports, Inc. v. Legg Mason, Inc., 302 F. Supp. 2d 455, 461 (D. Md. 2004) (“[T]he jury’s consideration of [the defendant’s] wealth was a correct application of the deterrent role of statutory damages.”); In re Exxon Valdez, 296 F. Supp. 2d 1071, 1105 (D. Alaska 2004) (citing State Farm for the proposition that “it is neither unlawful nor inappropriate to consider the defendant’s wealth”); Hollock v. Erie Ins. Exch., 842 A.2d 409, 419 (Pa. Super. Ct. 2004) (noting that governing state law called for a consideration of defendant’s wealth); Stroud v. Lins, 790 N.E.2d 440, 446 (Ind. 2003) (“The defendant’s wealth is ordinarily cited as a reason to escalate a punitive award, and that is consistent with the goal of deterrence.”).

V. Opportunities to Limit / Dispose of Punitive Damages Post-State Farm

Although courts are bound to apply the guideposts announced in Gore and State Farm, many “gray areas” remain. For example, “reprehensibility” is a broad concept left to interpretation by trial courts. Likewise, there is no “bright line” rule regarding ratios. Lower courts are also left to decide which civil penalties are most “comparable” to the case at bar and whether and to what extent a defendant’s wealth should be considered. Because so much of Gore and State Farm is open to interpretation, it is up to defence counsel to educate the trial judge about the restrictions imposed by State Farm. As a practical matter, defence counsel should consider opportunities throughout the litigation to ensure that the holding and rationale of State Farm is understood and applied during trial.

In addition, during all stages of the case, it is essential that defendants keep the appellate process in mind in order to preserve any potential constitutional challenges because a court may decline to apply portions of State Farm if the record is not properly preserved. See e.g., Henley v. Philip Morris Inc., 9 Cal. Rptr. 3d 29, 71 (Cal Ct. App. 2004) (“Unlike the defendant in Campbell, however, defendant made no attempt to anticipate the Supreme Court’s direction by objecting to the evidence or seeking a limiting instruction.”).
A. Affirmative Defences

In assessing potential affirmative defences to a claim for punitive damages, the facts of the particular case, the jurisdiction in which the case is pending, and the state’s substantive law should all be taken into consideration. One goal is to preserve the defence’s arguments regarding the constitutionality of punitive damages. Typically, defendants should consider an affirmative defence stating that an award of punitive damages would violate defendant’s procedural and substantive due process rights and equal protection rights (see State Farm; First, Fifth, Sixth, Eighth, and Fourteenth Amendments to the United States Constitution and similar Articles of state Constitutions).

B. Bifurcation

Bifurcation is a procedural device whereby different issues are tried sequentially, “with the presentation of proof on the trailing claims or issues contingent upon the outcome of the previously considered questions.” Landsman, Stephan et al., Be Careful What You Wish For: The Paradoxical Effects of Bifurcating Claims for Punitive Damages, 1998 Wis. L. Rev. 297, 299. In federal court, bifurcation is governed by Federal Rule of Civil Procedure 42(b). Rule 42(b) provides that “[t]he court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim... or of any separate issue.” F.R.C.P. 42(b). Many states have similar rules regarding bifurcation. Other states’ rules of civil procedure provide that a party is entitled to bifurcation of punitive damage issues as a matter of right. See, e.g., Mo. Rev. Stat. § 510.263(1) (“All actions tried before a jury involving punitive damages shall be conducted in a bifurcated trial before the same jury if requested by any party.”).

Some states (e.g., Minnesota) completely bifurcate the punitive claim. In those states, the jury first determines whether defendant is liable for compensatory damages. Then, if compensatory damages are awarded and if the judge determines that punitive damages will be submitted to the jury, a separate trial (in front of the same jury) is held to determine whether punitive damages will be awarded and, if so, in what amount. Other states (e.g., California) only bifurcate the amount of punitive damages.

In states that allow complete bifurcation, State Farm may have an impact on the scope of evidence presented in Phase I. In those states, bifurcation offers defendants “significant protection from prejudice arising out of the misuse of information relevant only to the punitive damage decision.” Landsman, Stephan et al., 1998 Wis. L. Rev. at 335. Specifically, the jury should not hear evidence that is only relevant to punitive damages. This would arguably include all “bad company” evidence and evidence regarding defendant’s net worth.

State Farm will have less of an impact in states where the effect of bifurcation is only to defer evidence regarding the amount of punitive damages until Phase II. In those states, evidence relevant to whether punitive damages should be awarded is not deferred until Phase II. Accordingly, the evidence relevant to punitive damages that is heard during the first phase is generally similar to the evidence presented in the second phase. A defendant may not gain much, if anything, in the way of excluding evidence by bifurcating under these circumstances.

There are other potential risks and benefits associated with a bifurcated trial. On the “benefit” side, research suggests that defendants increase their likelihood of winning on liability in a bifurcated trial. See Landsman, Stephan et al., 1998 Wis. L. Rev. at 316. There are also risks associated with bifurcation. For example, some commentators have suggested that defendants who lose on liability “substantially increase the risk that punitive damages will be assessed against them if the case is bifurcated.” Id. at 335. Research further suggests that “not only does the incidence of punitive liability increase, but the size of the punitive award grows substantially if the case is bifurcated.” Id.

Because there are potential risks and benefits to bifurcation, the particular facts and circumstances of each case, and the effect of bifurcation in a particular jurisdiction, must be weighed prior to making this important decision.

C. Motion to Strike Punitive Damages

Before trial, defence counsel should consider moving to strike plaintiff’s claim for punitive damages on grounds that, under State Farm, the admissible evidence cannot support a claim for punitive damages.

D. Motions in Limine

A pre-trial motion in limine is an opportunity to educate the court about the parameters established by State Farm. The main objective is to limit introduction of evidence on the issue of punitive damages, including for example: (1) defendant’s business or sales practices in states other than the state where the case is pending; (2) defendant’s overall net worth; (3) arguments by counsel for a punitive damage award that will “send a message”; (4) evidence unrelated to plaintiff’s alleged harm; and (5) statements urging the jury to punish defendant for conduct that is lawful.

E. Voir Dire, Opening Statement, and Closing Argument

It is important to educate the jury at every stage of the trial. In most cases, they are the decision makers regarding whether to award punitive damages and, if so, in what amount. Voir dire, opening statement, and closing argument are significant opportunities to convey the defence themes. Throughout the trial, defence counsel should stress that a plaintiff is “made whole” by compensatory damages and, accordingly, no plaintiff is entitled to punitive damages as a matter of right. State Farm clearly delineated between punitive damages and compensatory damages noting that they serve different purposes. Specifically, compensatory damages are intended to compensate plaintiff for his loss, whereas punitive damages are “aimed at deterrence and retribution.” State Farm, 538 U.S. at 416. If the facts permit, defence counsel may want to consider argued that punitive damages are not necessary because: passage of time; the company has instituted a change in policy; or there has been a change in ownership of the business. See Fey et al., 56 Baylor L. Rev. at 857.
F. Jury Instructions

Jurors must be properly instructed regarding the scope of evidence they may consider in determining whether to assess punitive damages. It is essential to inform jurors that assessment of punitive damages is not required and should not be assessed simply because the defendant has sufficient assets to pay such an award. Potential elements of a punitive damages jury instruction include: (1) a punitive damage award is not required; (2) punitive damages should not be awarded as a result of anger, passion, or prejudice, or to redistribute wealth; (3) plaintiff has the burden of establishing entitlement to punitive damages by clear and convincing evidence establishing that defendant acted intentionally or with actual malice; (4) no punitive damages may be assessed for lawful conduct; (5) discretion should be used in determining the amount of any punitive damage award; (6) any punitive damage award must bear a reasonable relationship to the harm suffered by plaintiff; (7) defendant cannot be punished for conduct outside the state; and (8) there must be a nexus between the conduct of defendant and the harm suffered by plaintiff.

Jury instructions should also address the issue of the defendant's wealth. Specifically, if the court determines that defendant's financial condition is admissible, defendants should propose jury instructions that limit its use. For example, a jury should be instructed that they cannot use the defendant's wealth as a basis for rendering an excessively high punitive damage award and that the defendant's wealth cannot justify an otherwise unconstitutional punitive damages award.

G. Post-Trial Motions

If a jury awards punitive damages, defence counsel should be alert to reversing the award by filing a timely post-trial motion to preserve an appeal. Examples of post-trial motions are: a motion for new trial; a motion for judgment N.O.V. (notwithstanding the verdict, i.e., asking the court to set aside the jury's verdict); and/or a motion for remittitur (i.e., to reduce the amount of the punitive award). Arguments may include the following: (1) the jury failed to follow the jury instructions in awarding punitive damages; (2) the evidence submitted was insufficient to support the punitive damage award; (3) the trial court failed to properly apply State Farm in denying defendant's motion for new trial and/or remittitur of the punitive damage award; (4) the trial court admitted or failed to admit certain evidence in violation of State Farm; and (5) the punitive award is too large to satisfy the due process requirements of State Farm.

VI. Conclusion

Historically, the courts have not given juries specific guidelines to decide whether to award punitive damages and, if so, in what amount. This has led to wildly inconsistent punitive damage awards. Inconsistency and the fear of an astronomical punitive damage verdict has skewed the evaluation of litigation and fuelled unreasonable settlements.

Both BMW v. Gore and State Farm v. Campbell provide valuable insight to trial courts regarding factors to be considered in awarding punitive damages. Gore and State Farm present new opportunities to dispose of and/or limit punitive damage claims. Read broadly, State Farm suggests that punitive damages are not favoured and may not be appropriate in many cases. Further, State Farm also suggests that, in cases where punitive damages are submitted to the jury, restrictions must be imposed to ensure that the award comports with due process.

As a practical matter, many questions were left unanswered by the Supreme Court in Gore and State Farm. Neither case involved product liability or personal injury. Moreover, concepts such as “reprehensibility,” “ratio,” “comparable penalties,” and the role of the wealth of the defendant are left open to interpretation by trial courts. Lower courts have been grappling with these unanswered questions and have interpreted Gore and State Farm differently - some courts follow the letter and spirit of the opinions, while other courts skirt the directives by limiting the holdings of Gore and State Farm to their specific facts.

Because Gore and State Farm provided no “bright line” rules, it is essential that defence counsel seize every opportunity to argue that State Farm operates to prevent (or limit) punitive damages from being awarded in its case.
Avoiding/Minimising the Risk of Punitive Damages

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Chapter 3

The New Product Safety Regime in Practice in the EU

Lovells

Introduction

A revised General Product Safety Directive ("GPSD") was adopted on 3 December 2001 and published in the Official Journal on 15 January 2002. Member States were given until 5 January 2004 to implement the Directive, and most have now done so. The new GPSD will have a significant impact on manufacturers and suppliers throughout the EU.

The first Directive on General Product Safety (Directive 92.59/EEC) was adopted in 1992 and introduced into the EU the concept of a "general product safety obligation". The purpose of the 1992 Directive was to ensure a consistent, high level of safety in respect of consumer products throughout the EU. The 1992 Directive, however, was criticised for not going far enough to ensure consumer safety (particularly at an enforcement level), and for uncertainty as to the effect of several of its provisions.

These criticisms culminated in the revised General Product Safety Directive (Directive 2001/95/EC) which replaces the 1992 Directive and takes the regulation of product safety in the EU to a new level. The central objectives of the Commission in revising the Directive were to provide for increased transparency, more active market surveillance, more effective enforcement measures and simpler rules for rapid intervention to remove dangerous products from the market, all with a view to ensuring a high level of consumer protection and the proper functioning of the internal market. The Directive is intended to cover all products that are supplied to consumers, to the extent they are not subject to other sector-specific safety regulations. This means that all consumer products in the EU are fully covered either by the Directive, or by sector-specific safety regulations, or in some cases by a combination of the two.

The revised Directive has undoubtedly changed the face of product safety regulation. In addition to increasing the powers of the authorities to intervene in the management of product safety issues, it imposes new and more stringent obligations on manufacturers and suppliers, and calls on all those involved in the chain of supply to re-evaluate their internal safety management systems and procedures. Those who already have sophisticated and reliable systems in place to ensure product safety may simply need to review those systems to ensure they meet the specific requirements of the new laws. Those who do not will need to undertake significant modification of quality assurance systems, consumer complaint procedures and crisis management plans. In all cases, however, those who supply consumer products must be aware of the revised Directive’s provisions, and be prepared to rise to the challenges it presents.

Main Features of the New General Product Safety Directive

The GPSD regime is built around the “general safety obligation” i.e., an obligation to place only safe products on the market (Article 1). It is an offence to breach this requirement.

A “safe product” is defined in Article 2(b) to be:

"…any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- the categories of consumers at risk when using the product, in particular children and the elderly."

A product that does not meet this definition is considered “dangerous” (Article 2(c)).

The GPSD, in its original form, imposed a number of requirements on producers and suppliers to reduce the risk of placing dangerous products on the market, and to provide for appropriate action to be taken if dangerous products were placed on the market. It also bestowed powers on national authorities to enforce the provisions of the Directive and in particular to take action when the general safety requirement was breached.

The original GPSD, however, had relatively little impact on the regulation of product safety in the EU. The amendments are designed to ensure the Directive has a much greater...
impact. It is likely to achieve this objective.

**Major Changes Introduced by the New General Product Safety Directive**

### Clarification and Extension of Scope

The scope of the GPSD is clarified by the new Directive. It is now clear that the GPSD applies to all consumer products except to the extent that the risks are covered by specific EU legislation.

The new GPSD also expressly extends to products that are likely to be used by consumers, even if they are not designed for consumer use.

### New Powers and Responsibilities for National Authorities

For the first time, national authorities are specifically empowered by the GPSD to initiate product recalls. A product recall is to be considered a “last resort”, although national authorities are required to take into account the “precautionary principle” when assessing what action should be taken (Article 8(2)).

National authorities must also give “consumers and other interested parties” an opportunity to “submit complaints”, and these complaints must be followed up as appropriate (Article 9(2)).

### Notification Obligation

The new GPSD introduces a requirement that producers and distributors notify the competent authorities “immediately” they know, or ought to know, that a product they have marketed poses unacceptable risks (Article 5(3)). It is generally an offence not to comply with this requirement.

The broader implications of this new notification requirement will be obvious to those who have experience with the notification requirement under the Consumer Product Safety legislation in the US. In fact, the notification obligation under the GPSD is more onerous than that which applies in the US. This is because:

- the threshold for reporting product risks is likely to be, in most cases, much lower;
- the enforcement mechanisms will be decentralised and inevitably subject to inconsistent application as between various Member States; and
- there is less adequate protection of any confidential information supplied by manufacturers.

### Obligation to Recall Products

The new regime also introduces a positive obligation on producers to recall dangerous products in the appropriate circumstances. If they fail to do so, they can be ordered to recall products by the authorities. As stated above, authorities are given new powers to enforce this obligation, in the exercise of which, they are required to take into account the “precautionary principle”.

**Information-Sharing Requirements**

National authorities now have an obligation to share information with the Commission about product-related risks. The Commission is empowered to share that information with other EU countries, and even with their counterpart organisations in other countries. The Commission and the Consumer Product Safety Commission in the US have already agreed a system for sharing information about specific product safety risks that are notified to them.

The Commission has also begun to publish, on its website, information about unsafe products that are notified to it by the Member States under the new GPSD.

**Implications for Businesses of the New General Product Safety Directive**

The new GPSD regime makes it more important for businesses to have effective systems to manage product safety risks and for those systems to stand up in the scrutiny of the regulations.

Significantly, the new regime imposes the notification obligation on distributors as well as on producers. This means that producers could find themselves in a situation where the distributors of their products notify the authorities of alleged defects in their products, without necessarily first telling the producers.

The new regime brings particular problems for producers and suppliers who did not pay close attention to their obligations under the previous regime. Even under the 1992 Directive, producers were required to:

- provide customers with relevant information to enable them to assess risks inherent in the product;
- have in place adequate systems to enable them to be informed of the risks which a product might pose;
- have in place systems to enable them to take appropriate action to avoid risks (which might include being able to trace marketed products);
- keep distributors informed of any monitoring activities; and
- where appropriate:
  - carry out sample testing of marketed products;
  - keep a register of complaints; and
  - adequately investigate complaints.

Up to the present time, these obligations have rarely been enforced in any Member State, and as a result many businesses were tempted to overlook the importance of them. However, the new regime greatly increases the risk that any prior non-compliance with the requirements of the old regime will come to the attention of the regulatory authorities.

**The “Borderline” Industries**

The new GPSD affects all industries involved in the supply of products that may be used by consumers, except to the extent that the risks are subject to a separate comprehensive regulatory regime under EU law. This means that all consumer product industries will be affected by the new
regime, with the exception of food and possibly pharmaceuticals.
Several industries are subject to partial safety-regulation, such as those involved in the manufacture and supply of toys, cosmetics, motor vehicles, electrical products, construction equipment, machinery, tobacco and medical devices. For each of these industries, it is necessary to establish which matters are covered by the new GPSD and which are covered by sector specific regulations.

The European Commission has published a Guidance Paper on the relationship between the GPSD and the Directives affecting four specific categories of products, namely toys, electrical equipment, cosmetics and personal protective equipment. This guidance document, while it is of some assistance, does not deal with a number of the issues relevant to those industries, nor does it give much guidance on how the GPSD might operate in respect of other regulated industries. (See “Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety”, November 2003, at http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf).

The Notification Obligation

The new obligations under the GPSD come into sharp focus for producers and distributors when they are confronted by an unexpected safety risk presented by products they have marketed. This is when the adequacy of systems put in place to ensure safety will come to be scrutinised. This is also when management will be faced with the question of whether the legal obligation to notify authorities, and possibly then take corrective action, has been triggered.

The notification obligation, in particular, presents new and difficult challenges for producers and distributors in these circumstances. In recognition of that, the Commission has published guidelines which are intended to give producers, distributors, and national authorities alike, some guidance on how the notification obligation is to operate in practice. These guidelines do not have the status of law, nor can they override the express terms of the Directive. They are, however, useful in indicating how the Directive is likely to be interpreted and applied by national enforcement authorities.

Under the terms of the GPSD, as noted above, there is a legal obligation on producers and distributors to notify the competent authorities “immediately” they know, or ought to know, that a product they have marketed poses unacceptable risks. In most Member States, failure to comply with this notification obligation is itself a punishable offence, in some cases attracting severe penalties.

The new GPSD does not indicate what “immediately” means in this context. The guidelines do, however, offer some assistance. They say:

“...The GPSD requires that competent authorities be informed immediately. A company must therefore inform them without delay, as soon as the relevant information has become available, and in any case within 10 days since it has reportable information, even while investigations are continuing, indicating the existence of a dangerous product. When there is a serious risk companies are required to inform the authority(ies) and in no case later than three days after they have obtained notifiable information.

In an emergency situation, such as where immediate action is taken by a company, the company should inform the authorities immediately and by the fastest means.”

These time limits can be difficult to apply in practice, particularly if information about the nature and extent of the risk is still emerging. It will often be uncertain as to when information in the possession of a company is such that it ought to conclude that the product poses risks that are incompatible with the general safety requirement.

Likewise, difficult questions can arise as to whether the identified risk is one that might lead to the conclusion that the product is unacceptably dangerous. This may occur, for example, where a company has received one isolated report of a safety incident, or a potential risk is identified but there is no more than a theoretical possibility of the risk materialising.

The guidelines seek to offer some guidance on this aspect of the decision-making process by providing a “methodological framework” for risk estimation and evaluation. This framework suggests an approach based on a systematic evaluation of the following factors:

- severity of injury;
- overall probability of injury;
- type of person at risk (especially vulnerable people); and
- adequacy of warnings/obviousness of hazard.

The guidelines include a matrix which incorporates the results of the evaluation of the interaction of these factors, and indicates on that basis whether notification is required.

Despite the apparent complexity and sophistication of the system, the ultimate conclusion is that, unless the risk is obvious and adequately warned against, a notification to the authorities is always required except where:

(a) the probability of injury is “low” and the potential severity of injury is “slight”; or

(b) the probability of injury is “very low” and the potential severity of injury is no more than “serious” (but not “very serious”).

Given that under the methodology:

- all but minor, reversible injuries are to be categorised as either “serious” or “very serious”; and
- the probability will be “very low” only if the hazard affects only around 1% of total number of the products marketed, and the hazard only occurs if several improbable conditions are met;

if these guidelines are applied, in most cases a risk would be notified, even if the likelihood of the risk arising is very small.

The key lesson highlighted by these guidelines is that every potential safety risk arising in respect of marketed products needs to be considered carefully on its facts. For this purpose, it may be necessary to obtain the views of technical experts to assist with the conduct of the risk assessment. It may also be necessary to obtain the views of legal experts as to whether the risk is one that ought to be notified.

There will also be a range of other considerations, including the need to manage product liability risks, the need to manage the risks of damage to the producer’s reputation in...
the marketplace, the need to avoid unnecessarily alarming customers and consumers, and the question of whether relevant regulations have been complied with.

These challenges take on another level of complexity if the potentially-unsafe product has been marketed in more than one Member State of the EU. The producer or distributor is then faced with the prospect of having to give a notification “immediately” to the enforcement authorities in up to 25 Member States.

The Commission’s guidelines suggest a procedure whereby a producer or distributor may be partially-relieved of this onerous obligation if they notify the authorities in the Member State in which they are “established”, and those authorities agree to notify the other Member States. However, this procedure has not been embodied in the implementing laws in any Member State, which means that if it resulted in a failure in the prompt and accurate communication among the Member States, the producer or distributor would still be liable to prosecution.

In any event, a prudent producer will not consider the “central” notification option an appropriate course of action in the regime as it currently exists because of the need to protect its reputation in the markets where its products are sold and to maintain proper control over the conduct of the corrective action, for which it will be necessary to engage with local enforcement authorities in each Member State from the outset.

**Some Practical Tips for Undertaking Product Recalls Under the New GPSD Regime**

The new GPSD has changed the way in which product recalls and other corrective actions must be approached by producers and distributors in the EU. Once a potential safety risk is discovered, there are now legal obligations to be considered, and important time limits to be observed. Lovells’ team of product safety specialists has assisted many major producers of consumer products in Europe to prepare systems to meet the obligations of the new regime, and since its implementation, have worked with several companies in a range of industries to deal with product safety issues and corrective action in EU States. This work has included some of the first, as well as the largest, pan-European product recalls under the new GPSD. From that experience, there are a number of important lessons to be learned.

(a) Plan effectively

The first hint of a potential risk usually occurs well before all facts are available. Any decision on what action to take should ideally be made following proper and thorough investigations into the true nature and extent of the risk. Due to the strict nature of the notification obligation, and the tight time frame in which it is intended to operate, this may not always be possible, but a producer will be better able to manage the risk, and avoid having to undertake what might ultimately prove to be overly cautious corrective action, if it can quickly marshal its advisers to start dealing with the issue promptly.

(b) Co-ordinate notification action in all Member States

Notifications to authorities should take place simultaneously in all affected Member States. Information about product risks can be communicated swiftly among national authorities through the RAPEX system. It could be embarrassing for a producer or distributor, and lead to unnecessary conflict with authorities, if national authorities first learn of a risk affecting products in the markets for which they are responsible from a source other than the producer or distributor itself - particularly where it becomes apparent that authorities in other Member States have been notified earlier.

It is also essential that consistent information is communicated to the authorities in all the relevant countries to avoid any suggestion that the same risk is being handled differently in different markets. In some cases, different steps may be justified, due to diverse market conditions, consumer behaviour, or modes of distribution of the product, but any discrepancies must be capable of ready justification.

For the same reasons, the flow of information during the course of the corrective action must be controlled. Usually, some authorities will raise questions or request further information about the risk or the proposed action. The responses to the authorities in the various Member States ought to be carefully co-ordinated to ensure a consistent flow of information.

(c) Get the balance right

When making initial notifications to authorities about a potential product risk and/or a proposed corrective action, it is important to provide the authorities with sufficient information to enable them to determine the adequacy of the proposed actions. However, the provision of too much detail can be confusing, can prompt further unnecessary inquiries from the authorities, and will increase the risk of miscommunication of information, particularly if the information is highly technical and has to be translated.

(d) Maintain good relations with the Authorities

Complications can, and regularly do, arise in pan-European recalls when the authorities take inconsistent views of the way in which the potential risk ought to be dealt with. In those cases, it is often necessary to enter into negotiations with local authorities in an effort to satisfy them that the steps proposed, which are also being undertaken in other countries, are appropriate to deal with the perceived risk. This is why it is important to ensure a good relationship with local authorities from the outset.

Since the new GPSD came into force, national safety authorities have become more experienced in dealing with product risks notified to them, and are becoming much more interventionist in relation to how corrective action should be handled in their countries. There are also emerging differences in the way particular authorities discharge their functions - with authorities in some countries typically taking a much more precautionary approach than others.

Generally, however, if the local authorities in each country can see that the recall action is being undertaken carefully and professionally, and that the producer or distributor is willing to be open and prompt in its communications with the authorities, there is much less risk that the authorities will question the judgment of the producer or distributor in how the potential problem needs to be dealt with.

**Conclusion**

The new amendments to the GPSD greatly increase the regulatory risks for those involved in the supply of consumer products to EU markets. This makes it more important than
ever for those businesses to understand their obligations under the GPSD, to manage their product safety risks, and to be in a position to respond swiftly and effectively if unexpected safety problems arise.

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Lovells is an international law firm, with more than 1,600 lawyers operating worldwide, from 26 offices in 19 countries.

Lovells, through its European Product Liability Network, has the largest specialist product liability practice in Europe. The practice comprises over 50 lawyers who are able to advise on all aspects of litigation, regulation and risk management.

Our lawyers have been closely involved in most of the major product liability controversies over the last decade and have experience of advising on a wide range of products including: pharmaceuticals; food; medical devices; cars; tobacco; vaccines; mobile phones; cosmetics; blood products; aircraft; and trains.

Lovells has particular expertise of co-ordinating multi-party product liability litigation and currently acts in respect of litigation in over 17 countries.

Lovells’ product liability lawyers are supported by dedicated Science and Project Management Units.

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Class Actions in The EU

Eversheds LLP

It is said that if you want to see the future, look at the United States. Applying that rubric to class actions reveals its limitations since a geographical comparison historically and currently shows a confusing and ironic pattern.

Until relatively recently class actions generally caused fear and alarm in Europe and juries in civil cases still do. Juries are said to produce irrational pro-claimant liability decisions and inflated damages and class actions have been regarded as a process by which defendants can be threatened with “liability in an indeterminate amount for an indeterminate time to an indeterminate class” (Judge Cardozo in Ultramares Corp -v- Louch (1991)).

However, the origins of the US civil jury system and class actions reveal a great irony given that these phenomena are said to represent the worst excesses of an over-zealous US litigation system. Both features were in fact imported from the English common law by the Founding Fathers. If the American revolutionaries rejected a tyrannical King and parliament, they embraced with enthusiasm the revered concept of the English jury and made it, for practical purposes, a permanent feature in civil cases by the seventh amendment to the US constitution in 1791. Class actions, on the other hand, developed from the adoption of representative actions in the English Court of Chancery.

Europe is used to being influenced by American culture and business practices. It is therefore unusual to find the archaic and rejected legal norms of 18th century England being such defining concepts in contemporary US legal practice.

Global harmonisation is growing in many respects but in the context of class actions the historical confusion and irony have a contemporary presence. Class actions similar to the US process are being introduced or contemplated in a number of EU jurisdictions whilst on 18th February 2005 President Bush signed the Class Action Fairness Act, designed to curtail some of the form’s worst features, with a declaration that it is “a practical way to begin restoring common sense and balance to America’s legal system”. Will the US and the EU, starting from opposite points, one day converge at a rationally conceived meeting place?

Before proceeding to review forms of collective action in the EU and legislative proposals, it is essential to define the relevant terms since there is clear evidence of a common tendency to apply the US term “class action” to forms of legal proceedings which are not such but which bear some of the elements which make up class actions. It is important to distinguish between different forms of collective action whilst recognising that in the EU collective actions are undergoing change, that the nature of such actions is developing and that class actions virtually identical to the US process are being introduced.

I shall use the generic “collective action” to cover class actions, group actions and other forms of representative actions where a more specific term is not required or appropriate.

By “class actions” I refer to a procedure whereby one or more persons sue in their own right and on behalf of unspecified other persons who have a claim to the same remedy arising from the same tort and where there are common questions of law or fact; the class members are bound by the outcome of the litigation unless they exercise any opting out provision.

US Class Actions

The numeric size of US class actions and their economic impact, with the potential to bring global companies to their knees, mean that the term resonates widely beyond the legal profession.

Class actions in the US are “an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only”, Califano -v- Yamasaki, 442 US 682, 700-701 (1979). Under the Federal Rules of Civil Procedure a class action must be certified by the trial court before it can proceed and the criteria set out in the rules must be satisfied.

Rule 23(a) requires “numerosity” (the class is so numerous that joinder of all class members is impracticable), “commonality” (common questions of law or fact exist), “typicality” (the claims of class representatives are typical of those of the unnamed class members) and “adequacy of representation” (the class representatives adequately represent the interests of the class).

If the requirements of Rule 23(a) are satisfied, the court must proceed to consider the case under Rule 23(b) which is designed to achieve judicial economy.

Rule 23(a) requires “numerosity” (the class is so numerous that joinder of all class members is impracticable), “commonality” (common questions of law or fact exist), “typicality” (the claims of class representatives are typical of those of the unnamed class members) and “adequacy of representation” (the class representatives adequately represent the interests of the class).

If the requirements of Rule 23(a) are satisfied, the court must consider the case under Rule 23(b) which is designed to achieve judicial economy.

Class members can opt out of the class within a specified time scale and are then free to pursue individual claims. Those who do not opt out are bound by the outcome of the class action.

Class Actions in the European Union

Class actions in the defined US sense have until very recently been unknown in Europe and the scope for
recovering damages by means of other forms of collective proceedings such as group or representative actions has been limited. However, the idea of adopting a more collective approach to attaining justice has certainly been under consideration and collective procedures have been implemented in all EU countries in recent years.

In 1998 the EU introduced the Injunctions Directive (98/27/EC) which allows public enforcement authorities and specific consumer bodies, subject to them meeting objective criteria, the right to seek injunctions in EU member states to stop traders infringing the collective interests of consumers under 11 existing consumer protection directives. The directives are misleading advertising (84/450, as amended by 97/55/EC), “doorstep selling” (85/577/EEC), consumer credit (87/102/EC as amended by 98/7/EC), TV broadcasting activities (89/552/EC as amended by 97/36/EC), package travel, package holidays and package tours (90/314/EC), advertising of medicinal products (90/28/EC), unfair terms in consumer contracts (93/13/EC), time share contracts (94/47/EC), distance contracts (97/7/EC), sale of consumer goods and associated guarantees (99/44/EC) and electronic commerce (2000/31/EC).

The purpose of the Injunctions Directive is to provide the means of actively preventing the infringement of general consumer interests: it is not designed to provide monetary redress. Its purpose is to benefit all consumers rather than to compensate individuals who have sustained some form of damage.

**Group Actions in the United Kingdom**

The UK was one of the first EU countries to introduce specific procedural provision for “group actions” seeking recovery of damages in product liability cases although the system is not confined to that category, being of general application. The UK also has probably the greatest practical experience of such actions in Europe.

The UK group action is different from the US class action in that it involves multiple named claimants. The group action model under Part 19.III of the Civil Procedure Rules 1998 (CPR) is based upon the desire to achieve the efficient administration and economic disposal of cases involving a group of identified claimants in cases where there are common issues of fact and law.

**Representative or Class Actions in the UK**

Extending the range of collective actions in the UK has been considered recently. The Lord Chancellor’s Department conducted a consultation exercise in 2001 and 2002 concerning the possible introduction of representative claims on a wider basis. The consultation document, “Representative Claims: Proposed New Procedures”, February 2001 (see www.leg.gov.uk/consult/general/repclaims:hdp) defined such claims as:

“Claims made by, or defended by, a representative or represented organisation on behalf of a group of individuals who may, or may not be individually named in a situation where an individual would have a direct cause of action”. The consultation paper described representative actions as an enhancement of consumer empowerment, providing additional and complementary methods of handling aggregated claims. Whilst it distinguished them from US class actions, it recognised that individuals “may not be individually named”, a critical feature of US class actions.

The paper considered various types of representative claims, focusing on whether representation would be of:

(i) individuals;
(ii) a named group (e.g. membership of trade union);
(iii) an unnamed but identified group - clearly defining the identity of the group by, for example, geographical area or purchase of a particular product; or
(iv) an unnamed and unidentifiable group - it envisaged the production of evidence in support from those the applicant sought to represent, for example, signed petitions, statements of support from relevant organisations or relevant local groups or bodies.

The Consultation Response was published in April 2002. The strongest opposition was recorded for proposals that would allow damages to be awarded to unnamed claimants and allow claims against defendants who were outside the usual causal relationship.

To close observers of the UK political scene, it was no surprise that the Lord Chancellor’s Department decided to leave such controversial legal developments to policymakers and law makers within the European Commission of the EU.

**Other European Jurisdictions**

It is in specific other EU jurisdictions that the trend of implementing or at least considering US style class actions emerges. Last year in this publication I observed that in the product liability field, and indeed almost all other areas of civil law, there was a general absence in the EU of collective procedures for the recovery of damages. I noted there were exceptions. The exceptions where class actions have been adopted or are being considered will, if the trend continues, become the norm.

**Spain**

Spain introduced a new procedural framework for collective claims in the Spanish Civil Procedure Act which came into force in January 2001. This allows claims to be filed by consumer associations on behalf of groups of individuals who have been injured by the same event. The preamble of the Act stresses that its principal concern is the protection of actionable collective interests of those who have been damaged directly.

This new process in Spain is similar to US class actions in that consumer associations are entitled to act on behalf of injured parties who are not identified and consumer associations are granted an exclusive right to defend the general interests of consumers, empowering them to act on behalf of “all consumers”. Anyone who has been injured by, for example, a product which is the subject of such an action, is allowed to join the proceedings and enforce their individual rights. The Act also provides that a court judgment pursuant to such proceedings will specify the details, characteristics and necessary requirements of those entitled to claim payment who may apply for enforcement of a judgment on their own behalf.
Sweden

Sweden introduced legislation allowing for what are described as class actions on 1 January 2003. This legislation is based upon the US system but also introduces a new public class action. Certain criteria must be satisfied before a class action is accepted by the court:

(i) questions of fact common to the entire class;
(ii) a well defined class;
(iii) a claimant suitable to represent the class; and
(iv) the class action must be the best process comparatively for resolving the issues.

In contrast to the US system, Swedish class actions are based on an opt-in system. Only class members who have given written notification to the court within a specified time limit will be allowed to participate. In that respect the process is more similar to the UK group actions form, where named claimants are required, than to the US class action covering unnamed class members. Members of the class in Sweden do not become parties to the legal proceedings and they are not required to actively participate but the court's judgment is binding on them. In general, passive class members will have no obligation to compensate a successful defendant for any legal costs, the “loser pays” cost principle applying in Sweden.

Three types of action are allowed under the recent legislation:

(i) Private Class Actions - any person (or entity) may initiate an action provided that person has an action and is part of the class;
(ii) Organisational Class Actions - certain organisations (consumer and labour organisations) may initiate actions without having a claim of their own. These actions must, as a general rule, concern disputes between consumers and the providers of goods and services; and
(iii) Public Class Actions - an authority appointed by the government may bring an action where the public interest dictates that action should be taken. The authority does not need to have an action of its own. The purpose is to create a court precedent for guidance for both the public and industry.

Any settlements must be approved by the court.

The Swedish model is an interesting combination of features of class, group and representative actions and goes furthest in providing a comprehensive framework for collective actions.

The Netherlands

The Netherlands currently has a system of collective action known as “General Interest Actions”, where those affected cannot be individualised because their interests are of such a general nature. A collective action is brought. The “Regulation of the Competence of Certain Legal Persons to Bring a Legal Action for the Protection of Other Persons Interests”, 1994 imbued corporations, associations with full legal capacity and public bodies with the ability to bring a legal action in order to protect the interests of others. However, the Act does not allow such organisations to claim compensation for third parties.

Legislation has been proposed similar to US class actions. The Act on the Collective Statement of Mass Claims was filed with the Dutch parliament on 2 February 2004 and was passed by one house of the Dutch parliament on 14 October 2004. It is awaiting a vote in the second chamber. The Act creates the possibility of asking the court to validate a settlement for a complete class of people which has suffered similar damage, save for those who opt-out. That means that the court should be able to make settlements for damages binding on all members of a defined class in a particular mass action. This will allow the liable parties to negotiate a settlement with the claimant class and to have the settlement recognised by the court for the full class of victims who have suffered damage. The Dutch business community seems to be fully supportive of the proposed legislation.

The proposed law would apply to Dutch citizens and other EU citizens doing business with a company in the Netherlands or one which has Dutch interests.

Germany

In Germany there are currently no class actions or GLO’s as in the US and the UK. However, in recent years there has been the emergence of quasi-class actions in Germany, a good example of which is the law suits against EM.TV concerning prospectus liability litigation. A litigation finance provider sought “injured parties” on the internet and through media publicity. This produced around 2000 claimants. The litigation finance provider then procured the assignment of the individual claims to a trustee who combined them in a single action. The notion is that the litigation provider covers the entire cost risk and retains a percentage of the proceeds if the action is successful, the similarity with US claimant lawyers being obvious.

However, on 7 April 2004 the German Federal Ministry of Justice announced a project to introduce a new type of proceeding that aims to assist litigation by individual investors in the arena of false or misleading information in the capital markets. The draft Capital Investors’ Model Proceeding Law will allow claimants in impending securities litigation to petition that one or more issues of fact or law be determined in a “model proceeding”, basically a way to simplify the handling of large numbers of individual security actions. When the model proceeding has been concluded and the issues have been determined, the individual actions are resumed on the basis of the model proceedings’ conclusion. Although there were originally plans to have the legislation in force by January 2005, it is not yet law.

France

French law allows for an “action representation conjointe” or “action in joint representation” which permits groups of claimants to bring a single action but each claimant must particularise his or her own claim which is evaluated separately. French claimants can only be represented on a collective basis if they register an association and prove that a wrong doing has subsequently occurred against that association, an often insurmountable hurdle.

On 4 January 2005 President Chirac announced plans to allow class-action law suits as part of a drive to strengthen consumer rights. He has said, not surprisingly, that he will
make sure that French class actions avoid many of the excesses of the US system. An advisory group has been set up to look at the issues. MEDEF, the organisation that represents the interests of French companies, is concerned that new class action legislation could lead to a sharp increase of litigation whereas consumer groups have welcomed the proposals.

**Italy**

Class actions are currently not allowed within the Italian legal system. However, there is a bill in the Italian parliament (known as the Investor Protection Bill) which is designed to protect Italian investors by introducing greater controls on, and transparency of, corporations. Amongst a number of other reforms the proposed bill would allow investors to bring class actions. This seems to be a reaction to the flooding of the courts by actions from investors who have lost money in bond investments in the Parmalat and Cirio debacles in recent years. The bill was stalled in the House Finance and Production Activities Committees on 5 November 2004 and developments are awaited.

**Will Class Actions Become the Norm in Europe?**

The current situation in the EU is that there are a number of different types of collective civil procedure, some of which are limited to specific classes of case and to specific remedies, such as the procedures available under the Injunctions Directive, and some in which a form of collective procedure for the recovery of damages in product liability and other cases is available, the latter having varying similarities with the US class action form. The stated objective of EU consumer legislation is a high level of consumer protection, the revised General Product Safety Directive, which came into force on 15 January 2004, being a good example. There is also a long standing practice in Europe of the voluntary and state-promoted adoption of collective methods for protecting and advancing consumer and other interests. On the other hand, all EU product liability legislation is expressly designed to balance the interests of consumers and producers in the context of establishing a harmonised system of product law in the creation of the single European market.

There is no EU horizontal directive requiring or empowering member states to introduce national legislation providing for a specific form of collective procedure in the product liability field or civil claims generally. Legislative proposals, which are ultimately the province of the European Commission, are the outcome of the negotiation, often protracted, of different national interests but it is the general policy of all member states to ensure a competitive business environment. In last year’s edition I observed that in many EU states the perception of the US class action and the significant risk it posed to even the largest corporation militated against any desire to introduce a pan-European requirement for a generic collective process. The alacrity with which, particularly over the last 12 months, a number of EU states have unilaterally implemented or proposed collective procedures very similar to the US class action is likely in the medium to long term to provide a political incentive, and political justification, for a pan-European procedure with a high level of uniformity, whilst retaining some procedural variation to reflect differing judicial and jurisprudential practices.

Any pan-European proposal is likely to contain many features of the US class actions. It is impossible to predict the timescale for such a development but recent events brings it nearer. This prognosis of course could be completely negated or seriously undermined by one or more of the major EU states delivering a no vote in a referendum on the draft EU Constitution. The outcome of the referendum in France will be particularly relevant.
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Paul Llewellyn is a partner in the Nottingham office of Eversheds, one of the world’s largest law firms with over 2000 lawyers. He practices exclusively in product liability defence work. In the early years of his career his practice involved large scale actions and disease cases on behalf of members of trade unions. For the last 10 years he has worked for major corporates and their insurers and leads a team of 9 lawyers involved in product liability cases, specialising in particular in medical device litigation. He has particular experience in negotiating innovative bespoke ADR agreements and medical device action litigation.
The Chambers Guide to the UK Legal Profession has described Mr Llewellyn as a leading product liability defence lawyer and a “tough negotiator”, a “driving force” and “prolific”. He has lectured on product liability in Europe and the US. He is a member of the Defense Research Institute, the largest organisation of civil defence attorneys in the US, and he is a member of the DRI’s Drug and Medical Device Committee and Deputy Chair of their International Special Litigation group. He is also a member of the Product Liability Advisory Council.

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We’re not just here to tell you the law - our lawyers are business advisers as well as legal experts. We believe in true partnerships with our clients: really getting to know you so our advice is the best it can be and adding value to our relationships through creative thinking and an open mind. The way we deliver our advice sets us apart: jargon free, when you want it, in the form you want it.

Our product liability expertise
We have dealt with product liability issues across the UK and Europe, and beyond, including the US and Asia. Many product liability issues have a gross-jurisdictional impact, especially given the international nature of our clients’ businesses. Our international expertise means that whatever the problem there will be an Eversheds lawyer able to deal with it, knowledgeably and efficiently.
II. Lure of the American Forum

It is not one factor that leads foreign plaintiffs gladly to accept the inconvenience of bringing suit across oceans, but rather a broad range of factors. These include the possibility of large damage awards, including punitive damages, the availability of jury trials, liberal pleading rules, broad discovery tools and the option to bring claims on a contingency fee basis.

Any discussion of product liability litigation in American courts cannot fail to notice the increasingly fabulous damage awards granted by juries in recent years. Damages in America are calculated on two principle bases: compensatory and punitive. Compensatory damages are meant to have a basis in the actual harm suffered. However, the addition and expansion of the concept of “pain and suffering” has muddied the waters somewhat. Compensation for lost wages and similar traditional categories of compensatory damages are clearly tethered to concrete figures. A determination of what is fair compensation for “pain and suffering” lacks a similar anchor.

Departing further from the realm of the quantifiable, the concept of punitive damages allows a jury to impose further damages on top of compensatory damages. In order to qualify for punitive damages, plaintiffs must make a threshold showing of certain egregious behaviour on the part of the defendant. This requirement has not always proven to be daunting in the product liability setting.

Further assisting plaintiffs in United States courts, judgments of whether to impose liability, and how much to award in damages, generally fall to a jury of laymen. In most contexts, plaintiffs in product liability actions do not even need to clear any meaningful substantive hurdles in order to receive a jury trial. Rather, plaintiffs generally have a “right” to a jury, under the federal and many state constitutions, unless they choose to waive that right. It virtually goes without saying that an injured person or group of people might prefer to place their claims before a panel of their peers, rather than an impartial (and arguably conservative) judge, particularly when (as in a product liability action) their opponent is a large international corporation.

Well before a trial even reaches a jury, however, plaintiffs enjoy significant advantages through the use of what are, generally speaking, liberal pleading rules. A plaintiff often may not need to spell out a well-articulated theory of the case to be able to move forward with the litigation. In most American courts, a plaintiff need only make the barest allegations to survive a motion to dismiss. This practice, called “notice pleading,” requires only a “short and plain statement of the grounds” for why the court has jurisdiction and the reasons the plaintiff should recover. See FED. R. CIV. P. 8(a) (West 2005). Even the model complaint offered by the Federal Rules of Civil Procedure contains only three paragraphs, which assert merely the basis for jurisdiction, the nature of the injury, and a demand for damages. Plaintiffs need not provide any other information in order to commence their suit and start the wheels of a civil action turning.

Once a plaintiff files a complaint and survives any motions to dismiss, he finds himself armed with the considerable powers of American discovery tools. He may now develop his case by demanding that a defendant produce huge volumes of documents, answer written questions and produce witnesses for examination. See FED. R. CIV. P. 26-37 (West 2005). Bearing the costs of meeting discovery obligations in a U.S. court can prove extraordinarily expensive for defendants who, in product liability actions, tend to have the bulk of relevant documents and witnesses in their possession or their employ. This expensive burden provides a strategic advantage to plaintiffs; as soon as litigation begins, costs borne by defendants rise no matter
how weak a plaintiff’s case.

As litigation continues and costs mount for defendants, the typical product liability plaintiff has had to pay not the slightest sum of money. The United States legal system permits plaintiffs’ lawyers to take cases on “contingent fee” arrangements, and they frequently do so. Under such arrangement, the plaintiff pays no costs to his attorneys unless the plaintiff prevails at trial, in which case the lawyers take a substantial share of the judgment - generally thirty-three percent, and sometimes as much as fifty percent. Not only are such arrangements uncommon in other legal systems, in many countries they are illegal.

Finally, in contrast to other Common Law systems, a failing plaintiff bears no responsibility for a defendant’s legal bills. With no costs up front, no downside risks at the conclusion and a range of advantages throughout the process, it is no surprise that a product liability (or any other) plaintiff would seek access to United States courts.

A. Jurisdiction Over Foreign Plaintiffs

It is clear that plaintiffs may wish to pursue their claims in American courts, but can foreign plaintiffs actually do so? If they can, in which courts may they bring their actions? Initially, the answers to these questions would be yes, they can, and plaintiffs will likely have access to a variety of state and federal venues.

The question of whether a court may hear a plaintiff’s case is governed by an inquiry into “jurisdiction,” the Common Law equivalent of the Civil Law’s concept of “competence.” In order to hear a given case, a U.S. court must have both subject matter and personal jurisdiction. Unless a plaintiff can show that a court has each, the court is unable to hear the case.

Subject matter jurisdiction concerns whether the claim presented is within a category of issues that a particular court has the power to hear. For current purposes, it is sufficient to say that American state courts are courts of general subject matter jurisdiction. With some exceptions not relevant here, a state court can hear claims on any issue, which includes product liability claims. The federal courts, on the other hand, are courts of limited subject matter jurisdiction. Federal courts only have subject matter jurisdiction in certain classes of cases. One basis for federal subject-matter jurisdiction is “diversity” of the parties, where the amount in dispute is in excess of US $75,000. 28 U.S.C. § 1332 (2005). Put simply, the parties are diverse when the plaintiff and defendant are not citizens of the same state. Thus, in any action against a U.S. company by a foreign plaintiff, diversity of the parties will exist.

Assuming the “amount in controversy” is in excess of US $75,000 (a safe assumption in the product liability context), a federal court will have subject matter jurisdiction over a product liability claim by a foreign national against a domestic corporation.

In addition to establishing subject matter jurisdiction, plaintiffs also must show that a court has personal or territorial jurisdiction. Traditionally, a court had personal jurisdiction over its citizens and those who could be found in, or who possessed property within, the boundaries its authority. Pennoyer v. Neff, 96 U.S. 714, 733 (1877). As this concept evolved with industrialisation, courts increasingly found that corporations were subject to jurisdiction in any state when they had “certain minimum contacts . . . such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.” Int’l Shoe v. Washington, 326 U.S. 310, 316 (1945). Manufacturers of widely-distributed products typically find themselves subject to personal jurisdiction in numerous fora.

The practical effect of the foregoing is that foreign product liability plaintiffs suing American corporations will usually have the ability to select from a wide array of American courts, including state or federal district courts. This should only make litigating in the United States more attractive to foreign plaintiffs - not only do they benefit from all the procedural and substantive rules discussed above, they also have the power to select the court and jurisdiction where all of those factors run most strongly in a plaintiff’s favour, and where the most favourable substantive law and sympathetic jury may be found. Rather than offend basic notions of American jurisprudence, this fact finds itself buttressed by the axiomatic principle that a plaintiff’s choice of forum is entitled to great deference. Piper Aircraft Co. v. Reyno, 454 U.S. 235, 255-56 (1981); Dowling v. Hyland Therapeutics Div., 767 F. Supp. 57, 58 (S.D.N.Y. 1991).

B. Forum Non Conveniens

At this point, it might appear that the prospect of litigating in the United States constitutes a foreign plaintiff’s dream come true. Save the last two words, that phrase might be accurate. American courts have developed doctrines that make it quite challenging for foreign plaintiffs to convert the theoretical into the actual.

While legal and political movements to dampen litigation have yet to achieve any global reform, product liability cases brought by foreign plaintiffs compose one of the categories of cases in which pro-reform forces have met with the most success. The impetus for turning away foreign plaintiffs has come not from the political branches, but from the judiciary itself. Relying on the traditional notion of forum non conveniens, the courts in recent decades routinely have dismissed foreign claims.

Just because an American court has jurisdiction to hear a claim does not mean that it must do so. Several grounds exist upon which it can decline to adjudicate a dispute, one of these grounds being known as the doctrine of forum non conveniens. It holds, that a court may decline to exercise jurisdiction when litigation makes more sense - is more convenient - elsewhere.

1. The Federal Test

The United States Supreme Court has developed a flexible approach to forum non-conveniens, which federal courts employ to evaluate whether a case ought to be dismissed on those grounds. The general framework was first announced in Gulf Oil Corp. v. Gilbert, 330 U.S. 501 (1947). As an initial matter, a court must find that there is an adequate available forum elsewhere. This condition is easily satisfied in most cases. If all parties may be brought before a particular court, it is generally considered adequate. That the alternate forum provides different substantive law, a lower likelihood of success or less significant available remedies does not render an alternative forum inadequate. Once a court satisfies itself that an acceptable alternative forum exists, it must weigh a variety of private and public considerations before reaching the decision of whether to
hear the case or send it back from whence it came. The private considerations include: access to evidence, availability and cost of compelling the presence of unwilling witnesses, the ability to view locations relevant to the action, and general considerations of ease, cost and timeliness. Id. at 508. While the Gulf Oil Court held that a plaintiff’s choice of forum ought to be disturbed only when a weighing of the factors strongly favors the defendant’s position, it also made clear that courts should not permit plaintiffs to choose a forum to harass a defendant. Id. at 507.

A court must also consider a multitude of public factors. These factors include, among others: administrative difficulties related to court congestion; the imposition of jury duty upon a community that bears no relation to the controversy; the interest in having “localized controversies” decided by local courts; and the appropriateness of having a local court make determinations with regard to its own local law. Id. at 508-09. If the public factors weigh in favour of the defendant, then a foreign plaintiff is unlikely to succeed in keeping the action in the United States.

The Supreme Court addressed the question of forum non conveniens in the products liability context for the first time in Piper, 454 U.S. at 235. In that case, an action was brought by the representative of the estates of British subjects who perished in an airplane crash in Scotland. The only connection the suit had to the United States was the fact that the manufacturers of the plane and its propellers were American companies. The plaintiffs admitted that the action was filed in the United States solely because its laws regarding liability, capacity to sue, and damages were more favourable than those of foreign courts. Id. at 240. Thus, it was the plaintiffs’ position that the case should not be dismissed on forum non conveniens grounds because it would result in an unfavourable change in substantive law.

The Supreme Court rejected the assertion and held that even the “possibility of a change in substantive law should ordinarily not be given conclusive, or even substantial, weight in the forum non conveniens inquiry.” Id. at 247. In its decision, the court made it clear that it was consciously limiting the access foreign plaintiffs have to United States courts. It explained that if it had reached a contrary result, “American courts, which are already extremely attractive to foreign plaintiffs, would become even more attractive. The flow of litigation into the United States would increase and further congest crowded courts.” Id. Accordingly, a change in substantive law would only be given substantial weight when “the alternative forum is so inadequate or unsatisfactory that it is no remedy at all.” Id. at 254.

The court also re-balanced the scales of the forum non conveniens analysis in terms of according deference to a plaintiff’s choice of forum. Whereas the traditional rule was to give plaintiffs’ choice of forum great deference, the Piper Court held that foreign plaintiffs were not entitled to any such deference. This conclusion significantly impaired the ability of foreign plaintiffs to maintain their actions in U.S. courts.

2. State Approaches

While a forum non conveniens analysis in state court would have to proceed under the relevant state’s particular laws and precedents, in reality, the analysis tends to be very similar to the federal approach. For example, the California Supreme Court explicitly adopted the framework of Gulf Oil in 1954.

C. Dismissals

Courts in the United States increasingly have relied on forum non conveniens to keep foreign product liability actions out of United States courts, so much so, that this has become the expected result. Following Piper, courts have found that a foreign court provides an adequate forum, even when the substantive foreign law offers plaintiffs significantly diminished prospects of recovery. Proyectos Orchimae ex Costa Rica v. E.I. DuPont de Nemors & Co., 896 F. Supp. 1197, 1201 (M.D. Fla. 1995). For example, a state court found that a US $10,000 recovery limit does not render a foreign forum inadequate; nor does a requirement of massive filing fees, the presence of a heavily congested and backlogged judicial system, and far-less favorable tort remedies. In re Union Carbide Corp. Gas Plant Disaster at Bhopal, India, 634 F. Supp. 842, 847-52 (S.D.N.Y. 1986); Wolf v. Boeing Co., 810 P.2d 943, 948-49 (Wash. Ct. App. 1991). Some courts have allowed dismissal on the ground of forum non conveniens even when the suit might be time-barred by the foreign country’s statute of limitations. Lonny S. Hoffman, Forum Non Conveniens- State and Federal Movements SF13 Ali-Aba 135, 144 (Nov. 2000). Perhaps most remarkable is that a court even upheld a dismissal on the ground of forum non conveniens when, due to political conflicts, no alternative forum was actually available at the time. Islamic Rep. of Iran v. Pahlavi, 467 N.E.2d 245 (N.Y. 1984).

Despite the trend indicating that United States courts will dismiss product liability claims brought by foreign plaintiffs, domestic defendants cannot count on such a result. Because the forum non conveniens analysis invokes a multi-factored balancing test, under no situation can the expected result be the anticipated result. Courts have broad discretion when making such determinations and the results of a motion to dismiss on these grounds will vary depending on the judge entertaining it and the specific facts making up the case at issue.

Examples of courts that have rejected a forum non conveniens argument include several that cannot easily be reconciled with the broader trend discussed above. For example, some courts have concluded that Bolivia and India could not provide an adequate alternative forum due to issues of corruption and congestion in their judicial systems. Eastman Kodak Co. v. Kavlin, 978 F. Supp. 1078, 1085 (S.D. Fla. 1997); Bhattacharjee v. Sarvendra Overseas LTD, 52 F.3d 1220, 1225-30 (3d. Cir. 1995). Moreover, contrary to their other judicial brethren, some courts have found that if an action would be time-barred in the foreign jurisdiction, then dismissal on forum non conveniens grounds is inappropriate. Silicone Gel Breast Implants, 887 F. Supp. 1469, 1475. Thus, while forum non conveniens can be an effective approach, it is not a surefire guarantee of dismissal.
method for dismissing foreign plaintiffs’ lawsuits, the results are not guaranteed.

Even if defendants could count on a dismissal on the ground of forum non conveniens, they should still take pause. Recent trends indicate that a favourable result on a motion to dismiss on the ground of forum non conveniens may come with strings attached. Prior to entering an order dismissing a case on the ground of forum non conveniens, courts have required defendants to make various concessions including agreeing to submit to process in foreign courts, agreeing to accept any judgment reached by that court and waiving statute of limitations defences. See, e.g., In re Silicone Gel Breast Implants Prod. Liab. Litig., 887 F. Supp. at 1479; Kilvert v. Tambrands, Inc., 906 F. Supp. 790, 798 (S.D.N.Y. 1995); Ministry of Health v. Shiley, 858 F. Supp. 1426, 1442 (C.D. Cal. 1994).

In short, a defendant should not expect to receive a forum non conveniens dismissal, and will need to muster the very best argument to succeed - and even then, there may be a price to be paid.

III. Fear of the American Forum

The same factors that lead foreign plaintiffs to bring suit across oceans, strike fear in the minds of foreign defendants who wish to avoid the inconvenience and arguably hostile and unfamiliar environment of American jurisdiction. These defendants shudder at the possibility of large damage awards, including punitive damages, the availability of jury trials, liberal pleading rules, broad discovery tools, and plaintiffs’ attorneys who will work on a contingent fee basis.

Though foreign defendants may wish to avoid American jurisdiction, can they actually do so? The answer to this question is yes; however, they should engage in strategic planning if they desire to insure an appropriate result.

A. Jurisdiction Over Foreign Defendants

As discussed above, plaintiffs must establish both subject matter and personal jurisdiction over a foreign defendant. Further, the existence of subject matter jurisdiction is rarely an issue in a products liability matter involving a foreign party. Therefore, the remainder of this article will focus on the limits of personal jurisdiction over foreign defendants.

B. Personal Jurisdiction

When a plaintiff institutes suit against a foreign defendant, an American court will engage in a two-step inquiry to determine if the court can assert personal jurisdiction. First, it will determine if the state legislature has granted statutory authority for the exercise of jurisdiction. Provided such statutory authority exists, the court will then consider whether an exercise of such jurisdiction is consistent with traditional notions of “fair play” inherent in the U.S. Constitution.

1. Statutory Authority

In the majority of cases, a state’s “long arm” provision will serve as statutory authority for jurisdiction. Some state long arm statutes grant jurisdiction to the state’s courts to the extent permissible under the United States Constitution. In other jurisdictions, however, the state long arm statute provides either a specific list of enumerated relationships or a stated nexus between the defendant and the forum that allow for jurisdiction. No bright line rule exists with regard to these states. Instead, the courts engage in fact specific inquiries. This article will not focus on state long arm statutes, as even the most restrictive state long arm statute will likely provide for jurisdiction in a products liability matter.

2. Minimum Contacts

Once a court determines that it can exercise jurisdiction under a state long arm statute, the court will consider if doing so will violate the due process clauses of Fifth and the Fourteenth Amendments of the United States Constitution. In the last half of the twentieth century, the Supreme Court set forth the basic analysis that should be conducted to determine whether jurisdiction over a defendant is proper. First, the defendant must have minimum contacts with the jurisdiction such that the exercise of personal jurisdiction would not “offend traditional notions of fair play and substantial justice.” Int'l Shoe, 326 U.S. at 316. Second, the defendant must have “purposefully avail[ed] itself of the privilege of conducting activities in the forum state” such that the defendant should have reasonably foreseen that a plaintiff would pursue litigation in that jurisdiction. World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980) (citation omitted). Under this purposeful availment standard, the mere fact that a defendant’s product enters a state does not subject that manufacturer to personal jurisdiction in that forum.

The question of how a defendant “purposefully avails” itself to the privileges provided by a forum and makes itself amenable to litigation in that forum became more complicated in 1987 when the Supreme Court decided the products liability case of Asahi Metal Industries Co., Ltd. v. Superior Court, 480 U.S. 102 (1987). In Asahi, the Court found that the state of California could not exercise personal jurisdiction over a Japanese manufacturer of component parts. Due to the divisiveness of the Asahi opinion, however, the court failed to set clear guidelines for litigants and judges in future cases.

The plaintiff, in Asahi, was injured in a motorcycle accident in California. He filed suit in California against various parties including Cheng Shim, a Taiwanese manufacturer, alleging a defect in the motorcycle’s rear tire and tube. Cheng Shim filed a cross-claim for indemnification against Asahi Metal Industry Co., the Japanese manufacturer of the tube’s valve. The plaintiff eventually settled his claim against all defendants except Asahi. Asahi challenged the court’s assertion of personal jurisdiction. While the United States Supreme Court unanimously agreed that assertion of jurisdiction over the company would violate due process, the court’s members did not present a uniform rationale for their decision.

Five of the nine justices found that Asahi had minimum contacts with the state of California by its mere act of placing a product in the stream of commerce; however, all of the justices except for one held that despite these minimum contacts it would be “unreasonable and unfair” for California to hear this case because of the burden placed on Asahi in defending itself in a foreign legal system. Moreover, they found California had very little interest in deciding an indemnification issue between two foreign defendants. Id. at 116.
In a plurality opinion three justices joined Justice O’Connor, who wrote that Asahi did not maintain the requisite minimum contacts for California to assert jurisdiction as such contacts could only occur “by an action of the defendant purposefully directed toward the forum State.” Id at 112. Referred to as the “purposeful availment” standard, O’Connor wrote that factors such as “designing the product for the market in the forum State, advertising in the forum State, establishing channels for providing regular advice to customers in the forum State, or marketing the product through a distributor who has agreed to serve as the sales agent in the forum State” would have demonstrated “contacts,” however, Asahi did not engage in such actions. Id. In contrast to the purposeful availment standard, three justices joined Justice Brennan in his “stream of commerce” opinion that Asahi had minimum contacts with California stating that as long as a manufacturer “is aware that [its] final product is being marketed in [a] forum State, the possibility of a lawsuit there cannot come as a surprise.” Id. at 117. Justice Stevens, in a separate concurrence, joined the majority of justices in his opinion that it would violate due process for California to exercise jurisdiction over Asahi, however, he refused to decide the minimum contacts issue, instead discussing the purposeful availment standard in the abstract. Id. at 121.

The ever-changing alliances and varied opinions that emerged from the Asahi opinion left litigants wondering how either the minimum contacts or the purposeful availment analysis would ultimately be decided in later litigation. Lower courts, therefore, often struggle with this analysis and decisions vary widely.

C. Dismissals - Recommendations

To avoid being subject to the risks and burdens of litigation in the United States, foreign parties should engage in certain strategic planning mechanisms. While no strategy offers a full-proof solution, the following proposals can strengthen a foreign party's ability to stay out of U.S. courts.

1. Refrain From Direct Sales, Shipping and Marketing

Foreign parties who wish to avoid the reach of American courts should avoid direct sales and shipping to American jurisdictions. For example, courts in Texas and California refused to grant motions to dismiss because foreign defendants directly sold their products in those jurisdictions in “mass quantities” for a number of years. S.P.A. Giacomini v. Lamping, 42 S.W.3d 265, 273 (Tex. App. 2001); In Cassier Mining Corp. v. Superior Court of Orange County, 78 Cal. Rptr. 2d. 167 (Cal. App. 1998).

Foreign parties seeking to avoid American jurisdiction also should avoid targeting their advertisements to residents of a forum state. Such direct-to-consumer advertising will weigh against a defendant in jurisdictions using the minimum contacts test. For instance, in Turpin v. Mori Seki Co., Ltd., a federal district court held that the defendant had “purposefully availed” itself of the protection of the forum state by providing brochures to help distributors market its products in the U.S. and publishing promotional literature advertising that the company had a Boston office (which was actually the office of a dealer or a subsidiary). 56 F. Supp. 2d 121, 127-28 (D. Mass. 1999).

2. Monitor Internet Infrastructure and Contacts

The internet creates a new realm of exposure to American jurisdiction for foreign entities. Therefore, it remains important for foreign parties that wish to avoid American courts to monitor their internet dealings with residents of American jurisdictions. American courts have adopted a sliding scale approach with regard to jurisdiction created by internet exposure. Zippo Mfg. Co. v. Zippo Dot Com, Inc., F. Supp. 1119, 1124 (W.D. Pa. 1997). The more embracing the interaction between the entity’s website and residents of the forum state, the more likely a court will assert personal jurisdiction.

One end of the sliding scale consists of websites established for the primary purpose of conducting business activities with residents of other jurisdictions, which will subject parties to jurisdiction. Compuserve Inc. v. Patterson, 89 F.3d 1257 (6th Cir. 1996). The other extreme of the scale includes passive websites where companies merely post information, rather than conduct business activities. These websites will not subject companies to U.S. jurisdiction. Bensusan Restaurant Corp. v. King, 937 F. Supp. 295 (S.D.N.Y. 1996), aff’d 126 F.3d 25 (2d Cir. 1997). The middle of the scale contains the difficult cases. These types of websites provide some interaction between forum state consumers and the corporation; however, the interaction does not result in consistent business activity or communication. Courts hearing the cases in the middle scale will address personal jurisdiction on a case-by-case basis focusing on whether the defendant targeted residents of the forum state. Millennium Enter. Inc. v. Millennium Music, Ltd. 33 F. Supp. 907 (Ore. 1999).

3. Maintain Corporate Formalities

Plaintiffs can attempt to bring actions against foreign defendants in American courts by citing the activities of related American entities (typically subsidiary or parent corporations of the foreign defendant). If the plaintiff can demonstrate that the subsidiary constitutes a mere extension of the parent or vice versa, the foreign entity can find itself subject to American jurisdiction. See, e.g., Hawes v. Honda Motor Co., Ltd., 738 F. Supp. 1247 (E.D. Ark. 1990). Furthermore, a foreign corporation that itself maintains operations in the United States will be hard-pressed to avoid personal jurisdiction in a forum in which those operations are based.

4. Avoid Territorial or Exclusive Agreements with American Distributors

Foreign parties who wish to avoid the reach of American courts should avoid territorial and exclusive agreements with American distributors. Treatment of supplier to distributor relationships varies from state to state; however, the mere fact that a product is sold to a distributor rather than directly to customers in a particular state is not an effective method for avoiding liability. See, e.g., S.P.A. Giacomini, 42 S.W.3d at 273.

When considering personal jurisdiction, courts view certain supplier to distributor relationships in a more skeptical manner than others. Courts typically find that defendants who maintain exclusive relationships with American distributors, or that impose territorial restrictions on American distributors, possess minimum contacts with states in which those distributors are located or in which those distributors regularly conduct business. See Lister v. Marangoni Meccanica, S.P.A., 728 F. Supp. 1524, 1528 (D.
By contrast, suppliers who employ distributors without exclusivity or territorial restrictions may be able to avoid personal jurisdiction in certain states. For example, in *Mullins v. Harley-Davidson Yamaha BMW of Memphis, Inc.*, a Tennessee state court dismissed a complaint against a foreign corporation for lack of personal jurisdiction even though the corporation’s products were distributed in the forum state. 924 S.W.2d 907 (Tenn. App. 1996). The court reasoned that the defendant had no control over the products’ distribution and the agreement noted that the defendant’s distributors were “free to sell to any dealer of their choosing anywhere in the United States.” *Id.* at 909. Thus, this type of arrangement might provide foreign defendants with some protection against U.S. jurisdiction, depending upon their other U.S. contacts.

5. Assert a Due Process Defence

As *Asahi* demonstrates, there are a number of individualised factors that determine whether foreign defendants can be subjected to U.S. jurisdiction. Courts are directed to consider “the burden on the defendant, the interests of the forum State, and the plaintiff’s interest in obtaining relief. It also must weigh in its determination “the interstate judicial system’s interest in obtaining the most efficient resolution of controversies; and the shared interest of the several States in furthering fundamental substantive social policies.” *Asahi*, 480 U.S. at 113 (citation omitted). A defendant must be prepared with evidence supporting an argument for each of these factors to convince the forum court that an assertion of jurisdiction would violate traditional notions of fair play and substantial justice.

6. Contact Local Counsel

American law clearly provides that American plaintiffs can bring product liability actions against foreign defendants in American courts, provided such defendants exhibit minimum contacts with the forum jurisdiction and adjudication of the matter will not interfere with fair play and substantial justice. Foreign parties can follow the guidelines set forth in an attempt to avoid such an assertion of jurisdiction; however, a foreign party that wishes to minimise its potential of facing litigation in American courts should contact local American counsel to provide advice on the structure of their business operations. Similarly, a foreign party that finds itself named in a lawsuit in an American court should contact American counsel immediately in order to preserve and articulate its very best challenge to the court’s assertion of personal jurisdiction.
Chapter 6

Cross-Border Product Risk Management

Freshfields Bruckhaus Deringer

Introduction

The key to avoiding product liability claims, product safety prosecutions, regulatory intervention and attendant adverse publicity is proper product risk management. But what does this mean in a cross-border marketplace, where companies are faced with ever-increasing layers of regulation, demands for heightened corporate responsibility and a growing consumer claim psychology?

It certainly does not mean that transnational companies can afford simply to meet national safety and quality standards in their home market and then hope for the best. Rather, they need to take account of the ways in which the legal and regulatory systems of markets in which they operate differ. And this often requires not simply an understanding of the differences in black-letter law, but also of local political systems, regulatory attitudes, best practice, consumer concerns and historically sensitive issues.

The first section of this chapter sets out the main challenges to effective cross-border product risk management. The second contains principles of general application to companies and their management on how to manage cross-border product risks in the face of these challenges.

The Main Challenges to Cross-Border Product Risk Management

1. The Trouble With Regulation

Governments are typically responsible for regulating product risks, but they are hampered by two important factors. First, state regulation tends to be national or regional in scope, a product of concerns and political motives which may have no resonance outside the individual member state. Second, the ability of states to design and implement effective regulation of product risks is constrained by their need to work with industry, the judiciary, organised pressure groups, the press and the public in their jurisdiction and by the competence and attitudes of individuals within their regulatory bodies.

Even in the European Union (EU), where member states are united under an umbrella of common product liability and safety legislation, the need for states to implement much of that legislation in their own jurisdiction - alongside pre-existing national regimes - results in significant differences in its interpretation and enforcement. In part, this may be a reflection of the fact that it is not always clear, even to regulators, what constitutes compliance with government regulation. Despite the progress made in recent years towards properly assessing the impact of proposed regulation before it is passed, a great deal of “bad” regulation - ill thought through, unnecessary, disproportionate to its objectives - still manages to find its way onto the statute books at both European and national level.

There can also be little doubt that, within the EU, the burden of regulation, both good and bad, is growing. The consumer products sector, in particular, is increasingly highly regulated. Within recent years, for example, the EU has:

- adopted new, harmonised rules on general product safety (via Directive 2001/95/EC) and general food law (via Regulation 178/2002/EC) that impose stringent quality management and recall obligations on producers and distributors and create new rights of market intervention for both national and EU authorities;
- overhauled the pharmaceuticals regime; and
- launched its “REACH” proposals to reform the entirety of chemicals regulation.

If enacted, these proposals will have significant implications both for the chemicals industry and for manufacturing companies that use chemical products. Merely keeping up with these regulatory changes, let alone ensuring compliance, is no mean feat.

Sudan I and Para Red Food Dye Alerts

Sudan I is a red chemical dye used for colouring solvents, oils, waxes, petrol and certain polishes. It is also a suspected human carcinogen banned from use in food products in the EU. In early February 2005, UK company Premier Foods informed the Food Standards Agency (FSA) that a sample of its Crosse and Blackwell Worcester Sauce had tested positive for the dye in Italy. Further tests suggested that the source of the dye was a 2002 batch of chilli powder purchased from an overseas supplier and that a wide range of third party products had become contaminated through the use of the sauce as a food ingredient.

In response, the FSA began working with local authorities
and industry to coordinate what would become the largest-ever UK recall of consumer products. On 18 February 2005, the FSA issued a consumer health warning providing a list of over 350 affected products (the total was to rise to close to 600 by May 2005) and advised that, although the associated risk was small, consumers should not eat the listed items but return them to retailers for a refund. The “vast majority” of products contaminated with the illegal dye were subsequently removed from sale.

The recall ultimately extended beyond the UK and the EU to many other countries, including the US, Canada, South Africa, China, Australia, and New Zealand. More recently still, further recalls have been necessitated by the discovery of a second red dye - Para Red - in UK food products.

These recalls are important for two reasons. First, they show the increasing scrutiny faced by food business operators since important provisions of the general food law (via Regulation 178/2002/EC) entered into force in January 2005. The new provisions place new food safety obligations on the food industry, but oblige national regulators to take enforcement measures, where required, on a precautionary basis. The FSA’s decision to order the recall of products containing a contaminant at levels that pose miniscule risks to consumer health illustrates this precautionary approach in action. Second, the recalls illustrate the difficulties for industry in complying with the new food law regime cross-border. In contrast to the UK’s “zero tolerance” stance, for example, the regulators in the Czech Republic, Spain, the Netherlands, Germany and Belgium have reportedly allowed products with extremely low levels of Sudan dye contamination to stay on the market. So - despite the new “harmonised” regime - it seems that industry still faces differing obligations from one member state to the next.

None of this bodes well for transnational manufacturing and supply companies: how can they ensure compliance and manage their risks in changing circumstances across a host of countries, where the law is being shaped by parties outside government; where regulators applying the same legislation do not react similarly to a product problem; where regulation may not always be of a high quality; and to compare different companies’ products and complementary services; and where political issues may determine regulatory controls?

2. Demands for Heightened Corporate Social Responsibility

Consumers in many countries worldwide are placing significant pressure on producers to respond to emerging product risks. That pressure comes from a number of trends, including:

- increased consumer muscle, a by-product of consumers’ greater awareness of their rights and increased scepticism (in part media-fuelled) about corporate ethics and what they are told to believe;
- the growing importance of the health and lifestyle agenda;
- increased access to the internet, enabling consumers better access to information on corporate behaviour and to compare different companies’ products and complementary services; and
- consumers’ greater awareness of the inadequacies of product regulation.

Public pressure on producers to respond to emerging product risks comes in the form of an intensified demand for corporations to be more accountable to the public and shoulder greater social responsibility. International organisations, governments, NGOs and the media - faced with issues such as BSE, rail safety, alternative medicines and genetically modified foods, which appear to highlight the limits of product regulation - are joining in the clamour for corporate social responsibility. Anything related to a company’s brand is of interest: the ingredients of its products; product design and marketing; the company’s history; its environmental performance; and its stance on a range of other economic, social and political issues. There are even signs that the lending banks may be extending their traditional focus on the human rights and environmental impacts of project finance into their more general lending and export credit business. How long before a products company finds it hard to obtain finance because of its stance on consumer safety or the environment?

The demand for heightened corporate responsibility has led to a large number of bodies endeavouring to be the “last word” on corporate governance and corporate social responsibility. Corporate responsibility policies have been spawned by the OECD, the EU, the UN and a host of national governments and NGOs. It also brings with it a willingness to take action in pursuit of those ends. Nowadays, virtually anything a company does, wherever in the world, will either enhance or prejudice brand value - witness the ongoing criticism over certain pharmaceutical companies’ exploitation of their patent rights in Africa (particularly regarding HIV/AIDS therapies) and the problems encountered by Nike and GAP following media allegations of poor working conditions at some of their suppliers’ premises.

3. The “Best Practice” Industry

Allied to increasing demands for general “good corporate behaviour” is the proliferation of standards, guidelines and suggestions for best practice dealing with more specific areas of product design, manufacture, stewardship and disposal. Some of this literature may be genuinely helpful to companies seeking advice on the management of product risks, particularly where it places somewhat nebulous regulatory concepts into a more practical context: exemplary sets of guidelines on corrective action in a product crisis produced by the UK Department of Trade and Industry (1999), the British Retail Consortium (2003) and PROSAFE (the EU association of national product safety enforcement agencies) (2004) being cases in point. However, other commercial publications, designed to fit as wide a range of organisations as possible, may be more nebulous in their advice.

The real risk for products companies is that systems and policies which specify non-mandatory, “soft law” standards of this sort may bring in product liability and negligence claims “through the back door”, if corporations fail to meet those standards. Already, the revised general product safety regime mentioned above directs producers and regulators to have regard to national “standards”, “Commission recommendations setting guidelines on product safety assessment” and “product safety codes of good practice in force in the sector concerned” in determining whether a product is safe - and whether the producer and its directors
will therefore escape potential criminal or administrative liability. And more and more businesses are demanding that their suppliers meet ISO or other quasi-regulatory commercial standards as a prerequisite for supply. It follows that awareness of such standards is fast becoming a business necessity (and compliance a staple of corporate due diligence).

4. Growing Consumer Claim Psychology

There is always debate as to whether the Western world has, in fact, seen a growth in “compensation culture” and consumer claims mentality in recent years. The UK’s Better Regulation Taskforce, in a report published in May 2004, decried “the myth of compensation culture”, but the law firm Lovells’ report for the European Commission of February 2003 did indicate that there was a perception among consumers, insurers and industry that product liability risks had increased since the introduction of the EU-wide strict liability regime embodied in 1985’s Product Liability Directive (85/374/EEC). Equally, recent class action reforms and pronouncements from the Bush administration indicate that the growth of product liability litigation in the US is a matter of some political concern.

Intense media coverage of successful compensation claims, the development of an organised plaintiffs’ bar adept at transferring skills learnt in one battlefield (for example, tobacco) to another (for example, the ongoing health litigation against fast food companies in the US) and the availability of novel fee arrangements (such as conditional “no win, no fee” deals) and insurance for legal costs in many jurisdictions may all have affected consumer claims psychology. In the EU, the willingness to litigate is only likely to increase as both the European and national authorities introduce reforms aimed at improving access to justice. By way of example, the UK, Spain, Germany and Sweden have, in recent years, overhauled their group litigation mechanisms, while US-style class action mechanisms, or their variants, are under consideration in the Netherlands, France, Norway, Finland, Denmark and Ireland.

Management of Cross-Border Product Risks

The challenges outlined above lead to the inevitable conclusion that product risk management for a transnational company is a great deal more complicated than ever before. Meeting substantive legal requirements will often not, by itself, suffice. A company will also have to understand the different legal and regulatory systems across the jurisdictions in which it operates; appreciating the differences between relevant political systems, regulatory attitudes, local practices and consumer concerns; adopting responsible corporate policies; and being aware of historically sensitive issues.

This has resulted in prominent product manufacturing and supply companies developing their management of product risks into an integral part of their operations. But what product risk management systems are necessary and how can they help?

For a transnational company to eradicate all product risks in the circumstances outlined above would be impossible. There is no blueprint that applies to every company and every country, and it is not possible to predict all risks - even the best-managed and most responsible companies experience product crises. The most effective means of managing risk, therefore, is to review the known risks inherent in the products sold, be aware of other potential risks, have reliable systems in place to avoid those risks and to remedy their occurrence if they materialise into liability in the future; but in each case to tailor these policies to the demands of the company’s individual markets. The product risk management principles listed below are intended to be of general application to transnational manufacturing and supply companies and their management.

Identification of Product Risks

Before launching a product, the manufacturer will of course want to consider the likely risks associated with the product. However, doing so is not as easy as it may sound. It is important that the analysis is entirely objective and undertaken with a view to defending the product’s design in the face of civil litigation or criminal prosecution, should it ever be necessary to do so. Independent expert advice/verification may be of assistance (indeed, this may be a legal requirement in some cases, e.g. where the company wishes to obtain CE-marking). Pre-marketing risk analysis will involve consideration of the nature of the product and the likely risks associated with its use, misuse and disposal. The likelihood and extent of damage or injury resulting from the use of a product will dictate the level of risk management preparedness towards which a company should gear itself.

Prototypes and Compliance

Product prototypes should be constructed and subjected to extensive and, where possible, independent tests. The methods involved in these tests and the test results need to be recorded.

Manufacturers need to consider the extent to which the prototypes comply with supra-national and national standards, plus industry standards and codes of practice. Manufacturers should also establish whether there are similar, but safer products available anywhere in the world and whether there is any research available, even in remote parts of the world, on the possible risks presented by the type of product that they intend to produce. If so, the expectations of consumers (and the courts) regarding the products may be higher than any established standards.

Selection of Suppliers

Suppliers of raw materials or component parts should be selected on the basis of their suitability and reliability and precise, written specifications should be given to them in relation to the raw materials and parts that are needed. Increasingly, many companies with substantial market presence require their suppliers to behave in an ethical and socially responsible manner.

Quality Control

A key aim of a manufacturing company’s quality control procedures should be to enable the rapid identification of product defects - preferably before products enter the supply chain. Where different component parts are to be assembled into a more complex structure, each component should be examined for defects before it is incorporated. If possible, samples of the product should be tested at each important stage of production and, again, records kept of the test results. Samples from each batch of finished products
should similarly be tested. Regular internal audits of the processes and systems relating to quality control should be carried out, to ensure that they are working properly and the auditor’s findings should be recorded. Provided that all of the documents created during these processes show that any problems were properly resolved, these measures will help a company to avail itself of any “due diligence” defence that might exist and avoid potential negligence liability.

**Product Traceability**

Each product should be marked with a batch and serial number (as well as any other information required by applicable labelling laws). Records of the identity of the party to whom each batch of products is sent should be maintained. Where the product is made up of different component parts assembled together, records should also be kept showing which batch of component parts went into which products. In the EU, ensuring “one up, one down” traceability is a prerequisite for compliance with both the general product safety and food law regimes and these records may also be important in the event of a product liability claim or product crisis.

**Instructions and warnings**

Providing appropriate product information can be crucial to the safe use of a product and may therefore help mitigate the producer’s legal exposure. Companies should ensure that relevant product instructions and warnings are communicated effectively to consumers, whether by labelling, package inserts or other means.

National laws generally specify the information that is to be given to consumers on product labels. As a minimum, labels are usually required to include information identifying the product (for example, by batch or individual code) and its manufacturer; describing methods and conditions for its proper use; and warning of any particular hazards associated with the product. However, product labelling requirements in e.g. the food and pharmaceuticals sectors are far more complex.

Once instructions and warnings have been drafted, but before they are finalised, producers should test them out on a cross-section of likely users of the product, to ensure that they are unambiguous and effective.

The duty to inform and warn consumers does not end once the product has been placed on the market. Producers should continually monitor the performance of products throughout the lifetime of each product and update product information and warnings where necessary, to ensure safe use of the product. In the EU, post-sale monitoring, complaints-handling and consumer information are all required by the general product safety and food law regimes. Downstream distributors and suppliers may also be required to assist in monitoring the safety of products that they have supplied to the market.

**Marketing and Advertising**

When marketing or advertising a product, care should be taken to ensure that a valid impression is given of the product and that applicable advertising standards or regulations are fulfilled. Particular care should be taken over advertising materials that make a comparison, express or implied, with a competitor’s product.

Companies should ensure that they are consistent in the claims that they make for products in different jurisdictions. Companies should also check that their advertising and marketing practices comply with any statements that they make on corporate ethics or social responsibility.

**Corporate Structure**

A company may wish to consider how it can manage its risks through its corporate structure, for example by carrying out its activities in relation to a high risk product as a separate entity, such as a limited liability company or limited partnership. Local professional advice should always be taken, to ensure that the ownership and control of the structure will not result in any courts treating the structure as one entity or “piercing the corporate veil”. Corporate structure may also be designed so as to limit the risk of personal liability falling on particular individuals within the company.

**Contractual Terms and Conditions**

One of the main functions of any contract is risk allocation. Disputes can be avoided or their financial impact limited through contractual arrangements. The following points are important in minimising product liability risks, and the risk of regulatory intervention, in the supply, manufacturing and distribution chain. The word “manufacturer” here may therefore be taken to mean “supplier” and “distributor”, where appropriate:

- written contracts should be used wherever possible and potential risks should be clearly identified and allocated within these contracts;
- where the manufacture of a product or component part is sub-contracted, the contract should contain detailed product specifications and list the uses to which the product is likely to be put (a large proportion of product disputes arise from inadequate product specification);
- suppliers should try to obtain an indemnity from the party from whom they purchase the goods, or use some other form of allocating risk to the seller, covering the costs of litigation and, in the event of a product crisis, of taking corrective action (e.g. a product recall). A manufacturer should try to secure its supplier’s agreement to the its own corrective action policy and in any event oblige it to cooperate with the manufacturer in the event of such action;
- manufacturers should contractually oblige their suppliers and distributors to pass any warnings or instructions for use provided with the product to the next party in the chain of supply. They should also try to ensure that their suppliers and distributors pass on this obligation in their own contracts;
- a manufacturer may impose contractual obligations upon key suppliers’ quality assurance systems and undertake regular checks to ensure that suppliers are complying with these obligations and with relevant regulations. At the very least, suppliers should be required to warrant that component parts, when supplied, conform to all applicable laws and regulations. A manufacturer may also require suppliers to take out their own product liability insurance;
- where possible, appropriate warranties, indemnities and exclusion clauses should be included in the...
company’s contracts with relevant parties. Clauses limiting or excluding liability are particularly important, as, in some jurisdictions, they may prevent liability for downstream recall and other product-related costs passing to the manufacturer. In certain jurisdictions, however, these clauses may not be legally enforceable;

- it may be prudent for a manufacturer to require its suppliers and distributors to notify the company immediately of any claims threatened or made against them, or any approaches they receive from the regulator, in relation to goods that they supply or distribute;

- contracts should clearly specify which law governs the contractual relationship and which court is to have jurisdiction over any disputes arising out of or connected with the contract, to prevent forum shopping by claimants. (Some countries have a particularly bad reputation for defence litigation - relevant factors include large damages awards; an inadequate or slow legal system; and a biased or even corrupt judiciary);

- standard terms and conditions should be reviewed and simplified, if possible. Even small claims may bear a significant risk to a company by reason of volume - a lot of small claims can be just as damaging as one large one, and simplifying terms and conditions may reduce minor disputes, as well as consumer inquiries; and

- regular contract reviews should be instigated once the product is on the market, to ensure that: important transactions have been properly documented; key contractual terms have been incorporated; residual risks have been quantified and alternative measures taken to prevent them from arising; and that documents have been properly filed.

**Insurance**

For risks that cannot be eliminated, companies should consider taking out insurance, if it is available. However, insurance should never be resorted to as a substitute for risk prevention measures. The following points are important to consider when negotiating insurance cover for product risks:

- in deciding the appropriate level of coverage, it is important to consider both the risk and type of damage that may be caused by the product and bear in mind the countries in which the product is likely to be used. (In the United States, for example, product liability claims are frequently heard by juries who tend to make higher awards of damages than judges and may also award punitive damages.) Moreover, a defective batch of products may lead to many claims, so it is worth noting that claims relating to serious injury may take many years to settle and will be paid in accordance with the law which prevails at the time of payment, rather than when the injury happened;

- standard “all risks” policies generally do not cover the repair, replacement or recall of products that may cause, or have caused, harm. This exclusion can come as a surprise to many companies when faced with a product safety crisis. Even specific product recall costs insurance, where available, may not provide coverage for “voluntary” recalls (which are far more common than recalls ordered by the regulatory authorities);

- insurance arrangements may contain elements of both financial cover and claims handling. Companies should consider whether the arrangements proposed for claims handling are satisfactory when purchasing insurance cover. A particular issue is the extent to which the insured will be able to control any litigation, rather than be subject to the insurers’ decisions, which may conflict with the company’s desired profile or other interests;

- owing to the potential in certain jurisdictions for directors, officers and managers of a company to incur personal liability for failure to ensure the safety of a company’s products, companies may wish to take out personal insurance for some individuals; and

- companies should ensure that contractual and insurance arrangements compliment each other, as insurance cover can be invalidated by contractual terms. This may happen if, for example, a supplier accepts liability in its conditions of sale.

Where insurance cover is in place, the policy will almost definitely include a requirement to notify insurers of any potential product liability claim or product crisis. Failure to comply with this requirement may enable the insurer to void the policy. Accordingly, it is important to inform and involve insurers from the outset. However, care needs to be taken with the information that is given to insurers, as the commercial objectives of the insured and the insurer may differ. As mentioned above, it is therefore important that ultimate control of a product claim or crisis should remain in the hands of the company, not least because the risk in question could be excluded from coverage on policy renewal.

Insurance cannot be expected to cover all of the financial consequences to the business of an issue over a product defect. Serious repercussions to the brand image may arise from the supply of defective products; valued customers and contracts may be lost and interruption to production could occur, particularly if the product needs to be redesigned or new safety features incorporated. Management time may be diverted to investigate the problem or to perform a product recall. Companies should bear in mind that uninsured losses may exceed any claims for compensation or regulatory penalties, when deciding on the level of insurance cover required.

**Document Management**

Litigants have an obligation in some jurisdictions to produce documents relevant to a court action or regulatory investigation which are not covered by that jurisdiction’s concept of legal privilege. In some jurisdictions, documents which are routed through lawyers may benefit from the protection of legal privilege and need not be disclosed to the opposing party in legal proceedings. Companies should attempt to secure the benefit of privilege, where appropriate, and should be aware that privilege, once gained, can still be lost, if, for example, a piece of legal advice is circulated too widely.

Product liability cases abound with stories of damaging company documents being produced in evidence. Care should therefore be taken in the creation of documents that may damage the company, for example by suggesting that...
consumer safety is being compromised for the sake of profitability. Company employees should be given frequent reminders about the importance of sensible writing, including the need to avoid speculation, exaggeration and ambiguous statements when writing on product safety or liability issues. This applies not only to formal memos and letters, but also internal e-mails and notes and other forms of recorded material.

Many claims are won or lost according to the amount of evidence that can be produced. The management of document retention is therefore an important element of product risk management. It is particularly important that companies keep the following documentation:

- contracts;
- information on company procedures, such as quality control procedures, and the reason for any changes in those procedures;
- information which shows that company procedures were followed, such as internal audit reports;
- the results of any tests made on the company’s products during manufacture, pursuant to quality control procedures;
- details of the suppliers of raw materials and component parts;
- details of the consumers or businesses to whom the company’s products were supplied, together with relevant batch numbers;
- information showing the state of scientific and technical knowledge regarding that type of product at the time that the company placed its products on the market (this may be relevant to establishing a “state of the art” defence in some jurisdictions);
- copies of marketing and promotional material relating to the products;
- records of customer complaints;
- documentation showing how customer complaints or any safety concerns over the products were resolved. Companies should be especially careful to guard against documents that indicate an awareness of risk unaccompanied by appropriate remedial action;
- communications with regulators; and
- communications with insurers.

National laws differ as to the applicable limitation periods for product liability claims and claims in contract or tort. Transnational companies should therefore keep the above records for as long as possible. To play safe, some companies deem it necessary to keep such records for twelve years, others favour six years. It is, of course, particularly important that no relevant documentation is destroyed where there is any hint that litigation might be pending.

Product Monitoring

Whether or not they are under a legal obligation to do so (which will, as discussed above, often be the case), producers should monitor the safety and performance of the products they place on the market throughout the products’ lifetime.

Producers should also monitor the safety and performance of products on the market which are similar to their own, so that they will be aware of any safety-related technological advances and any accompanying increase in consumers’ expectations of the products.

Handling Inquiries and Complaints

The manner in which a company responds to inquiries and complaints from its customers may make all the difference between escalating and resolving an issue. Companies should therefore train staff to handle customer inquiries and complaints and establish systems which will enable them to respond quickly to common complaints.

Any products which are alleged to be defective should be recovered, where possible, and the defect investigated, to establish whether any action is necessary, such as re-design or production changes.

A system of reviewing repeated types of complaints should be set up, to ascertain whether they indicate a problem with a batch or series of products. The reviews should involve people from different departments, for example, engineering, design, public relations and legal, to help identify and resolve problems at an early stage. As mentioned above, customer complaints records, together with details of how the complaints were resolved, should be retained by the company.

Product Response Team

A multi-disciplinary team responsible for deciding how to respond to a serious product problem and for supervising any action taken to protect consumers should be set up, preferably before any problems emerge. Individuals on the team should be designated as contact points for regulators and the media and should be given training to equip them for these tasks.

Corporate authorities should be prepared, giving the team the power to act on behalf of the company in the event of a product crisis. The team should prepare a product response plan, if the company does not already have one, setting out the types of product problems that are likely to be encountered and their attendant risks. The plan should also detail the appropriate responses to each problem and the company’s systems for putting the responses in motion. The team should be trained through simulated product crisis exercises, to ensure that each member is familiar with his own role, the role of his teammates and reporting lines.

It is advisable for the team to keep up-to-date information on:

- the key decision-making individuals in the relevant national regulatory authorities and the media; and
- external experts whom the company would use to investigate any product defect and its impact, along with a list of public relations, legal, management and information technology contacts.

Monitoring and Responding to Regulation and Handling Relationships with Regulators

It is imperative for transnational companies both to keep on top of applicable regulation and to manage carefully their relationships with regulators in all countries in which their products are sold.

As regards regulatory monitoring, regard should be had not only to legislation which may directly impact the company and its products (e.g. a new piece of food labelling legislation for a drinks manufacturer), but also regulation that may affect its own suppliers or customers. For example, the proposed REACH chemicals reforms - while not, in
generally, directly applicable to the consumer products sector - may lead to chemicals companies passing on cost increases to their own customers and withdrawing or substituting key product components or raw materials. Obtaining early information about legislative changes allows businesses to prepare for compliance and, if they so desire, influence regulation’s final form (for example, by participating in the public affairs activities of a relevant trade association). A company may also wish to challenge “bad” regulation that directly impacts on its affairs (see insert).

In terms of handling relationships with the regulator, a company should, at the very least, be aware of the identity of the relevant regulatory authorities and be familiar with their powers, which can differ from country to country, even across EU member states. Transnational companies should also try and identify different regulators’ attitudes to product issues in the countries where their products are marketed. As mentioned above, this may not be easy, as the regulators’ attitudes may be shaped by political systems, local practices, consumer concerns and historic events. Given that, in the EU, both the general product safety and food law regimes require producers and other market operators to notify regulators “immediately” in the event of a product crisis, understanding such attitudes can make the difference between convincing the regulator to sign off on the company’s suggested approach, on the one hand, and invoke its independent intervention powers, on the other.

### Challenging ‘Bad’ EU Regulation

Council and European Directive 2002/2 on compound animal feeding stuffs was adopted in January 2002. The Directive required manufacturers of such feedstuffs to declare their precise composition (including the percentage of all ingredients) as from November 2003. Manufacturers claimed that these requirements, if implemented by the EU’s Member States, would force them to disclose their trade secrets. In particular, they feared that the percentage declaration requirement would give away the precise constitution of their products to competitors.

In May 2002, one such company launched an action seeking the annulment of the directive in the European Court of First Instance (case T-167/02, Toulorge). However, the challenge was rejected for lack of standing. Meanwhile, the implementation process across the EU continued.

In October 2003, following a judicial review of the UK implementing legislation adopted in July 2003, the High Court of England and Wales took the unprecedented step of suspending the percentage declaration requirement of the UK regulations, pending a referral of the question of its validity to the European Court of Justice (case C-453/03, ABNA and others). This is the first time that any EU national court has suspended national implementing legislation in such a manner. Similar suspensory relief was subsequently obtained in Northern Ireland, Scotland, France and Italy.

The feedstuffs case illustrates the difficulties of challenging ‘bad’ regulation within the EU. It is necessary to bring coordinated actions in each jurisdiction where the claimant company is active, because a grant of interim relief in one member state does not bind the courts of another. Fighting such regulation may therefore be expensive and time-consuming. However, where a core business interest is at stake, it may nevertheless be unavoidable.

### Dealing with the Media

No matter what systems and procedures are in place, identified risk scenarios and unexpected incidents will occur and they may well provoke media attention.

Corporate management often reacts to a crisis situation by concentrating on resolving product design and business issues at the cost of public and consumer relations. It is the company’s response to the latter, however, that will be remembered long after the crisis has been solved.

In these circumstances, political perception and a degree of control over external events are important. One route to achieving these objectives is establishing relationships with the media, keeping them informed and using them to the company’s advantage wherever possible. It is possible to convert the challenges raised by media attention into an opportunity to show how responsibly the company is handling a crisis.

### Corrective action, Including Product Recall

In many jurisdictions, producers will have a legal obligation to take appropriate corrective action (as well as notify the applicable regulators) as soon as they know a product that they have marketed to be unsafe. Corrective action may involve withdrawing product from the supply chain, issuing public warnings, amending packaging, recalling product from consumers or any one of almost innumerable alternatives. Product recall is the tool of last resort and certainly not the only response to a crisis. It will often be disproportionate to the risk involved.

That said, in the most serious crises, product recall has become commonplace as a means by which producers can avoid the risk of harm to consumers and, in doing so, reduce the risk of being subjected to civil suits and criminal sanctions. Handled effectively, a product recall and other types of corrective action can engender confidence, both among consumers and regulatory authorities, that the supplier takes its consumer protection obligations seriously.

The key in choosing what corrective action (if any) to take in a product crisis is to conduct a proper assessment of the risks to end users of the product in question and the best means of mitigating those risks. Since it will often be appropriate to institute a corrective action programme before or at the same time as contacting regulators - which, under the new EU general product safety and food law regimes should happen “immediately”, glossed by the Commission’s own guidance as “without undue delay” - the risk assessment procedure must be both fast and effective. Being prepared for a product crisis therefore means that the company and its designated product response team should be in a position to access relevant data, legal advice and external expertise at very short notice.

### Conclusion

With a legal, regulatory and social landscape that is in a constant state of development and flux and continually buffeted by product scares, the effective management of product risks for producers and suppliers involves management time, effort and expense in creating effective internal systems of control and embedding them across their operational activities worldwide. Preparation, as so often in business, is the key.

What is effective will generally reflect the exigencies of a
company’s business and the multifarious idiosyncrasies of the markets in which it sells products. All the trends, however, point to expectations of increased corporate self-regulation and corporate responsibility, particularly in relation to the sale of products across borders, and corporate management needs to react to these expectations.

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Chapter 7

Product Liability Insurance

Reynolds Porter Chamberlain

1. Introduction

In the light of developments in product safety regulation and legislation, at both national and international levels, appropriate and effective product liability insurance has become increasingly important. Notwithstanding all due risk management measures being in place, an insured may find itself subject to significant claims in respect of products manufactured or supplied. Product liability insurance which will respond in a manner fitting to both the insured’s profile and business is essential to protect the insured from the consequences of such claims.

The purpose of this chapter is to provide an overview of product liability insurance principles in the UK, including certain common terms of cover, and to highlight some of the differences of law and principle in other jurisdictions.

2. Insurance Principles

Prior to considering various specific issues relating to product liability insurance, it will assist to review some general principles which apply to all insurance contracts subject to English law. Notably, and in contrast to some other jurisdictions we have considered, these general principles tend to provide a degree of protection to the insurer both prior to the formation of the insurance contract and during the period of the insurance itself.

2.1 Utmost Good Faith

The principle of “utmost good faith” applies to all insurance contracts and has a number of consequences for both insureds and insurers. The most important (and a frequent subject of litigation) is the duty on the insured to disclose all facts which are material to the insurer’s consideration of the risk at the proposal stage. The insured is deemed to know, and is required to disclose, every material fact which in the ordinary course of his business ought to be known to him. The exceptions to this duty of disclosure are material facts which the underwriter already knows, which are in the public domain or of which the underwriter has waived disclosure. The duty of disclosure is in addition to the insured’s general contractual duty not to make false representations in respect of material facts which induce the insurer to enter into the insurance contract.

For the purposes of both non-disclosure and misrepresentation, whether or not facts are material is judged by a two part test (Pan Atlantic v Pine Top [1994] 2 Lloyd’s Rep 427). Facts are material if:

1) A prudent underwriter would have deemed the facts not disclosed or misrepresented to have been material.

2) The non-disclosure or misrepresentation induced the actual underwriter to accept the risks on the terms which he agreed.

If an insured misrepresents or fails to disclose a material fact prior to the formation of the insurance contract, the insurer may avoid (that is to say treat the insurance contract as if it had never existed). On avoidance, the insurer must repay any premium received and the insured must return any claims paid.

The remedy of avoidance applies even if the misrepresentation or non-disclosure was entirely innocent. To limit the harsh consequences of this principle, insurance contracts may include an “innocent non-disclosure” clause, which provides that the insurer will not rely on a non-disclosure or misrepresentation if the insured can establish that it was innocent. Such clauses are, however, rarely found in product liability insurance contracts.

A duty is imposed on the insured to make complete and accurate disclosure at the proposal stage in most jurisdictions. However, the remedies for breach and the circumstances in which those remedies are available vary widely.

In some jurisdictions, the position is similar to the UK. For example, in Switzerland, failure to make proper disclosure enables the insurer to treat the insurance contract as void without proof of prejudice (article 6 Federal Law on Insurance Contracts). In addition, the insurer may retain the premium paid, a more onerous position than in the UK. In Austria, incomplete or inaccurate disclosure entitles the insurer to rescind (section 16 Versicherungsvertragsgesetz (“VersVG”)). In Portugal, whether in good or bad faith, failure to inform the insurer of all facts and matters relating to the risk renders the insurance contract a nullity. In the Netherlands, provided that with true knowledge of the facts the insurer either would not have accepted the risk or would have accepted it on different terms, incomplete or inaccurate disclosure will entitle the insurer to avoid, again, whether or not it was in bad faith (paragraph 251 of the Code of Commerce).

In Japan, both insured and insurer are under an obligation not to betray the other’s trust. This obligation imposes a duty on the insured to be honest and straightforward and to make full and accurate disclosure of all material facts. The insurer...
is likewise under a duty to make full and accurate disclosure. A failure by the insured to disclose a material fact will render the policy voidable at the option of the insurer. Prejudice to the insurer is not required. Further, the insurance contract usually contains an express stipulation regarding the duty of disclosure and prescribing the manner in which it is to be performed. Breach of the duty of disclosure will, accordingly, also amount to a breach of the insurance contract.

In most jurisdictions, however, the situation is more favourable to the insured. In the USA (New York), the failure of an insured to respond truthfully to a question asked by an insurer, the answer to which is material to the risk, may render the insurance contract voidable irrespective of bad faith. If, however, the insured fails to disclose material information that was not enquired into by the insurer, the non-disclosure may need to be intentional for the insurer to be entitled to avoid.

In Australia, the insured is required to disclose every matter that he knows, or a reasonable person in the circumstances could be expected to know, is relevant to the insurer’s decision to accept the risk and the terms to accept it on (section 21 Insurance Contracts Act 1984). If the insured fails to make complete and accurate disclosure, unless the insurer would have entered into the insurance contract for the same premium and on the same terms in any event, the insurer may avoid the insurance contract if the misrepresentation or non-disclosure was fraudulent. Otherwise (or if the insurer elects not to avoid) the liability of the insurer in respect of any claim under the insurance contract is reduced to the amount that would place the insurer in the position he would have been in if complete and accurate disclosure had been made (section 28 Insurance Contracts Act 1984).

In Spain, if the insured fails to make proper disclosure, the insurer is entitled to terminate the insurance contract in the month following the discovery of the failure and retain the premium for the expired period of the insurance contract (section 10 Insurance Contracts Law). If, in the meantime, a loss has occurred, the insurer will be entitled to reduce proportionately any payment made in respect of that loss to reflect the difference between the premium actually paid and the premium that would have been charged had proper disclosure been made. Furthermore, during the course of the insurance contract, the insured is also obliged to disclose any circumstances arising which may aggravate the risk (section 11 Insurance Contracts Law). If such disclosure is made, the insurer may either re-rate or terminate the insurance contract (section 12 Insurance Contracts Law). If it is not made, if a loss has occurred, the insurer may decline cover if the insured acted in bad faith. Alternatively, the insurer may proportionately reduce any payment made in respect of the loss to reflect the difference between the premium actually paid and the premium that would have been charged had a re-rating occurred.

In France, the insurance contract will be null and void only if the failure to make proper disclosure is intentional and either changes the subject of the risk or decreases the insurer’s assessment of the risk (article L.113-8 of the Insurance Code). If there is no bad faith and the failure is discovered prior to a loss occurring, the insurer may continue the insurance contract in consideration for an increase in premium or terminate the insurance contract and return the premium for the unexpired period of the policy.

Once a loss has occurred, as in Spain, the amount to be paid by the insurer in respect of the loss will be proportionately reduced to reflect the difference between the premium actually paid and the premium that should have been paid (article L.113-9 of the Insurance Code).

In Italy, incomplete or inaccurate disclosure may result in total or partial inability to recover or termination of the insurance contract (articles 1892 to 1894 of the Civil Code).

In Malaysia, the insurer may repudiate liability, but must show prejudice. Unusually, if the insurer breaches the duty to disclose, he may be liable to a penalty of RM1 million (Insurance Act 1996).

In Denmark, the position is particularly favourable to the insured. The insurance contract remains binding on the insurer save where the misrepresentation or non-disclosure is fraudulent (section 4 of the Insurance Contracts Act). If it is innocent, the contract is unaffected (section 5 Insurance Contracts Act). If it is negligent, the insurer will only be exempt from liability under the insurance if it would not have insured the risk had the true facts had been known (section 6 Insurance Contracts Act).

2.2 Warranties

A warranty in an insurance contract is a contractual promise made by the insured that a condition has been or will be fulfilled or a state of affairs exists or will continue to exist. Whether or not a particular term of an insurance contract is a warranty will be construed by reference to the policy as a whole. The fact that the insurance contract in some way describes the term as a warranty will be persuasive, although not conclusive. A number of factors point to a term being a warranty, including the fact that it goes to the root of the insurance contract and that damages would be an unsatisfactory or inadequate remedy for breach. If there is any doubt as to whether a term is a warranty, the term will be construed in favour of the insured.

One of the most common warranties is known as a “basis clause”. A proposal form will usually contain a declaration by the insured that the information contained in it will form the basis of any subsequent insurance contract. As a consequence, the declaration will be incorporated into the insurance contract by reference. The effect of this provision is that the insured warrants the truth of the information in the proposal so that insurers may be discharged from liability if any of it should prove untrue.

The insurer must comply with a warranty strictly. If a warranty is breached, the insurer is automatically discharged from all liability from the date of the breach. The insurer need not show prejudice.

Warranties are not universally recognised in jurisdictions other than the UK. Jurisdictions where they are recognised include the Netherlands and Spain. In the Netherlands, breach of warranty will allow the insurer to terminate the insurance contract unless, in certain circumstances, the insured can prove that the breach is not related to the recovery they seek. In Spain, the duty on the insured to mitigate any loss suffered is recognised as a warranty. If the insured wilfully breaches this duty, the insurer is entitled to refuse an indemnity or reduce the indemnity by an appropriate amount (section 17 Insurance Contracts Law).

In Japan, a "basis clause", pursuant to which the insurer may
be discharged from liability in the event that the proposal contains false information, is also a common feature.

In Australia, by contrast, there is no meaningful distinction between a warranty and any other term of the insurance contract. In any event, statutory restrictions mean that where any term of an insurance contract is breached, the insurer may not refuse to pay a claim. Instead the claim will simply be reduced by the extent to which the breach prejudices the insurer (section 54 Insurance Contracts Act 1984). In the USA (New York), whilst warranties are recognised, they are not often encountered.

### 2.3 Conditions Precedent

Breach by the insured of the terms of an insurance contract, other than warranties, will generally entitle the insurer only to claim damages, unless the term breached is a condition precedent.

Conditions precedent may relate to validity or, more usually, to liability. Where there is a breach of a condition precedent to the validity of an insurance contract, the insurer will not come on risk and any premium paid is returned. Conditions precedent to liability under the insurance contract are usually concerned with claims (i.e. taking precautions against claims and notification of claims). If the insured breaches a condition precedent to liability, irrespective of whether it has suffered prejudice, the insurer will be entitled to refuse to provide an indemnity in respect of the claim in question.

Whether or not a term is a condition precedent will depend on both the nature of the term and the construction of the insurance contract as a whole. The insurer’s intention in relation to the term must be clear. In this regard, explicit language will assist, but will not be conclusive. Conditions precedent may be specifically so described, or words may be used to make it plain that breach will prevent recovery. Alternatively, the insurance contract may include a “due observance” clause which provides that the observance of all or certain terms shall be a condition precedent to the insurer’s liability. In rare circumstances, compliance with a term will be so fundamental that it will be held that the insurer intended the term to be a condition precedent despite the absence of express language.

Conditions precedent are recognised in some jurisdictions other than the UK. For example, in Malaysia, breach of a condition precedent will entitle the insurer to resist a claim made by the insured irrespective of whether the insurer has suffered prejudice. Having said that, in 1995, the Malaysian Central Bank issued Claims Settlement Guidelines which stipulate that, save where fraud is suspected, a claim cannot be denied merely on the basis of technical breaches of policy conditions or warranties which are not material to or connected with the loss. The scope and force of these guidelines have not, however, been tested in the courts. In civil law jurisdictions, the law may impose duties on the insured in respect of claims, breach of which may have the same effect as breach of a condition precedent (see section 5 below).

### 3. The Product Liability Insurance Contract

#### 3.1 The Insuring Clause

The insuring clause in a product liability insurance contract typically provides that the insurer will indemnify the insured for:

“all sums which the insured shall become legally liable to pay as damages or compensation in respect of accidental death or bodily injury of any person and/or accidental loss of or damage to property in the course of or in connection with the insured’s business caused by or arising out of the insured’s products”

Most product liability insurance contracts contain definitions of terms such as “products” (usually to include labelling, packaging, instructions etc.) and “property” (usually to include only tangible property). If there is no relevant definition, or the definition is unclear, the court will construe such terms with the aim of giving them the meaning intended by the parties.

#### 3.2 Damage

“Damage to property” will usually be defined in the insurance contract. The definition, however, can be tautological and may do little to elucidate what is actually meant. As a result, what constitutes “damage”, particularly in the context of the mixing of different products and the contamination of one product by another, has been the subject of several recent court decisions.

One case concerned carbon dioxide supplied to the drinks industry for mixing with other ingredients to produce carbonated drinks. As a result of a breakdown in the manufacturing process, the carbon dioxide contained benzene. The Court of Appeal held that, on mixing with the carbon dioxide, the other ingredients ceased to exist and a new product was formed. Therefore, there was no damage to property (that is to say damage to the other ingredients) but, instead, the creation of a new defective product. Accordingly, the policy did not respond (Bacardi-Martini Beverages Ltd v Thomas Hardy Packaging Ltd and Others [2002] 2 Lloyd’s Rep 379).

Another case involved white pigment used in the production of u-PVC compounds, from which doors and window frames were subsequently manufactured. In certain environmental conditions, the white pigment caused the doors and window frames to turn pink. The issue was whether this amounted to damage to property, defined in the relevant insurance contract as including “physical injury to or destruction of tangible property”. The Commercial Court held that an unwanted change in colour was a physical change and, if the discolouration impaired the value of the product, was a physical injury. Accordingly, there was property damage under the insurance contract (Tioxide Europe Ltd v CGU International Insurance Plc [2004] 1 Lloyd’s Rep 114). Unlike the carbonated drinks in the above case, the doors and windows were not defective from the outset but instead became defective at a later stage.

In other jurisdictions, damage to property generally requires damage to the substance or the integrity of an object, to include loss or destruction. The position as regards mixing and contamination in some jurisdictions, such as Portugal...
and Denmark, is the same as in the UK. In the USA (New York) whether mixing causes damage will depend on the degree of the mixing and whether it is possible to separate the products. In other jurisdictions, for example France and Malaysia, the point is yet to be decided by the courts.

### 3.3 ‘In respect of’

Most product liability insurances cover only claims for bodily injury and property damage caused by defective products. There is generally no intention to cover claims for “pure economic loss”, that is to say financial loss which is not consequent on bodily injury or damage to property. For this reason, the UK courts have consistently held that the words “in respect of” bodily injury or damage to property require a causative link between the event giving rise to liability and its physical consequences, such that pure economic loss will not be covered.

In one case, the insured supplied loose soap powder to a wholesaler for packaging in cartons. The soap powder was defective in that it stained the cartons. This allowed moisture in to the cartons which caused the soap powder to cake. The wholesaler claimed against the insured and was awarded damages, including damages for the cost of cartons purchased for future sales and loss of future profits. The insured’s product liability insurance covered liability “in respect of any Occurrences”. The definition of “Occurrence” included loss or damage to physical property caused by the insured’s goods. The Court of Appeal held that this definition confined cover to liability for physical consequences caused by the insured’s goods. The damages for the cost of cartons and loss of profits for future sales were not covered. Those damages were not recoverable to the liability in respect of the material “Occurrence” (the damage caused by the defective soap powder to the cartons it was packed in) but were instead recoverable to the insured’s failure to supply soap powder thereafter (Rodan International Ltd v Commercial Union Assurance Co [1999] Lloyd’s Rep IR 495).

Restrictions are put on the insured’s ability to recover pure economic loss under a product liability insurance contract in most jurisdictions, whether by the relevant law, the courts’ decisions on phrases such as “in respect of”, or the terms of the insurance contract itself. In Spain, for example, the Supreme Court has decided that pure economic loss is not recoverable against insurers. In Australia, however, in certain circumstances, claims for pure economic loss may be held by the courts to be covered.

### 3.4 Financial Loss Extensions

Had the product liability insurance in the Rodan case contained a financial loss extension, the insured’s liabilities arising from the damages awarded for the cost of cartons and future loss of profits may well have been covered.

A financial loss extension, covering the insured’s liabilities in respect of claims for pure economic loss (generally loss of profits or loss of goodwill) caused by the insured’s products, is commonly offered with product liability insurance. Such liabilities usually arise from claims against the insured for breach of contract, pure economic loss not being recoverable for negligence save in limited circumstances. A number of exclusions are applied by insurers to financial loss cover including loss arising from liability assumed by contract and from failure to supply.

Financial loss extensions are available in many other jurisdictions on similar terms.

### 3.5 Claims Made / Losses Occurring

Product liability insurance may be offered either on a “losses occurring” or a “claims made” basis. Losses occurring insurance covers bodily injury or property damage which happens during the period of insurance, notwithstanding the fact that a claim may not be made until a much later date. Difficulties may arise in establishing when the injury or damage has occurred. Unless the insurance contract states otherwise, this will generally be when material injury or damage first occurs.

Claims made insurance covers claims in respect of bodily injury or property damage which are made during the period of insurance. A “claim” in this context is usually defined as a demand for payment or any other remedy (be it through legal proceedings or less formally) against the insured by a third party. The advantage for the insurer of claims made cover is certainty. At the end of the period of insurance, they will know precisely what claims have been made.

Whilst product liability insurance contracts are increasingly being offered on a claims made basis, losses occurring cover remains the most common in the UK. In most other jurisdictions, losses occurring cover is also most common, although in some jurisdictions, for example the Netherlands, it is becoming increasingly unavailable. To prevent uncertainty for the insurer, losses occurring insurance contracts may include a term excluding cover for claims made outside a fixed period after the expiry of the period of insurance. This is common in Switzerland. In addition, in Switzerland, only claims made cover is usually available for risks in the USA or Canada. It is noteworthy that in France, following a number of court decisions holding claims made clauses null and void, the law now specifically provides that claims made insurance cover is available in certain circumstances (law 2003-706 dated 1 August 2003).

### 4. Exclusions

Product liability insurance contracts in all jurisdictions contain a variety of common exclusions. These generally relate to risks which are likely to be covered by other insurances, risks arising from the deliberate conduct of the insured, uncertain or potentially catastrophic risks or damage to the product itself. The standardisation of these exclusions is, to a large extent, driven by the requirements of international reinsurers.

A number of these common exclusions are described below.

#### 4.1 Designs, Specifications, Instructions and Advice

Product liability insurance frequently excludes liability arising from designs, specifications, plans, formulas, instructions or advice in connection with the insured’s product.

As the purpose of this exclusion is to avoid overlap with the insured’s professional indemnity cover, rather than to exclude liability for design (rather than manufacturing)
defects, it usually applies only where a fee is charged. If the insured has no professional indemnity cover, a professional indemnity extension to the product liability insurance may be available.

4.2 Deliberate Conduct

Product liability insurance is designed to cover injury and damage caused accidentally rather than purposely. Accordingly, the consequences of the insured’s deliberate acts will normally be excluded. In France and Portugal, the consequences of deliberate acts are excluded by law.

4.3 Fines, Penalties, Liquidated and other Enhanced Damages

The indemnity provided by product liability insurance is for compensatory damages the insured is liable to pay to a third party. It is not for aggravated, exemplary or punitive damages, which reflect the level of culpability of the insured rather than compensate the third party. Likewise, it is not for fines the insured may be ordered to pay in criminal courts, nor penalties or liquidated damages the insured may have agreed to pay in the event of a breach of contract. Accordingly, most product liability insurance contracts exclude these types of losses arising from the insured’s products.

4.4 Standard: Pollution, Asbestos, Electromagnetic Fields

Due to potentially catastrophic losses and high clean up costs, product liability insurance contracts frequently exclude, whether partially or completely, the insured’s liability for asbestos, pollution and contamination, radiation and electromagnetic fields.

Most UK product liability insurance contracts implement the wording, either in its original or an adapted form, recommended by the Association of British Insurers to exclude liability for gradual pollution or contamination (such as long standing leaks from pipes or tanks). This wording excludes all liability for pollution or contamination other than that caused by “a sudden identifiable unintended and unexpected incident which takes place in its entirety at a specific time and place during the period of insurance”.

4.5 Contractual Liability

At the time of agreeing to provide cover, the insurer will not know the extent of the insured’s contractual liabilities and will not, therefore, be able to consider the risk with reference to them. That being so, liability assumed by the insured under an agreement, which would not otherwise have attached, is usually excluded.

The excluded liability may take a variety of forms including, for example, sums which the insured is required to pay under any guarantee. The insured’s liability pursuant to certain contract terms implied by statute (i.e. terms as to satisfactory quality or fitness for purpose implied by the Sale of Goods Act 1979) will often not be excluded.

4.6 Product Recall, Repair and Replacement

The insured’s liability arising out of recalling, removing, repairing, replacing or reinstating any defective products and the loss of, damage to or diminution in value of the insured’s products which arises out of any defect in the product or the harmful nature or unsuitability of the product is usually excluded from cover. Cover in respect of these types of liability may be available by way of separate product guarantee or product recall insurance (see sections 6 and 7 below).

5. Conditions

Product liability insurance contracts in the UK commonly contain terms governing how the insured should conduct itself both generally during the period of the insurance and in the event that a claim is made against it. These terms are frequently expressed to be conditions precedent to the insurer’s obligation to indemnify the insured, although whether they are in fact conditions precedent will depend on the considerations in section 2.3 above. Similar obligations are placed on the insured in most other jurisdictions, whether by the terms of the insurance contract or by law, with varying sanctions for breach.

A number of these common conditions are described below.

5.1 Reasonable Care

The insured will usually be required by a condition of the insurance contract to take all reasonable precautions to prevent any occurrence, accident, injury or damage which may give rise to liability under the insurance and to prevent the sale or supply of goods which are defective in any way. However, as the purpose of product liability insurance is to provide cover to the insured in respect of negligence, in the UK, such a condition will not be breached merely because the insured was negligent in not taking reasonable precautions. What must be proved is that the insured acted recklessly, in that he recognised a danger and did not care whether or not it was averted. “Reasonable precautions” does not mean every practicable precaution. Whether a precaution is reasonable or not will depend on the circumstances of the case and will be determined by what is reasonable as between the insured and the insurer with regard to the commercial purpose of the insurance contract.

In the Netherlands, except in relation to certain specified insurances, the insured is obliged to take measures to prevent or minimise loss. If he does not do so, he may be required to indemnify the insurer for any damage caused (paragraph 283(2) of the Code of Commerce).

5.2 Notification Requirements

A condition requiring the insured to give notice within a certain time of any circumstances which may or are likely to give rise to a claim and of any claims or legal proceedings actually brought against the insured will be included in all UK product liability insurance contracts. “Likely” in this context means there is a more than 50% chance of a claim being made on an objective assessment. “May” requires a smaller chance of a claim being made, although a claim must at least be possible. Compliance with this condition enables
the insurer to investigate the (potential) claim, control any proceedings and take steps to mitigate any loss as soon as possible.

The condition will usually require the insured to give notice within a specified time frame, alternatively either “immediately” (with all reasonable speed in the circumstances) or “as soon as possible” (as soon as reasonably possible for a person in the position of the insured). If no time is set out in the condition, notice must be given within a “reasonable” time. The form of the notice, to whom it must be given and what information it must contain will also usually be set out in the condition.

In Switzerland the insured is under a duty to give immediate notice of loss. If there is an intentional breach of this duty, the loss will not be covered. If there is a negligent breach which causes prejudice to the insurer, the indemnity may be reduced or, if the insurance contract so provides, extinguished (article 39 Federal Law on Insurance Contracts). In the Netherlands, except in relation to certain specified insurances, the insured is also obliged immediately to notify the insurer of any loss. If the insured does not do so, if there are sufficient grounds, he will be liable to indemnify the insurer for any damage caused (paragraph 283(2) of the Code of Commerce). In Denmark, the insured must report any loss without undue delay. If he does not do so, the insurer will be liable for the loss only to the extent that it would have been liable had the loss been properly reported (section 21 Insurance Contracts Act).

In Italy, notice of loss must be given within three days, failing which the insurer may refuse the indemnity or reduce it to the extent of the prejudice suffered (articles 1913 and 1915 of the Civil Code). In Spain, the insured has seven days in which to notify the insurer of any loss. If he fails to do so, the insurer will be entitled to damages for any loss caused by the delay (article 16 Insurance Contracts Law). In Portugal, the insured must notify the loss within eight days. If the insured notifies late, he will be liable for any damage to the insurer resulting from the late notification (article 440 of the Commercial Code). In the USA (New York), a failure to provide notice for a period as short as one month has been held to bar cover as a matter of law. An insurer need generally not show prejudice to bar cover on grounds of late notice.

5.3 Claims Co-operation and Claims Control

Product liability insurance contracts in the UK usually contain a claims co-operation and/or a claims control condition.

A claims co-operation condition requires the insured to cooperate with the insurer in respect of any claim brought against it. The co-operation required may include prompt notification of the claim, the provision of any information and assistance required by the insurer and refraining from settling claims without the insurer’s consent.

A claims control condition will entitle the insurer, if they wish, to control and settle any claims against the insured and to take proceedings in the name of the insured against third parties to recovery their outlay under the insurance contract. Where an insurer conducts the defence of or settles any claim against the insured, it must do so in good faith and in the interests of both itself and the insured.

In Austria, if all information and documents demanded by the insurer are not provided by the insured, the insurer may by law decline to make any payment (article 34 VersVG). In Spain, the insurer may refuse an indemnity if the insured wilfully or grossly negligently fails to provide information about a loss (article 16 Insurance Contracts Law).

6. Product Recall Cover

In most jurisdictions, insurers offer product recall cover, either by way of separate insurance or (more rarely) by way of an extension to an insurer’s product liability insurance. In the UK it is more usual for product recall cover to be offered by way of separate insurance, providing also product guarantee and financial loss cover. The recall expenses covered are likely to include the costs of transporting the defective products, the costs of advertising the recall, storage and disposal costs, the costs of replacing the products and, in some cases, product rehabilitation and (albeit to a limited extent) loss of profits.

In the UK, product recall cover may be provided on one of two bases. Firstly, cover may be provided in respect of the insurer’s expenses in recalling its products following malicious or accidental contamination and in meeting any extortion demand in respect of its products. Secondly, cover may be provided in respect of expenses incurred by the insured as a result of recalling any defective product because its use may cause the insured to incur a legal liability to pay third party damages or because, as a result of its failure to perform in accordance with its specification, it requires removal, repair or replacement.

The insurer of a product recall insurance contract will wish to ensure that the insured does not knowingly supply defective products to the market. For this reason, most product recall insurance contracts will exclude claims arising from products in the custody of the insured or not accepted by the insurers’ customers and from circumstances of which the insured is aware at inception. In some jurisdictions, the consent of the insurer will be required before any recall takes place. In other jurisdictions, for example Switzerland and Spain, before cover is given, the insurer may require the decision of a court or other competent authority that a recall is necessary. A recall plan or recall organisation may also be required.

Following the introduction of the General Product Safety Directive (Directive 2001/95/EC of 3 December 2001), the number of product recalls in Europe has increased significantly. New General Product Safety Regulations, implementing the directive, will come into force in the UK later this year. The impact of these regulations on product recall cover in the UK remains to be seen.

7. Product Guarantee Cover

Product guarantee cover may also be available, either by way of separate insurance or by way of an extension to the insured’s product liability insurance. As noted above, in the UK, product guarantee cover tends to be offered by way of separate insurance providing product recall, product guarantee and financial loss cover.

Product guarantee cover provides an indemnity to the insured, not where the product has caused bodily injury or property damage to a third party, but instead where the product is defective or has failed to perform in accordance...
Manufacturers and suppliers require insurance programmes that will respond to international liabilities. Some multinational businesses will have both a global master product liability insurance contract and local product liability insurance contracts. The master product liability insurance contract will provide cover to the extent that it is not available in certain individual jurisdictions by law.

There is a large degree of commonality in both the general conditions and the exclusions to be found in product liability insurance contracts in various jurisdictions. These similarities are, to a large extent, driven by the requirements of international reinsurers. However, there are plainly very significant differences between the underlying principles of insurance contract law in different jurisdictions.

Insurers and insureds alike need to take care in transacting insurance business and consult with both their insurance brokers and their legal advisers for the jurisdictions in which they intend to make their products available.

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8. Concluding Remarks

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Chapter 8

U.S. Consumer Litigation Against Electronics Companies: Understanding and Mitigating Risks

Morrison & Foerster LLP

I. Introduction

Consumer electronics technology has reached into nearly every aspect of our everyday lives. When something goes wrong with a consumer device, the problem can affect the business and personal lives of many people. A defect in a consumer electronics product thus potentially exposes a manufacturer to significant liability. This chapter summarises the main theories under which consumers often bring products liability claims against electronics manufacturers and other sellers, and how such consumer electronics sellers can reduce the risk posed by such lawsuits.

We include below an overview of traditional products liability claims, such as strict liability and breach of warranty. These claims may be particularly troublesome for consumer electronics manufacturers, for example, when a component that is incorporated in a final consumer product is defective or fails. Under general principles of U.S. products liability law, the manufacturer of a finished product may be held liable for a defective component, even if the manufacturer was not involved in the design or manufacture of the component or even if the manufacturer was unaware of the defect at the time the component was incorporated into the finished product.

In addition to these traditional products liability claims, electronics manufacturers and sellers are vulnerable to consumer fraud actions, usually brought under state law, in which plaintiffs claim that the products do not live up to statements made by the seller. Unfair trade practice and other consumer protection statutes, especially those in California, can be extremely broad and in the past have served as powerful tools for consumer plaintiffs to sue electronics sellers. Consumer electronics products are particularly easy targets for plaintiffs because the features of these products, such as battery life, memory capacity, or system performance are subject to many external variables, such as the operating environment or software or peripherals being used.

II. Federalism and Jurisdiction

Because of the many overlapping sources of law in the United States that govern the manufacture and sale of consumer electronics goods, the legal landscape in the United States can be daunting, even for the domestic U.S. consumer electronics manufacturer or seller, and especially for such a company outside the United States. The body of law covering products liability and consumer fraud is like a three-dimensional patchwork made up of both federal statutes and state statutes from each of the 50 different states, as well case law and important administrative regulations at both the state and federal level.

In general, federal law addresses matters of interstate or international commerce. At the federal level, there are consumer safety laws, such as the Consumer Products Safety Act. There are also laws governing what must be contained in certain warranties, such as the Magnuson-Moss Warranty Act. Consumer claims may be brought in federal court, where these federal statutes or standards are implicated, but also where state law governs and there is diversity of citizenship between the parties.

At the state level, there are statutes relating to the sale of consumer goods that many U.S. jurisdictions share in common. For example, the Uniform Commercial Code (“U.C.C.”), which governs contracts for the sale of goods, has been adopted in almost every U.S. jurisdiction. Each jurisdiction’s enactment may vary slightly; however, in general, the text of the U.C.C. is the same in every jurisdiction. There are other statutes, however, that are unique to each jurisdiction, but which may have broad application to consumer products manufacturers and sellers outside the jurisdiction. State unfair and deceptive trade practice statutes, for example, California’s Unfair Competition Law (“UCL”), (Cal. Bus. & Prof. Code §§ 17200 et seq.), discussed later in this chapter, may cover many types of activities, and may even reach defendants located outside the state.

III. Consumer Electronics and Class Actions

Although discussed in other chapters, class actions are a very important part of consumer litigation in the United States, and they are often invoked in consumer electronics products liability cases. We thus provide a quick overview of their importance in the consumer electronics area.

A class action is a procedural device that allows a court to consider the claims of a large number of plaintiffs at the same time. Class actions are especially appropriate where each individual member of the class has only a small claim for damages. If the class is large enough, these small damage amounts can collectively result in a very large total amount damage claim for the class.

Before a case can proceed as a class action, the court must
certify the class, that is, the court must evaluate whether the claims in the case are appropriate for class treatment. There are generally four requirements for class certification: (i) numerosity, i.e., that the plaintiff class is so numerous that individual lawsuits would not be practical; (ii) commonality, i.e., that there are issues of law and fact predominate over individualised questions. (See Fed. R. Civ. P. 23(a).)

In addition, the rules governing class actions, especially class actions in federal court, generally require, among other things, that common questions of law or fact predominate over individualised questions. (See Fed. R. Civ. P. 23(b)(3).) This “predominance” requirement is very complicated, however, if a court finds that the individual issues overwhelm common issues, it may deny class certification on the basis that each case should be decided separately. In consumer products liability cases, the argument that class action treatment of products liability claims is not appropriate because the predominance requirement is not met may be a very important tool for the consumer electronics defendant to avoid class certification. Cases that involve individualised questions of causation, reliance on a defendant’s statements, or a large disparity among potential class members in the type of damage or extent to which damage suffered, are often held not to satisfy the predominance requirement.

Many consumer electronics classes are certified as nationwide classes, rather than those limited to one state. California is perceived to be particularly hospitable to such nationwide class actions, especially in cases where the defendant is based in California, and where a significant aspect of the conduct alleged, for example, the sale or marketing of the product at issue, took place in California. Even for non-U.S. consumer electronics manufacturers, this can be significant, because often such companies’ U.S. subsidiaries are located in California.

Nationwide class actions filed in state court may be limited in the future, however, by the Class Action Fairness Act of 2005 (“CAFA”), signed into law by President Bush in February 2005. (119 Stat 4 (2005) (to be codified at 28 U.S.C. §§ 1711 et seq.).) CAFA permits defendants to move large, multi-state class actions into federal court, by eliminating, for the most part, such restrictions on federal jurisdiction as complete diversity of citizenship in class actions in which the amount in controversy exceeds $5,000,000. Among other things, CAFA also prohibits discrimination in settlements based on the geographic location of the class members, and prescribes the way in which attorneys’ fees are awarded in “coupon settlements,” that is, settlements in which the plaintiff class members receive coupons for discounts on new purchases, rather than cash. The theory is that these mechanisms will reduce “forum shopping,” and prevent attorneys’ fees that are disproportionately high relative to the value received by individual class members.

IV. Common Theories of Liability in Consumer Electronics Cases

A. Tort Claims

There are generally three types of tort claims brought by plaintiffs against manufacturers or other sellers of consumer products: (i) the product was defectively designed (defective design); (ii) the product was defectively manufactured (defective manufacture); or (iii) the seller failed to include adequate warnings of reasonable foreseeable dangers associated with the use or operation of the product (failure to warn). Consumers suing on a tort theory can seek compensatory damages, that is, an amount that would make them whole for the injury suffered, and in cases where the consumer can show fraud, malice, or other outrageous conduct, they may be able to obtain punitive damages. Because punitive damages cannot easily be passed on to consumers, the possibility of such damages is intended to incentivise manufacturers and sellers of consumer goods to make and sell safe products.

1. Negligence

Negligence is generally the breach of the duty to use reasonable care. Any party in the chain of distribution, including manufacturers, distributors, and retailers, may be liable for product liability negligence if the consumer can show that such party failed to use reasonable care in, among other things, a product’s design, manufacture, and/or warnings. The manufacturer or other seller owes a duty not only to the purchaser, but also to anyone who may be reasonably foreseen to be injured by the product, including the purchaser’s family, innocent bystanders, or lessors of the product. To succeed in a negligence action, however, a consumer must also show that the seller’s breach of the duty to use reasonable care caused the consumer harm.

2. Strict Liability

Similar to a negligence action, any party in the chain of distribution, including manufacturers, distributors, and retailers, can be liable under a theory of strict liability. In contrast to a negligence action, however, under strict liability, such a seller may be liable for a defective product without proof that the party failed to meet the standard of care. This is because the law assumes that sellers are in a better position than consumers to avoid the manufacture of unsafe products. For that reason, the law places the costs of product defects on sellers.

To hold a seller strictly liable for product defects, a plaintiff must generally establish that: (1) the seller was engaged in the business of selling the product that caused the harm; (2) the product was defective because it was unreasonably dangerous or not reasonably made safe for the user or consumer when sold; (3) the product was intended to and did reach the consumer without substantial change in the condition in which it was sold; and (4) the defect caused physical harm to the consumer or damage to the consumer’s property. The types of strict liability claims that may be brought are very similar to the types of traditional negligence claims, i.e., defective design, defective manufacture, and failure to warn.
3. Negligent and Fraudulent Misrepresentation

Consumers alleging that a product did not live up to representations made by the manufacturer or seller may bring tort claims for misrepresentation. The elements of a cause of action for negligent misrepresentation generally are: (1) a duty to communicate accurate information; (2) a false statement of material facts; (3) the falsity of which defendant should have known; (4) justifiable reliance by the plaintiff; and (5) damages resulting from the misrepresentation. The elements of a cause of action for fraudulent misrepresentation are generally: (1) a false statement of material fact; (2) knowledge of the falsity; (3) intent to induce action or inaction in reliance on the statement; (4) justifiable reliance; and (5) damages resulting from the misrepresentation. In terms of damages, the main difference between fraudulent misrepresentation claims and negligent misrepresentation claims is that punitive damages are available for fraudulent, but not negligent, misrepresentation.

B. Contract Claims

Consumers often bring claims against electronics sellers alleging that the product did not meet the promises made in the seller’s warranty. These claims are brought for breach of what is expressly promised in the warranty (express warranty), or for those promises that the law implies in all warranties (implied warranty). Consumer breach of warranty claims are frequently brought as class actions. Even in cases where there is a latent defect, some plaintiffs have sought certification for classes of all purchasers of the potentially defective product, including those whose products have not failed, under the theory that the present risk of failure renders all the products inherently defective, and therefore in breach of warranty.

1. Breach of Express Warranty

Consumers often bring claims alleging that the seller did not keep the promises contained in the express warranty provided with the product. According to the U.C.C., “[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.” (U.C.C. § 2-313(1)(a).) The U.C.C. provides that “any affirmation of fact or promise made” creates an express warranty, thus, no specific, formal language is necessary.

The scope of express warranties and their applicability to an individual case depends on the specific language used in the warranty. In determining whether an express warranty has been created, courts will look to the language of sales contracts and to product manuals or other documentation describing the product. Often consumer electronics plaintiffs allege that a company’s marketing materials create the basis for a breach of express warranty claim. Common consumer claims for breach of an express warranty include allegations such as that the battery did not last as long as stated in the packaging or that the processor did not run as fast as stated in the promotional materials. The fact that a manufacturer did not manufacture a particular component within its product that is defective is generally not a defense to an express warranty claim.

In general, the measure of damages for a breach of warranty is the difference between the value of the goods as accepted and the value they would have had if they had been as warranted. (U.C.C. § 2-714(2).) In California, the Song-Beverly Consumer Warranty Act, (U.C.C. § 2-714(2)), supplements the U.C.C. with regard to consumer warranties. For goods sold to a consumer, that statute provides that if the seller cannot repair the product to conform to its express warranties within a reasonable number of attempts, than the buyer is entitled to replacement or a refund of the full purchase price, less any amount attributable to use by the buyer prior to discovery of the problem. (Cal. Civ. Code § 1793.2(d)(1).) In cases in which there is a latent defect there is often a dispute as to what constitutes the proper remedy. Sellers may argue that replacement of the defective part should be sufficient. However, consumers may argue that the latent defect renders the entire product defective and may seek to hold the manufacturer liable for replacement of a new product, rather than just the defective component. Obviously, if the defect lies in a component, and the manufacturer of the finished product is liable for refunding the entire purchase price, the exposure can be significant.

The U.C.C. also provides that a buyer may recover incidental and consequential damages resulting from the seller’s breach of warranty. (U.C.C. § 2-715.) Incidental damages recoverable by the buyer include expenses paid or incurred in properly obtaining replacement goods (so-called “cover”) or other reasonable expenses incidental to the breach. (U.C.C. § 2-715(1).) Consequential damages include “(a) any loss resulting from general or particular requirements and needs of which the seller at the time of contracting had reason to know and which could not reasonably be prevented by cover or otherwise; and (b) injury to person or property proximately resulting from any breach of warranty.” (U.C.C. § 2-715(2).)

Consumer electronics limited warranties often disclaim liability for incidental and consequential damages. Such disclaimers are generally enforced unless a court deems them unconscionable, (U.C.C. § 2-719(3)), or concludes that the limited warranty failed of its essential purpose, (U.C.C. § 2-719(2)). If the remedy provided by the warranty provides at least “minimum adequate remedies,” (U.C.C. § 2-719, cmt. 1), the limitation is not likely to be found unconscionable.

A remedy is considered to have failed of its essential purpose if, although the remedy appeared to be fair at the time of contract, subsequent events cause a party to be left without a remedy or to be deprived the benefit of the bargain. Consumer plaintiffs may argue that even if a limited remedy was reasonable and valid when it was offered, it “failed of its essential purpose” if it the seller cannot make repairs to cure the defect, either within a reasonable period, or at all, leaving the purchaser without minimum adequate remedies. In the consumer electronics context, these claims may be made where there has been an allegation of lost time, money, or data such that repair or replacement can not cure the loss incurred. However, because claims for consequential damages such as for lost time, money or data are by their nature highly individualised, they are not likely suitable for class treatment because the predominance requirement would be difficult to satisfy.

2. Breach of Implied Warranties

An action for breach of the implied warranty of merchantability requires that a product sold by a “merchant” have a defect that, among other things, renders it unfit for the
ordinary purposes for which it is used. (U.C.C. § 2-314(2)(c).) The warranty, unless modified or excluded, is implied in a sales contract if the seller is a merchant with respect to goods of that kind. (U.C.C. § 2-314(1).)

A warranty of fitness for a particular purpose is implied, unless modified or excluded, when the seller, at the time of contracting, has reason to know any particular purpose for which goods are required and that the buyer is relying on the seller’s skill or judgment to select or furnish a suitable product. (U.C.C. § 2-315.) Unlike with the implied warranty of merchantability, the seller does not have to be a merchant: any sale by someone possessing sufficient skill and knowledge to justify the buyer’s reliance could be subject to the warranty for fitness for a particular purpose. The California Song-Beverly Consumer Warranty Act expressly extends the warranty of fitness for a particular purpose to consumer goods sold at retail by a manufacturer, retailer, or distributor. (Cal. Civ. Code §§ 1791.1(b), 1792.1, 1792.2(a).) There is generally no requirement that the product must meet all of the buyer’s expectations -- the warranty is only that the goods will be suitable for the “particular purposes for which the goods are required.” (U.C.C. § 2-315.)

The implied warranties cannot be easily disclaimed. The U.C.C. requires that such disclaimers must be in writing and conspicuous. (U.C.C. § 2-316(2).) The California Song-Beverly Consumer Warranty Act limits the circumstances under which the implied warranties can be disclaimed even more explicitly. The Act only permits disclaimer of the implied warranties where the seller explicitly states that (i) the sale is “as is” or “with all faults”; (ii) the buyer bears the entire risk of the quality and performance of the goods; and (iii) the buyer assumes the entire cost of all necessary service or repair. (Cal. Civ. Code §§ 1792.4.) New York courts have also held that if an injured third party was not a party to the contract containing disclaimers of the implied warranties, the disclaimers may not apply. (Velez v. Craine & Clark Lumber Corp., 33 N.Y.2d 117, 124-25 (1973).)

C. Unfair and Deceptive Trade Practices

Consumers also frequently make claims against electronics manufacturers based on state unfair and deceptive trade practices statutes. We include by way of example a broad overview of the California statutes -- claims under which have been a common feature of consumer electronics products litigation. While many consumer electronics manufacturers, and other sellers have a presence in California, California’s consumer protection statutes are also relevant to even non-California sellers because California’s long-arm statute is extremely broad and allows California courts to exercise jurisdiction over both residents and non-residents to the outer limits of Constitutional Due Process; that is, as long as a defendant has “minimum contacts” with California, it may be subject to suit in California. In a recent case in which a plaintiff brought claims under California Business and Professions Code Sections 17200 and 17500, the California Supreme Court held that certain advertising activities, such as the use of television and newspaper and magazine ads and billboards in California, as well as toll-free numbers and interactive web sites, subjected out-of-state hotels to jurisdiction in California. (Snowney v. Harrah’s Entertainment, Inc., No. S124286 (Cal. June 6, 2005.).) Thus, the risk posed by California’s consumer protection statutes to out-of-state companies that use these methods to reach customers may now be greater.

1. California Unfair Competition Law

California’s Unfair Competition Law, California Business and Professions Code Sections 17200 et seq., prohibits any “unlawful, unfair or fraudulent” business practices. Section 17500 prohibits false advertising. In the past, under these statutes, any individual could sue as a private attorney general for restitution on behalf of California consumers, without certifying a class. However, recent amendments to the UCL now require that representative actions meet the requirements for class certification. (Cal. Bus. & Prof. Code § 17203.) While in the past, proof of actual injury was not required, these amendments also now require that private UCL plaintiffs have actually suffered injury and lost money or property as a result of the conduct of which they complain. (Cal. Civ. Code § 17204.) Because the substantive nature of Section 17200 claims, however, remains broad, they still may be brought as part of consumer electronics litigation.

The “unlawful” prong of Section 17200 permits a plaintiff to make a separate claim based on a violation of any other statute or law. Such other statutes may include, for example, Section 17500 (false advertising), the Song-Beverly Consumer Warranty Act or the Consumer Legal Remedies Act (discussed below), but also any other statute, including criminal statutes and regulatory provisions.

“The unfair” or “unlawful” prong of Section 17200 permits a plaintiff to make a separate claim based on a violation of any other statute or law. Such other statutes may include, for example, Section 17500 (false advertising), the Song-Beverly Consumer Warranty Act or the Consumer Legal Remedies Act (discussed below), but also any other statute, including criminal statutes and regulatory provisions.

Under the “unlawful” prong of Section 17200, plaintiffs may assert that a seller’s claims that its products were of high quality or reliable were improper in light of defects that have now come to light. Under Section 17200, before the recent amendments, the plaintiff did not need to show that the defendant intended to cause injury. (State Farm Fire & Casualty Co v. Superior Court, 45 Cal. App. 4th 1093, 1102 (1996)). Rather, it was enough to show members of the public were “likely to be deceived.” (Committee on Children’s Television, Inc. v. General Foods Corp., 35 Cal.3d 197, 211 (1983)). In other words, the statute imposed strict liability. (State Farm, 45 Cal. App. 4th at 1102.) Although it is too soon to know for certain, the recent amendments to the UCL, now requiring a plaintiff to show actual injury, may make this burden more difficult for the plaintiff.

Under Section 17500, the false advertising statute, almost any statement can be considered “advertising”, and like under Section 17200, the statute prohibits statements that are likely to mislead or deceive. However, unlike Section 17200, which imposed strict liability, a Section 17500 plaintiff must show that the defendant knew or reasonably should have known that the statements in question were likely to mislead. (Cal. Bus. & Prof. Code § 17500.) The recent amendments to the UCL also require that private
plaintiffs bringing claims under Section 17500 must also have suffered actual injury, and representative actions must meet the requirements for class certification. (Cal. Bus. & Prof. Code § 17535.)

Damages are not available for violations of the UCL -- only equitable remedies, primarily injunctive relief and restitution are available. (Cal. Bus. & Prof. Code § 17203.) In the case of a defective component, a manufacturer may argue that replacement of the component makes the plaintiff whole. Plaintiffs may respond, however, that such a remedy is inadequate because, for example, there is a risk of some undetected loss, such as a data loss. Thus, they may argue, plaintiffs should be entitled to a refund of the full purchase price for the entire product. Because restitution is an equitable remedy, however, courts have significant discretion in fashioning an adequate remedy.

2. California Consumers Legal Remedies Act

The California Consumer Legal Remedies Act (“CLRA”) provides a cause of action for consumers where one of several enumerated violations has occurred. (Cal. Civ. Code §§ 1750 et seq.) Some of these grounds provided by the CLRA are similar to Business and Professions Code Sections 17200 and 17500, and are quite broad, such as: “[r]epresenting that goods or services have... characteristics, ingredients, uses, benefits, or quantities which they do not have...,” (Cal. Civ. Code § 1770(a)(5)); “[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another,” (Cal. Civ. Code § 1770(a)(7)); or “[a]dvertising goods or services with intent not to sell them as advertised,” (Cal. Civ. Code § 1770(a)(9)). Under the CLRA, a plaintiff must also show that the defendant’s deceptive conduct actually caused injury. (Massachusetts Mut. Life Ins. Co. v. Superior Court, 97 Cal. App. 4th 1282, 1292 (2002).) This causation requirement does not necessarily serve as an obstacle to class certification, however, because reliance by the entire class may be necessary to prevent a remedy that is inequitable, because, for example, there is a risk of some undetected loss, such as a data loss. Thus, they may argue, plaintiffs should be entitled to a refund of the full purchase price for the entire product. Because restitution is an equitable remedy, however, courts have significant discretion in fashioning an adequate remedy.

V. Risk Reduction

A. Internal Education for Business and Engineering Personnel

In terms of preventive measures consumer electronics manufacturers and other sellers can take, the first step is to understand the risks and to educate members of the relevant business and engineering departments of those risks.

B. Prevention Through Design

It may seem elementary, but an important step to avoiding products liability litigation is through design, starting when the product design is first conceptualised. Because manufacturers and sellers may be liable to all ultimate users of a product, all such potential users of the product should be considered during design. Also, because a manufacturer or seller may be liable for misuse of a product, if such misuse was reasonably foreseeable, all possible uses and misuses should also be identified during the design stage. If the product, as designed, still poses a risk of harm, alternative designs and the effect of those alternative designs on the usefulness of the product should be considered. Keeping current with the state of the art in the field, and staying abreast of safety features used by competitors is also an important part of designing safe products.

C. Document Creation and Retention

It is also important to keep in mind how liberal, and often intrusive, discovery is in civil litigation in the United States. Manufacturers and other sellers must, therefore, anticipate that the design process, and the documents created and maintained in that process, will be viewed and evaluated by others in litigation. Manufacturers and sellers should, therefore, always consider how design decisions might be viewed by those outside of the company, and whether those evaluating the company’s actions would expect the company to have acted differently or done more to protect consumers.

D. Product Labeling and Warnings

Under tort theories of recovery, a manufacturer or other seller generally has a duty to warn of foreseeable danger in connection with the use of a product. The warning must reasonably inform the user of the full scope of the potential dangers posed by such use, must be adequate in relation to the danger, and must be appropriate under the circumstances - the more dangerous a product, the more extensive a warning that will be required. While warnings on their own may not prevent a manufacturer or seller from being sued in a products liability case, warnings are one of several factors that can help a manufacturer or seller show that it complied with its duty to protect consumers.

The laws governing consumer products are complicated. It is important that counsel is involved in the development of promotional materials and product manuals to make sure that warnings are sufficient and that all representations are accurate.
E. Remedial Action

Replacement programmes or recalls can be very helpful in minimising the risk of exposure to significant damages awards. Most consumer electronics limited warranties state that the product is free from defects, and that, in the even of a defect, the manufacturer will repair or replace the product. In light of such a warranty, a replacement programme may be sufficient to fulfill warranty obligations. From a practical point of view, replacement programmes, if done properly, can keep consumers happy and prevent them from becoming so dissatisfied with a product such that they would sue a manufacturer or seller. However, because of the complex nature of products liability law, it is important to involve counsel early in designing and implementing a replacement programme. If the replacement programme is not handled properly, there is the risk that consumers could have additional claims against a manufacturer based on the improper or insufficient replacement programme.

VI. Conclusion

As a practical matter, it is nearly impossible for an electronics manufacturer or seller to completely avoid products liability litigation in the United States. However, with knowledge of the risks, there are practical steps manufacturers can take to minimise exposure to such litigation. Through education and prevention programmes and the early involvement of counsel, it is possible to effectively manage the risk of consumer litigation in the United States.

End Notes

2. The Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 et seq., prescribes rules for the contents of “full” and “limited” warranties for consumer products that are sold in interstate commerce, including the federal minimum requirements for such warranties.
3. With respect to consumers, one important difference among the states is the extent to which the implied warranties can be disclaimed, and the extent to which remedies can be limited.
4. Punitive damages are available for products liability claims in order to make a strong economic incentive for manufacturers to create safe products. Without the risk of punitive damages, the fear is that manufacturers or other sellers of consumer goods might simply regard products liability claims as a normal cost of business, much like the costs of obtaining raw materials, labour, and energy, etc.
5. These amendments were approved by a voter referendum known as Proposition 64, which passed in November 2004. We expect these amendments will have a limiting effect on UCL litigation, but the extent of their impact remains to be seen.

Acknowledgement

The authors would like to thank their colleague James E. Hough for his assistance in the preparation of this chapter.
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Morrison & Foerster has extensive product liability experience. The firm has served as trial and national coordinating counsel for hundreds of companies in product liability and toxic tort cases, including numerous large class actions, multi-party serial tort litigation, and mass tort litigation.

The firm has handled and tried product cases in a wide variety of industries involving claims of manufacturing defect, design defect, and failure to warn. The firm has also handled and tried cases involving alleged exposures to toxic substances. In addition, the firm has defended tort, statutory, and other consumer claims (including various class actions) arising out of consumer products, industrial accidents, transportation accidents, and environmental releases.

Morrison & Foerster is often called upon to analyze complex product liability claims, develop product warnings and product recall campaigns, and serve as national coordinating counsel for leading manufacturers across the country.

Morrison & Foerster has extensive experience under both federal and state law with a full range of industrial chemical issues, including claims for personal injury, wrongful death, medical monitoring, fear of cancer, and property damage claims.

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Chapter 9

Argentina

M. & M. Bomchil

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

The following systems of product liability are available: (a) one established by the Civil Code; (b) one set down by the Consumer Protection Act; and (iii) one that relates to hidden defects, with some specific rules on commercial matters, which is governed by the Civil Code.

The one established by the Civil Code regulates damages to the purchaser or to a third party by virtue of the risk or the defect of a product.

The Consumer Protection Act governs the relation whereby a consumer (understood to be an individual or legal person who will not use the product as part of its commercial or industrial activity) appears before a professional merchant (which could be an individual or a company). On this regard, the Federal Constitution establishes in section 43 the protection of the consumer. The damages produced as a consequence of said relation are ruled by said Act, which is complemented by the Civil Code rules.

On the other hand, section 2164, and followings, of the Civil Code regulates the existence of hidden defects on the product. This regulation involves civil or commercial matters.

1.2 Does the state operate any schemes of compensation for particular products?

No, it does not.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

According to the Consumer Protection Act (section 40), responsibility lies upon all the legal or human persons who participated at any stage of the production or selling proceedings, including the owner of the trademark of the product. This responsibility is faced against the consumer notwithstanding that those who are not accountable can recover from the responsible party any sum paid to the consumer.

On the Civil Code system, the responsible persons are the seller, the manufacturer and the owner or keeper of the product.

The seller is responsible on a contractual basis as they are the person who engage the purchaser. According to the court precedents and the scholars, the seller holds an obligation of guarantee which implies that the product it sells will not produce any damage to the purchaser, while the manufacturer owes the same duty towards any potential purchaser of the product, based upon the principle, set down by section 1109, that anyone who by its action or omission generates damage to any other person responsible for its indemnification. The seller and the manufacturer are several and jointly liable towards the purchaser.

Regarding the owner or the guardian of the product, it is responsible towards any person who suffered damage by virtue of the risk or defect of a product, irrespective of the responsibility of the seller and the manufacturer. Nonetheless, the latter holds a reimbursement action against the manufacturer for the recovering of any amount paid to the injured person.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The recalling of products is ruled by section 17 of the Consumer Protection Act. According to sections 11 and 13 of said Act, the manufacturer, the importer, the distributor and the seller hold a guarantee before the consumer for any defect or fault of any type even if it is not a hidden one. Said guarantee is enforced for three months as from the delivery of the product and it can be extended for a further period by agreement of the parties.

In those cases whereby the product is defective and its reparation is not satisfactory, the consumer is entitled to exercise the following rights: (A) to demand a replacement of the product for one of similar characteristics; (B) to return the product and recover the price paid according to the current value of the product on the market; and (C) to obtain a proportional reduction of the price paid.
2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The general principle established in our procedural code is that the plaintiff bears the burden of proof.

Nonetheless, in trials where the damages generated by defects of products are discussed, the courts take into consideration that the manufacturer is in a better position than the consumer to produce technical evidence, and accordingly lays on them the burden of proving that the product was not defective.

The seller is deemed to hold a final obligation on the security of the product sold, therefore, if the product exhibits a defect, there is a presumption of the fault of the seller, which must be overruled by him through the defences mentioned in question 3.1. below.

Regarding the manufacturer, said presumption is based on two different considerations: (A) the minority one considers that the existence of the defect implies a presumption of the manufacturer’s fault; while (B) the majority position understands that it is applicable on an analogous basis, as they understand that the list of responsible persons included in section 1113 of the Civil Code must be construed as embracing any person who creates a risk through a product.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The plaintiff bears the burden to prove the existence of the defect and the relation between said defect and the damages alleged. It is not required to prove that the damages would not have arisen without such exposure to the product.

The mere exposure to potential damage does not produce any responsibility.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

There is no form of market-share liability to be applied, but all the manufacturers of similar products will stand liable before the consumer or the purchaser (this was ruled by the Civil Court of Appeals in a precedent issued in 1994) without prejudice of the actions that they could bring against the actual responsible party.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

According to section 4 of the Consumer Protection Act, the seller, the manufacturer, the importer, the distributor and any other person involved in the production or selling proceedings all have the obligation to provide the consumer with actual, complete and precise information.

There is no possibility to exclude said responsibility based on the grounds that the information should have been provided by the intermediary. On this regard, it is immaterial, whether said intermediary is or not a learned one. Nonetheless, the manufacturer shall not be responsible if its instructions are not followed when using the product.

The information taken into account is that directly provided to the consumer by one of the persons listed as responsible but it shall also be taken into consideration the information set down in any kind of publicity even when addressed to the public in general (section 8 of the Consumer Protection Act).

As mentioned, the responsibility of the manufacturer is not excluded on the basis that the product was used under recommendation of a learned intermediary (a concept that does not exist in our law) unless when using the product the consumer did not respect the manufacturer’s instructions. It makes no difference if the product can only be purchased through an intermediary, as the law places the duty of providing information on the manufacturer as well.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Despite procedural defences (e.g. time bar defence), the substantial law authorises the following ones: (i) that the product is not defective nor risky; (ii) that there is no relation between the alleged damages and the defect, even when this existed; (iii) the existence of a third party for whom neither the manufacturer nor seller are liable; (iv) the occurrence of a force majeure event; and (v) the fault of the victim itself.

The defence can obtain a total or partial exclusion of responsibility.
3.2 **Is there a state of the art/development risk defence?**

Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There are no cases ruled by the courts applying the state of the art/risk development defence understood as the situation whereby a product is not considered as defective at the time it was sold in the market but further scientific discoveries or technical knowledge show that it is.

3.3 **Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?**

No, such defence is not eligible for the manufacturer as the regulatory requirements are deemed to be granted under the condition that the product is harmless to consumers.

3.4 **Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?**

Yes they can, as different injured persons are not required to file a sole proceeding.

Nonetheless, the defendant may file with the court a petition to have all the trials involving the same product heard by the same court in order to avoid the issuance of contradictory decisions.

### 4 Procedure

4.1 **Is the trial by a judge or a jury?**

The trial is by a judge as long as no trials by jury are developed in Argentina.

The Consumer Protection Act also regulates an administrative proceeding and may impose fines, but not award damages. The Secretariat of Industry and Trade (DIT), subordinate to the Executive Branch, is the national enforcement authority. Provincial governments and municipalities act as the local judiciary.

4.2 **Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?**

The court is empowered to order all the measures that it considers necessary in order to have the facts proved provided that neutrality from the parties is upheld.

Consequently, the court is entitled to appoint technical specialists. Despite having this power, courts do not usually use it but leave it up to the parties to produce said kind of evidence.

If the parties ask for it, the specialist shall be appointed by the judge on a random system from a list previously prepared by the Court of Appeals. The parties have the right to designate a specialist to support or contradict the conclusions of the one appointed by the judge.

4.3 **Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?**

There is no class action procedure. Nonetheless, many persons can file the same claim against an unique defendant on the basis of similar facts (e.g., the same defect in a product) and said claim can be brought through a sole proceeding.

4.4 **Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?**

Yes, a representative body can bring the claim. This standing is ruled by section 58 of the Consumer Protection Act. The association standing as plaintiff shall be authorised by its memorandum of association and should have been appointed as proxy by the consumers damaged.

4.5 **How long does it normally take to get to trial?**

It depends on the particular case. Before getting to the trial, parties shall go through a mandatory mediation proceeding, which usually takes two or three hearings, but which can take no longer than three months. Once this proceeding is over, the plaintiff is empowered to bring the action with no other limit than the statutory limitation time.

4.6 **Can the court try preliminary issues, the results of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?**

The court is not empowered to order said type of preliminary issues. Notwithstanding, at the parties request (usually the plaintiff), the court can order the production of certain evidence before the filing of the complaint (e.g., a technical report on the product, which cannot be adjourned until the proper procedural stage).

4.7 **What appeal options are available?**

The final decision can be appealed before the Court of Appeals insofar as the amount involved exceeds US$ 1,500 approximately. Against the decision handed down by the Court of Appeals, parties can only file an extraordinary appeal before the Federal Supreme Court insofar as the previous decision was arbitrary. This type of case does not usually get to the Supreme Court as it does not involve the interpretation of a federal law, which is the main requisite to bring a case to said court.
### 4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Although the court at its own discretion may appoint an expert, it does not usually do it. On the other hand, the parties are entitled to produce expert evidence; the expert must be a neutral one, appointed by the court.

### 4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

No, they are not. In our system, there is no pre-trial activity, with the exception of the mediation proceeding and, potentially, the production of anticipated evidence, as mentioned in question 4.6 above.

### 4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

There is no obligation to disclose documentary evidence. If one of the parties claims for it, the court can request the counter-party to exhibit certain documentation, clearly detailed by the party that requested it. If the required party failed to exhibit it, when reaching the final decision, the court may consider said omission as a presumption against said party.

### 5 Time Limits

#### 5.1 Are there any time limits on bringing or issuing proceedings?

Yes, there are time limits on bringing the proceedings, as explained in question 5.2 below.

#### 5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The time limits are as follows: (i) three months for a claim based on a hidden defect, ruled by the Civil Code; (ii) six months, if the relation is ruled by the Commercial Code (in both cases, the term commences at the delivering of the product); (iii) two years, for the action brought by the purchaser against the non-seller manufacturer; (iv) ten years against the seller (it does not matter whether it also stands as manufacturer); and (v) three years against any party if the case fell within the Consumer Protection Act regulation.

#### 5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

As principle, the commencement of the time limit begins at the time the damages occur or the product is delivered, as explained in question 5.2. If a fraud was committed, the beginning of said time shall commence as from the time the fraud is discovered and consequently, the party takes notice of the event.

### 6 Damages

#### 6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

All the damages suffered can be recovered. Therefore, the injured party may claim the indemnification of all the damages, including physical, economic and psychical damages. To be admitted by the court, damages must be in direct relation with the defect of the product.

#### 6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No indemnification can be pursued if no damage or no injury has occurred. Therefore no medical monitoring as mentioned might be indemnified.

#### 6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not admitted in our system.

#### 6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no limit. The plaintiff shall recover all the damages that it proves.

### 7 Costs / Funding

#### 7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As a principle, the losing party shall bear the costs of the proceeding. These costs include: (i) fees of the winning party as determined by the court; (ii) the court tax; (iii) fees of the experts appointed by the court; and (iv) any expense related to the trial that can be proved through authentic means (e.g. costs of notifications).

The fees are determined by the court based upon the amount claimed by the plaintiff and the complexity and extension of the duties performed before the court.

This assumption of fees and costs does not include the agreement between the winning party and its attorney.

#### 7.2 Is public funding e.g. legal aid, available?

No public funding is available. Regarding legal aid, it can be requested to the court through an ancillary proceeding (“beneficio de litigar sin gastos”)
whereby the party must prove that although it is not in total poverty, it does not have the funds nor the means to obtain the funds as to afford the costs of the proceeding.

7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

No, there is not.

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Introduction

Since 2002 Australia has undergone an intense programme of tort law reform, particularly in relation to the laws governing negligence in response to a perceived “public liability crisis” informed by rising insurance costs.


The impact of the recent tort law reforms is yet to be fully realised. These reforms continue to take place and, despite a desire for consistency, are not uniform across the various jurisdictions. Throughout these questions we will refer to this continuing process of reform as the “Tort Reform Process”.

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Australia’s product liability laws are a mixture of the common law and various Federal and State statutes.

A person who claims to have been injured or who has otherwise suffered loss or damage, can commence an action for compensation or damages on the following bases:

- the common law tort of negligence which is fault based;
- contract; and

Typically, product liability claims for damage to persons will involve causes of action based on negligence and breaches of various provisions of the TPA. Claims based on breach of contract do play a role but are limited to claims where privity of contract can be established.

1.2 Does the state operate any schemes of compensation for particular products?

No formal schemes for particular products exist, except for asbestos related claims in one state, New South Wales. In that state, the Dust Diseases Tribunal has exclusive jurisdiction to determine “dust diseases” claims (which are not subject to the recent changes to the law of negligence made by the Tort Reform Process).

However, there are state-based schemes requiring compulsory insurance in respect of motor vehicle accidents. As a result, personal injury claims arising from motor vehicle accidents have, to date, generally been brought under these statutory schemes, as opposed to being brought against motor vehicle manufacturers.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Liability for fault or defect depends upon the particular facts and cause of action relied upon.

Negligence

It is generally accepted that the manufacturer of goods owes a duty of care to the purchaser and user to safeguard them against the foreseeable risks of injury when using the product as intended.

Retailers, importers and distributors are not expected to test or inspect products which the manufacturer delivers in sealed containers which would not normally be opened until they reach the ultimate consumer. However, in these circumstances, the retailer still has a duty to guard against those dangers known to it or which it has reasonable grounds to expect.

To the extent that any party in the supply chain adds to or modifies a product including packaging and labelling, that party will also owe a common law duty to the purchaser and user in respect of those changes.

Contract

Parties are free to enter into contracts on terms agreed between them, subject to terms implied into the contract by common law or statute. Thus, it is for the manufacturer, importer, distributor, and retail supplier to negotiate the terms of their business relationship.

Part V Division 2 of the TPA and sale of goods legislation in

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each state and territory require certain implied terms to be included in contracts for the supply of goods to a person - whether that contract be written or oral. These include warranties that the goods are:

- merchantable quality, and
- fit for the purpose for which they are supplied.

As noted in question 1.1 above, contractual remedies are only available to parties to the contract. Since, in most circumstances, it is the retailer that will have a contractual relationship with the purchaser, the retailer will bear the liability for any defect or fault in accordance with the express and implied terms of the contract of sale.

**Trade Practices Act**

Under Part V Division 2A of the TPA, manufacturers will be liable directly to consumers for:

- goods which do not correspond with their description;
- goods of unmerchantable quality;
- which do not conform to sample;
- goods unfit for a stated purpose; and
- non-compliance with express warranties;

thus overcoming the restrictions of privity of contract.

The operation of Division 2A is restricted to claims of consumers who have suffered loss or damage as a result of their use or consumption of consumer goods. These are goods that are ordinarily acquired for personal, domestic or household use or consumption.

Under Part VA, manufacturers will be directly liable to consumers for injury to persons or property damage suffered as a result of a defective product. Goods are considered to be defective if their safety is not such as persons generally are entitled to expect.

The definition of “manufacturer” under Parts V and VA of the TPA is extremely broad. Apart from the actual manufacturer, it includes any corporation that:

- holds itself out to be the manufacturer;
- applies its name or brand to the goods;
- permits someone to promote the goods as those manufactured by the corporation; and
- imports the goods in circumstances where the actual manufacturer has no presence in Australia.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under the common law, manufacturers and suppliers of products owe a continuing duty to purchasers and users to prevent a product causing harm, including after the product is sold.

Failure to recall a product which may cause harm may amount to negligence and give rise to the obligation to pay compensation to persons suffering injury, loss and damage as a result.

The issues that will be considered in deciding whether recall action is necessary include the:

- magnitude of the potential harm involved;
- probability of such harm occurring;
- availability and effectiveness of alternative remedial action; and
- of knowledge in potential users of the potential harm.

In addition, the provisions of Part V Division 1A of the TPA create a stringent regime for the compulsory recall of goods which:

- do not comply with a prescribed safety standard;
- have been declared to be unsafe goods or permanently banned; or
- will or may cause injury to any person.

If a corporation fails to comply with an order under this regime, it will be guilty of an offence resulting in large fines. Non-compliance will also form the basis of a civil action. In addition, there are reporting requirements in the case of voluntary recalls to enable the recall process to be monitored.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In negligence, contract and under some of the provisions of the TPA, the claimant has the burden of proving that the product was defective.

Part V Division 2A and Part VA of the TPA are often referred to as “strict liability” provisions. In the former, a claimant need not prove fault but nonetheless must establish, on balance, that the subject goods are not fit for purpose or are not merchantable in the circumstances. In the latter, a claimant needs to prove that the subject goods are defective, namely, that they do not have the safety that persons generally are entitled to expect.

At common law, in contract and in actions based on the provisions of the TPA, the claimant must establish:

- that loss or damage has been suffered;
- that the relevant conduct is either in breach of the common law duty, in breach of the contract or contravenes one of the provisions of the TPA; and
- that the loss or damage was caused by the defendant’s conduct.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The test for causation depends upon the cause of action relied upon.

Prior to the Tort Reform Process, the position under the common law of negligence has been that causation is a question of fact which falls to be decided according to the evidence before the court. Australian courts have rejected the notion that there is any single legal test of causation. Rather courts have been encouraged to apply “common sense” to determine the question of causation. It is yet to be seen whether the position has changed.
following the Tort Reform Process, which includes a codified test for causation in negligence cases. While the test varies between jurisdictions, there are basically two requirements:

- first, that the negligence was a necessary condition of the occurrence of the harm (referred to as “factual causation”); and
- second, that it is appropriate for the scope of the negligent person’s liability to extend to the harm so caused (referred to as “the scope of liability”).

There is, however, an allowance for determining in an “exceptional” case, whether negligence that cannot be established as a necessary condition of the occurrence of harm should nonetheless be accepted as establishing factual causation.

To date (at least until the Tort Reform Process) Australian courts have not embraced the view that a plaintiff who demonstrates that the exposure which is alleged to have caused his or her injury causes an increased risk of that injury has either proved causation or reversed the onus of proof in relation to causation.

However in a recent case an Australian court held that causation is established under one of the no fault provisions. However in a recent case an Australian court held that causation is established under one of the no fault provisions. In such cases, each co-defendant will only be liable to the extent of its responsibility.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The TPA contains provisions designed to assist claimants in circumstances where it is not clear who actually manufactured the defective product.

In Part V Division 2A and in Part VA the definition of “manufacturer” is very broad and can potentially include anyone in the supply chain, particularly when the actual manufacturer is outside Australia.

In Part VA, a claimant is entitled to make a written request to the supplier for information about the manufacturer. If, after 30 days, the claimant does not know the identity of the manufacturer, the supplier is deemed to be the manufacturer.

At common law, it is up to the claimant to establish the identity of the manufacturer. There is one exception to this, namely, where a claimant is able to rely upon the principle of res ipsa loquitur (in this context, the negligence speaks for itself) and can prove, on the balance of probabilities, that a particular defendant, specified group or number of defendants who are parties was or were negligent. It is not enough for a claimant to only prove one of the defendants must have been negligent or all of them may have been negligent. Whilst no generally established system of market-share liability exists in Australia, as a result of the Tort Reform Process most jurisdictions have introduced proportionate liability for co-defendants in respect of non-personal injury claims for economic loss or property damage, or claims for misleading or deceptive conduct brought pursuant to state fair trading legislation. In such cases, each co-defendant will only be liable to the extent of its responsibility.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The common law of negligence imposes a duty of care on the manufacturer of a product to take reasonable steps to ensure that ultimate users of that product are given adequate warnings of risks associated with its use to enable users to adjust their use of the product so as to avoid or minimise danger or to make an informed decision about whether or not to use the product. A failure to warn may also found a claim that a product is defective under Part VA or unfit/unmerchantable under Part V Division 2A of the TPA. In deciding whether the product is defective or unfit/unmerchantable, the court may look at all relevant circumstances including any warnings and the marketing strategy adopted by the manufacturer or supplier to determine whether they placed the user in a position to properly understand the risks associated with the product.

The learned intermediary doctrine has never been considered by an Australian court. However for medical products which may only be accessed through a doctor, the doctrine is consistent with Australian law which acknowledges the importance of the relationship between doctor and patient in the provision of warnings about medical treatment.

Following the Tort Reform Process, in some jurisdictions, evidence from plaintiffs as to what they would have done had there been a warning about a risk of injury is inadmissible in negligence cases except to the extent that it is evidence against the plaintiffs’ interest. This is a change to the law in the relevant jurisdictions which previously required that this question be determined subjectively.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Limitation periods apply to all causes of action pleaded in product liability litigation. Details of these defences are set out in question 5.2 below.

Negligence

The following defences may be available to a claim in negligence:

- 
  volenti - or voluntary assumption of risk;
- contributory negligence; and
- the learned intermediary defence.
To establish the defence of volenti, the defendant must show that the plaintiff not only perceived the existence of the danger, but also fully appreciated it and voluntarily accepted the risk. This defence is difficult to establish, but is a complete answer to any claim. Contributory negligence may be relied on where the plaintiff’s conduct fails to meet the standard of care required for his or her own protection and safety and is a contributing cause in bringing about his or her injury. Damages are apportioned by the court in accordance with each party’s degree of fault. Following the Tort Reform Process, in some (but not all) jurisdictions, contributory negligence can be a complete defence to an action if the court thinks this just and equitable in the circumstances.

As explained in question 2.4, there is no express authority in Australia for a learned intermediary defence, although there is no reason why the defence cannot be accommodated within the existing common law principles. The Tort Reform Process has created new statutory defences to an action for negligence, although these differ from jurisdiction to jurisdiction.

For example, the following have been introduced as complete defences in New South Wales:

- where the harm was suffered as a result of the materialisation of an inherent risk, which is defined as the risk of something occurring that cannot be avoided by the exercise of reasonable care and skill;
- where the harm was suffered as a result of the materialisation of an obvious risk associated with a dangerous recreational activity. An obvious risk is a risk that, in the circumstances, would have been obvious to a reasonable person in the position of plaintiff and includes risks that are patent or a matter of common knowledge;
- where a professional defendant acted in a manner that, at the time the relevant service was provided, was widely accepted in Australia by peer professional opinion as competent professional practice (unless the court considers such opinion to be irrational); and
- where the defendant is a good Samaritan or volunteer or, in certain cases where the defendant is a public or other authority.

Part VA Trade Practices Act

There are a number of specific defences to an action brought under Part VA:

- the defect alleged did not exist when the goods were supplied by the manufacturer;
- the goods were defective only because there was compliance with a mandatory standard (see further question 3.3);
- the state of scientific or technical knowledge at the time the goods were supplied was not such as to enable the defect to be discovered (the so-called ‘development risk defence’) (see further question 3.2); or
- in the case of a manufacturer of a component used in the product, the defect is attributable to the design of the finished product or to any markings, instructions or warnings given by the manufacturer of the finished product, rather than a defect in the component.

3.2 Is there a state of the art/development risk defence?

If a product is found to be defective under Part VA of the TPA, the manufacturer or supplier can argue in its defence what is commonly referred to as the “state of the art defence” or “development risk defence”. The manufacturer or supplier must establish that the state of scientific or technical knowledge at the time when the product was supplied by its actual manufacturer was not such as to enable the defect to be discovered. Under Part V Division 2A of the TPA, the issue would be whether the product was fit for the purpose for which it was intended, giving consideration to any description applied to the goods by the corporation, the price received by the corporation for the goods, and all the other circumstances. In negligence, the claimant must establish that the manufacturer failed to exercise reasonable care. The state of scientific and technical knowledge is often pertinent to this issue and forms the basis of the manufacturer’s defence.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

In an action under Part VA of the TPA, it is a defence if it can be established that the goods had that defect only because there was compliance with a mandatory standard for them. A mandatory standard is a standard for the goods or anything relating to the goods which, under law, must be complied with when goods are supplied, and which carries a penalty for non-compliance. A standard which simply requires a minimum standard to be achieved is not a mandatory standard.

In an action for negligence and under Part V Division 2A of the TPA, compliance with regulations or standards is a relevant factor in determining whether goods are as fit for the purpose(s) for which goods of that kind are commonly bought as it is reasonable to expect. Non-compliance with a standard is usually considered to be strong evidence of negligence and lack of fitness or merchantable quality.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Claimants may re-litigate these issues. This is not possible in cases where the issue has already been determined in a representative proceeding (class action) in the Federal Court of Australia where the claimant is bound by a ruling made in that class action by virtue of their failure to “opt out” of the proceeding. There are also special rules in dust disease cases litigated in the New South Wales Dust Diseases Tribunal.
4 Procedure

4.1 Is the trial by a judge or a jury?

Product liability litigation may be brought in either the Federal Court of Australia or the State Supreme Courts. Civil proceedings in Australia are generally heard by a judge sitting without a jury. However, there is provision in the various court rules for some matters to be heard by jury.

As a matter of practice, juries are usually not available in matters before the Federal Court. However, juries are not uncommon in the State of Victoria where more civil jury trials take place than anywhere else in the country. No voir dire takes place during the jury selection process.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Courts in several jurisdictions are able to appoint a “court expert” to enquire and report on a question of fact arising in a matter before the court or an “expert assistant” to assist the court on any issue of fact or opinion identified by the court (other than an issue involving a question of law) in the proceeding, should the need arise. In some of these jurisdictions, such as the Federal Court, the court expert’s report will only be binding on a party to the extent that that party agrees to be bound by it. In other courts, the report is deemed to have been admitted into evidence unless the court otherwise orders.

An expert is generally accepted to be a person who has specialised knowledge about matters relevant to the question based on that person’s training, study or experience. The role of court experts or expert assistants does not extend to sitting with the judge and assessing evidence presented by the parties.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class actions can only be commenced in the Federal Court of Australia and the Supreme Court of Victoria. An action can only be commenced in the Federal Court where it attracts federal jurisdiction, for example, if it involves a claim under the TPA.

The incidence of class actions has increased markedly since the provisions were introduced and many have involved products including weight loss drugs, heart pacemakers, aircraft fuel, gas, water, tobacco and a variety of food stuffs ranging from oysters to peanut butter. Australia is now the most likely jurisdiction outside North America where a corporation will face a class action.

If these threshold requirements are met, any of those persons may commence an action on behalf of the group. There is no certification process as occurs in the United States. The representative plaintiff must describe the group but need not identify, name, or specify the number of group members.

With limited exceptions, a person’s consent to be a group member is not required.

Once proceedings have been commenced, the court will fix a date by which a group member may opt out by written notice to the court, and will give directions regarding the procedure for notifying potential group members of the existence of the proceedings. Unless a person actively opts out of the proceedings, they will continue to be a part of the action and be bound by its outcome.

In order to protect absent group members, the action may not be settled or discontinued without the approval of the court. Similarly, the representative plaintiff may only withdraw from the proceedings or settle his or her individual claim with the leave of the court.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes. The TPA expressly provides for the institution of proceedings by the Australian Competition and Consumer Commission (“ACCC”) on behalf of those who have suffered or are likely to suffer loss as a result of contraventions of the TPA, including Parts V and VA. Under these provisions the ACCC requires the prior written consent of the persons on whose behalf the application is being made. Thus, the ACCC is not entitled to pursue a representative action on behalf of a general class of aggrieved persons but can act on behalf of those who have been identified and who have given their consent to the action.

At the time of writing, amendments have been foreshadowed which will substantially affect the matters set out above.

4.5 How long does it normally take to get to trial?

Time to trial depends on the particular jurisdiction and the nature of the claim. It may take anywhere from six months to several years for a matter to be heard and determined.

Proceedings in the Federal Court are usually heard faster than those in the state and territory supreme courts, due in part to the Federal Court’s case management system whereby each proceeding is allocated to a particular judge who manages the case and usually hears and determines it, and the supreme courts’ heavier case load.

There are provisions in all jurisdictions for expedited hearings in appropriate circumstances, including the ill health of a litigant.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

In some jurisdictions, the court may try preliminary issues whether of fact or law or mixed fact and law.
Historically, courts have been of the view that trials of preliminary issues should only be granted on special grounds such as whether the preliminary issue will substantially narrow the field of controversy, shorten the trial and/or result in a significant saving in time or money. Preliminary issues are usually heard and determined by a judge.

4.7 What appeal options are available?

In virtually all jurisdictions there is a right of appeal from the judgment of a trial judge. The procedure varies depending on the jurisdiction in which the original trial was conducted. Leave to appeal is usually necessary when the appeal is from an interlocutory judgment.

Appeals from decisions of the supreme court in any of the states or territories are heard by the Court of Appeal or Full Court of that same state or territory. Similarly, an appeal from a judge of the Federal Court of Australia is heard by the Full Court of the Federal Court.

Even though appeals generally turn on questions of law, it is not uncommon for parts of the evidence used at trial to be reviewed during the course of an appeal. As a consequence, the hearing of an appeal in a complex matter may continue over a number of days or even weeks.

A party dissatisfied with the decision of a state or territory Court of Appeal or the Full Federal Court may seek leave to appeal to the High Court of Australia, the country’s ultimate appellate court. Appeals to the High Court are essentially restricted to questions of law. The High Court will only grant leave to appeal if it is convinced that there is a significant question to be determined.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

See question 4.2. Where the court has appointed an expert in relation to a question arising in the proceedings, the rules provide that the court may limit the number of other experts whose evidence may be adduced on that question, or that a party must obtain leave to adduce such evidence.

Court experts are rarely appointed. However, as a matter of course, parties adduce evidence from appropriate experts.

The nature and extent of expert evidence is subject to the discretion of the court. In a number of jurisdictions, practice notes provide guidance on the number of experts that might be called by any party in a particular area of expertise.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

In Australia, depositions of the parties and witnesses are not taken before trial. However, the Australian legal system is more onerous in terms of the obligations imposed on parties to give discovery of documents (see question 4.10).

In some jurisdictions, most notably the Federal Court of Australia, pre-trial directions are made in the ordinary course that witness statements and expert reports be exchanged before hearing and that those statements and reports comprise the evidence in chief of those witnesses. The plaintiff is usually required to file and serve its evidence first, followed by the defendant, and then the plaintiff in reply.

It is also common for directions to be made requiring the parties to exchange objections to their opponent’s statements and reports before trial. Any objections that are not conceded or otherwise addressed are then argued, and ruled upon, before cross-examination of the witnesses at trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

A party is obliged to discover - that is to identify and allow the other parties to access - all documents in its possession, custody or power which are relevant to a matter in issue in the proceedings. Discovery occurs at the pre-trial stage so that all documents relevant to the case are disclosed by the parties before the hearing commences.

“Documents” include paper records, photographs, videos, tape recordings and computer records. Generally, any record of information will be a document.

The obligation to give discovery extends to documents which are no longer in the party’s possession, custody or power, but which were previously. This may occur where a relevant document has been lost, destroyed or provided to someone else. In such a case, a description of the document must be provided to the other parties.

Documents that are relevant to a case include those documents on which the party relies, documents that adversely affect the party’s own case, documents that adversely affect another party’s case, documents that support another party’s case, and documents that the party is required by a relevant practice direction to disclose.

All discovered documents must be listed, and the parties’ lists sworn and exchanged. Parties are entitled to inspect each others’ documents and if desired, copy them, save for those in relation to which a claim for privilege has been advanced.

Discovery can also be used to assist a party to identify prospective defendants, or to gain information from third parties where any party to a proceeding reasonably believes that the party holds a document which relates to any question in the proceeding.

The obligation to discover all relevant documents continues throughout the proceedings. This means that any document created or found after providing initial discovery must also be discovered.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.
5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Contract and Tort

There are considerable variations between the limitation periods applicable to common law proceedings in the various Australian states and territories, resulting from a profusion of specialist legislation and court decisions, although the Tort Reform Process has resulted in more uniformity in relation to the limitation period applicable to personal injury actions.

In general terms, limitation periods are routinely defined by reference to the nature of the cause of action, including whether the claimant alleges fault-based or strict liability. In most jurisdictions (as a result of the Tort Reform Process) the limitation period applicable to claims for personal injury is either:
- the earlier of three years from the date the cause of action is discoverable by the plaintiff (“the date of discoverability”) or twelve years from the date of the alleged act or omission (the “long-stop period”); or
- three years from the date the cause of action accrued.

Limitation periods - including those applicable to personal injury claims - are usually suspended while a claimant is suffering from a legal incapacity, which encompasses the period prior to a claimant turning 18, or during which a claimant suffers from a mental or physical disability which impedes them from properly managing their affairs.

Trade Practices Act

Actions brought under Part V Division 2A and Part VA of the TPA must generally be commenced within three years after the time the person becomes aware, or ought reasonably to have become aware, of particular circumstances giving rise to the action. There is also a ten year period of repose, which requires actions to be commenced within ten years of the supply by the manufacturer of the goods.

Where a claim is brought under these provisions of the TPA for personal injury, the applicable limitation period (resulting from the Tort Reform Process) is the later of three years after the “date of discoverability” or the twelve year “long-stop period” as defined above.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Most Australian jurisdictions provide for the postponement of commencement of the limitation period where the plaintiff’s right of action or the identity of the person against whom a cause of action lies is fraudulently concealed. The limitation period is deemed to have commenced from the time the fraud was discovered or the plaintiff exercising reasonable diligence would have so discovered.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Common Law

The following damages are available for claims of bodily injury:
- general damages, including pain and suffering, loss of amenities and loss of expectation of life; and
- special damages, including loss of wages (both past and future), medical and hospital expenses and the like.

The Tort Reform Process has resulted in caps, thresholds and other limitations being placed on the amount of such damages that can be recovered.

Damages are assessed on a once and for all basis.

Damages are also recoverable for mental damage provided it can be established that the claimant is suffering from a diagnosed psychiatric condition. In addition, common law damages are available for damage to the product itself, or other consequential damage to property. One can recover damages for “pure economic loss” but the nature and extent of such damages is extremely complex.

Part VA of the Trade Practices Act

Under Part VA of the TPA, damages are recoverable for losses suffered as a result of personal injuries, including medical expenses (subject to similar caps, thresholds and other limitations imposed on common law damages following the Tort Reform Process). A person other than an injured party may also claim compensation where that person suffers loss as a result of the other person’s injury or death, for losses relating to personal, domestic or household goods other than the defective goods, and losses relating to private land, buildings and fixtures.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

As a general rule, damages for the costs of medical monitoring in the absence of any established injury or loss are not recoverable.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Exemplary, punitive or aggravated damages can be awarded by the courts, although not in relation to claims brought under the TPA and, in some jurisdictions (as a result of the Tort Reform Process) not in negligence actions seeking damages for personal injury.

Even where exemplary damages are available in negligence or contract, such awards are extremely unusual. Where such an award is made it will be significantly lower than similar amounts that have been awarded in the United States.
6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Generally no. However, the Tort Reform Process has resulted in caps, thresholds and other limitations being placed on the amount of damages a personal injury claimant can recover.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The unsuccessful party usually pays the costs of the successful party. These costs include, not only court filing fees, copying charges and other out-of-pocket expenses, but also the lawyer’s professional fees. In this context, a reference to costs is not a reference to the total or actual costs incurred by the successful party. Recoverable costs are generally calculated by reference to a court scale, which invariably limits the amounts a successful party can claim for disbursements and services performed by their lawyers. The Tort Reform Process in some jurisdictions has resulted in further limitations being imposed on the legal costs recoverable in small personal injury claims (although there are exceptions including where the lawyer and client have entered into a costs agreement that provides otherwise).

The common law rule has been significantly modified in the case of representative or class actions. Statutory provisions restrict a costs order being made against class members other than those who actually commenced the proceedings. Where the representative action is successful, a costs order may be made in favour of the class members who commenced the representative proceedings in an amount determined by the court.

7.2 Is public funding e.g. legal aid, available?

Yes, public funding is available.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid services rigorously apply means and merits tests to determine eligibility for aid. Each legal aid service also has guidelines identifying the types of claims where funding will be granted. As a general rule, very limited funding is available to assist claimants to bring civil actions, including product liability claims. Funding is available at the federal level for, inter alia, consumer protection matters, arising under a Federal statute such as the TPA.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fee arrangements of any type were previously illegal. Recently, rules prohibiting lawyers from entering into contingency fee arrangements were relaxed and a variety of arrangements are now sanctioned. These new arrangements allow lawyer and client to enter into an agreement which provides for the normal fee, or a fee calculated by reference to some pre-determined criteria such as the amount of time expended by a lawyer, to be increased by a pre-agreed percentage. The relevant rules generally impose a cap on the percentage by which such fees can be increased. Some jurisdictions allow lawyers to enter into an agreement to be paid an “uplift fee” where a fee is only payable if the case is successful. All jurisdictions continue to prohibit contingency fee arrangements where the lawyer’s fee is calculated by reference to a percentage of the client’s verdict.

Acknowledgement

The authors would like to acknowledge the assistance of their associate, Christina Harris, in preparing this chapter.
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Together with fellow Clayton Utz partner, Stuart Clark, he has been involved in most of the major product liability and class actions in Australia, including the successful defence of the Copper 7 IUD litigation, Sydney Water contamination and Fen-Phen class actions, taking a leading role in the presentation of expert medical and scientific evidence.

Colin is a member of the Australian National Product Liability Association, the Defense Research Institute Inc. and former Vice-Chair of Committee S (Product Liability) of the International Bar Association. He is the author of the chapters “Negligence” and “Product Recall” in the Product Liability Law and Practice service published by Legal Books.

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Stuart represents manufacturers and importers who are active in a broad cross section of industries including drugs and medical devices, motor vehicles and consumer products. He has particular expertise and experience in the defence of class actions and claims against drug and medical device manufacturers. He represents a range of clients based in Australia, the United States and Europe.

Over the past decade, Stuart has been intimately involved in the development of Australia’s product liability laws and the majority of leading Australian cases in this area. He provides specialist advice in all facets of product liability and his expertise in the defence of class action/mass tort litigation, involving complex scientific and medical issues, is internationally recognised.

Stuart is a member of the International Association of Defense Counsel (IADC), the Defense Research Institute (DRI) and the Australian National Product Liability Association. He regularly speaks and publishes, both in Australia and overseas, in relation to class actions and the defence of product liability claims.

Clayton Utz is one of Australia’s most successful national law firms. Our lawyers are results driven, commercially savvy and are often recognised as bona fide leaders in their respective practice areas. Our clients include many of Australia’s top 100 companies, as well as Federal and State government departments and agencies.

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Established in 1833, the firm has 204 partners and over 1700 other legal and support employees. Our offices are in Sydney, Melbourne, Brisbane, Perth, Canberra and Darwin.
Austria

Wolf Theiss Attorneys

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

According to the general rules of Austrian civil law, a damage claim may be based on either of two main “pillars” - tort liability or contractual liability. Contractual liability holds several privileges for the injured party. However, normally no contract exists between the producer and the (final) purchaser, if the latter acquired the product from a retailer. Therefore, the producer cannot - in principle - be held liable for breach of contract and the retailer has generally not breached any of its contractual obligations. Therefore, general civil liability rules have proven unsatisfactory for the compensation of damages caused by defective products. This situation led to the enactment of the Product Liability Act (Produkthaftungsgesetz; PHG), which improved the situation significantly.

Already prior to the enactment of the PHG, Austrian legal doctrine had developed a means to remedy the insufficient legal protection of the injured party resulting from this situation. It is assumed that the contract between the producer and the first purchaser (e.g. the wholesaler) has protective effects for third parties. Consequently, most of the privileges of contractual liability apply for the injured party. This legal concept is still valid. However, it does not always provide the necessary protection for the injured party.

Although the PHG constitutes a specific form of tort liability, its numerous specific rules suggest it should be considered separately from the general rules.

A. General rules

Under Austrian law, liability for damages generally requires the following prerequisites:

- existence of an injury;
- causal link between the conduct in question and the injury;
- the conduct causing the injury was unlawful; and
- the conduct causing the injury was negligent.

If the unlawful conduct constitutes a breach of a contract (or similar behaviour, e.g. liability for culpa in contrahendo), numerous specific rules outlined below apply. Therefore, Austrian law generally distinguishes between contractual liability and tort liability.

a) Rules for contractual liability

This form of liability entails several privileges in favour of the injured party, for instance:

- the injuring party must compensate for purely financial damages and not only damages incurred by interference in absolutely protected rights (corporal integrity, property, etc.);
- the damages subject to compensation include loss of profit if an entrepreneur is party to the contract;
- the party performing a contractual obligation is held responsible for the negligent behaviour of any assistant as if such party acted itself (sec. 1313a Austrian Civil Law Act [Allgemeines Bürgerliches Gesetzbuch; ABGB]); and
- the burden of proof regarding negligence is shifted to the party causing the injury (see below question 2.1).

b) Tort liability

If there is no contractual relationship between the injured party and the party causing the injury, it will normally be difficult to establish the prerequisites of a damage claim. The burden of proof regarding negligence in a tort claim lies with the injured party, who regularly has no insight in the production process and the organisation of the producer. In addition, the producer cannot be held liable for its assistants unless they are incapable or known to be dangerous (sec. 1315 ABGB). The retailer, however, who could theoretically be held liable, under the rules of contractual liability, will typically neither have breached his contract nor acted with negligence. Therefore, according to our experience, a product liability claim can hardly be established under these rules.

B. Liability under the PHG

The abovementioned deficiencies required specific rules improving the situation for persons injured by defective products. Although Austria was not yet an EC Member State at the time, it largely followed the provisions of the EC directive on product liability and enacted the PHG on 21 January 1988 (Federal Gazette (BGBI) 1988/99). The PHG provides for liability of producers and importers of a defective product that leads to the death or injury of a person or damages to property other than the product itself.
1.2 Does the state operate any schemes of compensation for particular products?

No. However, sec. 79a et seq. of the Law on Genetic Engineering (Gentechnikgesetz; GTK) provides for the specific liability of the operator (i.e. a natural or legal person operating a genetic engineering plant, or working on, or releasing genetically modified organisms), if a person is injured, killed or property is damaged during works on or following the exposure to genetically modified organisms.

1.3 Who bears responsibility for the fault/defect? The producer, the importer, the distributor, the “retail” supplier or all of these?

According to the general rules of civil law, the negligent person bears responsibility (see above question 1.1). Sec. 1 para. 1 PHG expressly defines the responsible persons for the purposes of the PHG as being:

- the entrepreneur that produced the product and put it into circulation; and
- the entrepreneur who imported it into the European Economic Area for sale (importer).

According to sec. 3 PHG, the producer means the manufacturer of:

- a finished product;
- any raw material;
- a component part; or
- any person who, by putting his name, trademark or other distinguishing feature on the product presents himself as its producer (quasi-producer).

Given that nowadays numerous products are made by more than one manufacturer, the injured person may have several producers (next to the importer) who are liable for the damage (see, however, the defence of component producers below in question 3.1).

The producer and the importer are jointly and severally liable for the damage (sec. 10 PHG). Furthermore, sec. 1 para. 2 PHG provides that if the producer or the importer cannot be determined, every entrepreneur who put the product into circulation becomes liable, unless it informs the injured person, within a reasonable time (very roughly, a time span of one to two weeks is considered as reasonable), of the identity of the producer, the importer, or the person who supplied him with the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

On 1 April 2005, the Law on the Safety of Products 2004 (Produktsicherheitsgesetz; PSG 2004) was enacted implementing EC-directive 2001/95/EG.

Pursuant to sec. 6 para. 2 PSG 2004, producers and importers of products have to take adequate measures in order to identify dangers and to take measures to avoid such dangers. If necessary they have to withdraw the products concerned from the market and to recall them from the consumers (sec. 6 para. 4 PSG 2004).

If the producers or importers do not take the necessary safety measures, the Federal Ministry is entitled to take regulatory measures addressed to the importers or producers or to any other person. If necessary, the ministry may take measures to withdraw products from the market or to recall them from the consumers (sec. 11 paras. 1-2 PSG 2004).

Breach of such regulatory measures are sanctioned by administrative fines. Individuals are not entitled to bring a claim for failure to recall a specific product. However, there are good arguments that sec. 6 and especially sec. 11 PSG 2004 are provisions aimed at protecting against dangerous products. The breach of such provisions may thus lead to civil liability if an injury occurs resulting from a dangerous product that had not been withdrawn from the market or recalled on time.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

A. General rule

In principle it is up to the injured party to establish all elements of a damage claim which are outlined below:

- injury (including the amount of damages);
- causation, i.e. that a certain injury is attributable to a product;
- unlawfulness; and
- negligence.

However, in a claim for breach of contract, the injured party does not bear the burden of proof regarding negligence. Pursuant to sec. 1298 ABGB, the burden is shifted to the party having unlawfully caused the damage. In a product liability case, it would therefore be up to the producer to prove that he did not act negligently (assuming that the contract between the producer and the first purchaser has protective effects for the injured third party, see above).

B. PHG

Under the PHG, the burden of proof is significantly easier to satisfy for the injured party. Such party needs to prove:

- an injury (including the amount of damages);
- a defect within the meaning of sec. 5 para. 1 PHG; and
- causation, i.e. that the injury is attributable to the defect of the product.

Unlawfulness and negligence (see sec. 8 PHG) are no prerequisites within the scope of the PHG.

A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- the presentation of the product;
- the use to which it could reasonably be expected that the product would be put; and
- the time when the product was put into circulation.

However, a product is not considered defective for the sole reason that a better product is subsequently put into circulation.

For two specific issues, the sec. 7 PHG provides for a reversal of the burden of proof:

- A producer or an importer bears the burden of proof if
he alleges that he has not put the respective product into circulation.

if a party, against whom a claim is made, asserts that the product was not yet defective when it put the product into circulation, it has to prove this as “probable”. Given that it is impossible to prove that a product was definitely not defective at a certain time, the law requires a lower standard of proof.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In principle, the claimant needs to prove that the damage would not have occurred if the product had not had the defect causing the damage. However, if it is established that a specific damage is normally attributable to a product (e.g. a certain medication) jurisprudence accepts a prima facie showing. Causation could then be established if the injured party used the product under certain circumstances and, subsequently, the typical injury occurred. However, the defendant may rebut the prima facie showing by showing other equally probable causes for the injury.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Sec. 1 PHG enumerates several alternatively responsible persons in order to provide the claimant a stronger position if the producer cannot be determined. A market-share liability is unknown to the PHG.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the producer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the producer to the ultimate consumer to make available appropriate product information?

A product can also be defective if the user is not or insufficiently instructed in how to use the product. Such instructions have to enable potential users to evaluate the positive and negative effects of a product. Issues that can be presumed to be known to the potential user do not have to be included into the instructions. The higher the risks involved with the use of a product are, the stricter the requirements to provide adequate instructions are.

The extent of information that has to be provided depends on the presumption of knowledge of the potential users (sec. 5 para. 1 PHG). It therefore makes a difference whether a certain product will be used by any consumer or only by trained personnel. For example, the instructions for a vaccine that must be administered by doctors need to be adapted to their information requirements.

The EC Council Resolution (98/C 411/01) of 17 December 1998 (O.J. 1998 C 411/1) provides voluntary guidelines on appropriate contents of instructions for technical consumer goods.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer or importer may prove that (sec. 8 PHG):

- the defect is due to compliance of the product with a legal provision or an administrative order;
- the state of scientific and technical knowledge at the time he put the product into circulation was not such as to enable the discovery of the existence of the defect; or
- the producer only manufactured a component and the defect is attributable to the design of the product, in which the component has been fitted, or to the instructions given by the manufacturer of the product.

The burden of proof regarding these defences lies with the producer or importer.

The liability of the producer is reduced if the damage is partially caused by the fault of the injured person (sec. 11 PHG, sec. 1304 ABGB).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the producer to prove that it was not?

See question 3.1.

3.3 Is it a defence for the producer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

See question 3.1.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Since a definitive court decision is only binding between the parties involved, Austrian procedural law does not prevent that the same factual issues regarding the defects of a certain
product are made subject to court proceedings again. A re-litigation between the same parties is possible if new factual findings are found (which were unknown during the prior proceedings).

4 Procedure

4.1 Is the trial by a judge or a jury?

Austrian law provides for a jury only in criminal law cases. Civil law cases are decided by single judges or judicial panel.

Claims up to €10,000 are decided by a single judge at the respective district court (Bezirksgericht). Claims exceeding this amount are decided by a single judge before the regional courts (Landesgerichte), in Vienna the Commercial Court (Handelsgericht Wien). Also damage claims exceeding €50,000 are usually decided by a single judge. However, in the latter case, at the beginning of the proceedings, the parties have the right to ask for a panel consisting of three judges. This right is rarely exercised.

Second instance proceedings (on appeal) are tried by panels consisting of three judges. The Austrian Supreme Court (OGH) - deciding in third instance - is regularly composed of five, or in exceptional cases eleven, judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court has the power to appoint a sworn objective expert (see below question 4.8).

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Austrian civil procedure does not have a specific group or class action procedure, yet. However, we note strong efforts to establish a class action procedure in the future. At present, Austrian civil procedure foresees that several claimants may jointly sue one defendant provided that (sec. 11.2 Code on Civil Procedure; Zivilprozessordnung, ZPO):
- their claims are similar and substantially based on similar factual elements; and
- the court is competent for the litigation with respect to every single claimant.

The legal effects of such a connection of multiple claims in a single court procedure are limited. Each claim of the involved claimants has to be considered independently and procedural steps taken by one claimant do not - subject to certain exceptions - affect the position of the others. Every claimant can therefore withdraw or settle his claim independently from the others.

If several persons suffered damage from one defective product type, their claim would be based on the same factual elements and a common claim could be a cost-effective means to obtain redress from the producer (importer).

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

The PHG does not provide for such types of actions in cases of product liability. However, several injured consumers may assign their claims to a consumer protection organisation for collection, provided that the court is competent for all claims (sec. 227 ZPO).

4.5 How long does it normally take to get to trial?

The claimant may file a written claim without taking any prior steps. The defendant has to file his reply within four weeks from receipt (otherwise the claimant may request a judgment in default). Afterwards, the court schedules the first hearing, which has the purpose of assessing the opportunities for a settlement and, failing this, to either commence or prepare the collection of evidence proposed by the parties. The first hearing takes place approximately three months after filing of the claim. The length of the further proceedings depends on the amount of evidence that needs to be taken up. Average court proceedings in such matters last - in first instance - approximately one to two years.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

No. However, Austrian civil procedure provides that an affirmative action for a right may be brought, if the claimant has a legal interest (sec. 228 ZPO). The provision is practically important in damage claims, where the claimant knows that he suffered damage, but cannot yet specify the amount. In order to avoid his claim being time-barred (see below question 5.2), he may need to file such an action. In a subsequent damage claim the court is bound by the affirmative judgment.

Furthermore, sec. 384 ZPO provides that even before the commencement of court proceedings, a request to secure specific evidence may be made. Such a request makes sense if the respective piece of evidence may no longer be at its disposal when the court proceedings take place, or if it is necessary that a piece of evidence be investigated in its present condition (e.g. foodstuff). In subsequent proceedings, the court will take into consideration the evidence obtained.

4.7 What appeal options are available?

Against judgments of the district court (Bezirksgericht), an appeal can be made to the competent regional court (Landesgericht). Against judgments of the regional court (or, in Vienna, the Commercial Court; Handelsgericht Wien), appeal can be made to the upper regional court (Oberlandesgericht). The third instance, the revision to the Supreme Court (Revision), is only admissible if the decision of the case depends on the resolution of a legal question of particular importance. Even in such cases, no revision may be filed if the amount in dispute does not exceed €4,000. If
4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The courts may appoint experts, if the decision depends on the assessment of facts that require specific knowledge. Both parties have the right to ask for such an appointment. In practice, the results of court appointed experts largely determine the outcome of court proceedings. Normally, the expert is chosen among a list of admitted court experts depending on the required field of expertise. The parties are free to present private expert opinions in court proceedings as documentary evidence. In general they enjoy a much lower authority than opinions given by the appointed court expert.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

No, expert witnesses are not required to present themselves for pre-trial depositions.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

There are no such obligations.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Time limits do not depend on the age or condition of the claimant. Neither does the court have the discretion to disapply time limits. However, the court will only raise the issue upon objection of the defendant. As to the applicable time limits, a distinction needs to be made between damage claims according to the general rules of civil law and claims under the PHG.

A. General damage claims

According to sec. 1489 ABGB, a damage claim becomes time barred after three years from the time when the injured person learns of (i) the injury and (ii) the person responsible for the injury. In any event, the claim becomes definitively time barred thirty years after the event causing the injury (see also below question 5.3).

B. Claims under the PHG

The above-mentioned three year prescription term pursuant to sec. 1489 ABGB also applies to claims under the PHG. However, the absolute prescription period for such claims is reduced to ten years (sec. 13 PHG).

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Sec. 1489 ABGB provides that a time limit of thirty years applies in cases where the damage was caused in the course of one or several criminal offences that are (i) committed intentionally and (ii) subject to punishment of more than one year imprisonment. However, this time limit does not apply within the scope of the PHG.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under general civil law rules, all damages to property and corporeal injuries are, in principle, recoverable. In the case of breach of a contractual obligation, loss of profit can also be claimed, provided that one of the parties is an entrepreneur, or the damaging party acted with gross negligence or intent. Under the PHG, only corporeal injury and damage to property other than the product itself may be recovered (sec. 1 PHG). Therefore pure financial loss cannot be recovered under the PHG. Furthermore, sec. 2 PHG provides that damages are only covered insofar as they exceed €500. Finally, the PHG does not apply if the damage is suffered by an entrepreneur who substantially used the defective product in his own business.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No, but in certain cases such costs may be recoverable if they served the purpose to keep the damages as low as possible.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

The notion of punitive damages is unknown to Austrian law.

6.4 Is there a maximum limit on the damages recoverable from one producer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit in Austria.
7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The costs of court proceedings in Austria basically consist of the court fees, the costs of the parties’ attorneys and cash expenditures. Pursuant to Austrian civil procedure the losing party has to bear its own costs and pay the costs incurred by the winning party (sec. 41 ZPO). If the parties win and lose partially, the costs are shared proportionally. The level of costs subject to reimbursement is determined according to a legal tariff system. Any costs in excess of the amount provided under the tariff system (e.g. one party’s attorney charges higher rates) cannot be reimbursed.

7.2 Is public funding e.g. legal aid, available?

Yes, Austrian civil procedure provides for legal aid (Verfahrenshilfe) under certain conditions.

7.3 If so, are there any restrictions on the availability of public funding?

Austrian Law prohibits lawyers agreeing on contingency fees.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Austrian Law prohibits lawyers agreeing on contingency fees.

Bettina Knötzl has been a partner of Wolf Theiss since 1999. Before joining Wolf Theiss in 1993 she worked as an assistant at the Vienna University institute for civil law and later as project manager with Bank Austria for approximately three years. Ms. Knötzl has been a mediator since 2000 (officially registered in accordance with the guidelines of the Austrian Mediator Law since 2004). At Wolf Theiss, she has advised and represented in court national as well as international clients in civil liability, commercial and corporate law disputes. She also acts as advisor and/or mediator in the area of dispute resolution.

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WOLF THEISS

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Wolf Theiss’ scope of activity is by no means confined to its offices in Albania, Austria, Croatia, the Czech Republic, Serbia and Montenegro, Slovakia, and Slovenia. Currently, 120 lawyers provide assistance to our clients in connection with their businesses throughout all of Central and Eastern Europe, particularly in the countries in which we have offices, as well as in Bosnia, Bulgaria, Hungary, Poland, Romania, and Macedonia. In the course of handling activity carried out in these countries, Wolf Theiss has established a network of contacts with local law firms and other service providers such as auditors, brokers, financial institutions, and business development organisations.

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Chapter 12

Belgium

Lovells

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

The Belgian system of product liability includes the law of contract, traditional extra-contractual liability under Articles 1382 et seq. of the Civil Code (‘C.C.’) and the Act of 25 February 1991 on Liability for Defective Products (Product Liability Act, or ‘PLA’).

Contractual liability plays a significant role in the Belgian system of product liability and in particular the latent defects warranty (garantie des vices cachés) under the sale of goods regime. This warranty covers hidden defects which ‘make the goods unfit for their purpose or reduce their usefulness’ (Article 1641 C.C.). Hidden defects entitle the buyer to claim all heads of damages, provided the defect existed at the time of sale and the buyer knew of it (Articles 1645 and 1646 C.C.). A commercial seller is presumed to know of the defect unless he proves otherwise (see question 2.3 below).

Under the PLA, a product is considered to be defective where it fails to offer the safety standards which could be reasonably expected, taking into account elements such as the appearance of the product and its normal or reasonable use (Article 5).

What renders the latent defects warranty particularly effective in product liability cases is the action directe, a type of third party action devised through case law. This action entitles a buyer despite the lack of a contractual relationship to sue any seller higher up in the chain of contracts (including the producer). However, someone who is not a buyer at any point in the chain of sales has, unlike the French obligation de sécurité, no contractual right against the producer or commercial sellers.

The seller is also under a duty to provide the buyer with correct and useful information as to the characteristics of the product and potential dangers associated with it. The Act of 14 July 1991 on commercial practices and the information and protection of consumers (Fair Commercial Practice Act 1991) defines various duties in this respect. Failure to provide the consumer with correct information on the product (especially with respect to its characteristics) can render the product defective and give the consumer a claim for latent defects (Article 1641 C.C.). Incorrect information relating purely to the safety of products will usually not constitute a defect, but may entitle the seller to a pre-contractual claim for negligent or fraudulent misrepresentation (culpa in contrahendo). The Cour de Cassation has made it clear however that reckless use of a defective product does not preclude liability where the manufacturer could not have been unaware of the risks arising from the product, notwithstanding any written warning given to users.

A claimant can also, at least with respect to personal injury and damage to property other than the sold good itself, base his claim on tort, even where he has a contractual relation with the defendant (principle of cumul limité).

Article 1384 C.C. stipulates strict liability for things under a person’s custody (garde). Belgian law construes the concept of fait de la chose as requiring that the item which caused the injury has a defect. Something is defective if it shows atypical characteristics capable of causing injury. However, Belgian case law has (unlike that in France) not developed this concept for the liability of producers further. The approach taken by the Belgian courts is that the producer gives up (all) custody over a product by putting it into circulation. Article 1384 C.C. is therefore not particularly relevant to the liability of producers and suppliers.

Fault based liability under Articles 1382 and 1383 C.C. requires the breach of an extra-contractual duty of care. Producers and suppliers are under a duty to exercise the care of a prudent and diligent professional of the same occupation. Statutes and regulations help define the duty of care within their occupational ambit, and breach of these laws will generally amount to fault.

The most important example of statutory law in the field of product liability is the Act of 9 February 1994 on consumer safety (Consumer Safety Act), which implements Directive 92/59/EEC on general product safety. This Act obliges producers to place only safe products on the market, to provide consumers with all relevant information and to take the appropriate measures against risks that emerge post-marketing. It also requires distributors not to supply products which they know or should have presumed to be dangerous and to cooperate in the necessary post-marketing measures. Note in this context that the revised Directive 2001/95/EC on general product safety further enhances the duties of producers and suppliers (for detailed information on the new directive see Lovells, Product Safety in the European Union, A Practical Guide to the General Product Safety Directive, 2002). This new directive has been
transposed into Belgian law by the Act of 18 December 2002 which amends the Consumer Safety Act (renamed as the ‘Act on products and services safety’ (Products and Services Safety Act).)

Other legislation regarding products and services safety includes the Act of 24 January 1977 on consumer health protection (amended several times since), the Act of 5 July 1994 on blood and blood by-products and the Royal Decree of 6 June 1960 on pharmaceutical products (amended several times since).

The PLA, which entered into force on 1 April 1991, implements Directive 85/374/EEC on liability for defective products (the ‘Directive’) and is, according to Article 13 PLA, in any case available alongside contract and tort liability (as to the possibility of making the Directive the only legal basis in product liability claims, see Lovells, Product Liability in the European Union: A Report for the European Commission, 2003, pp. 44). The PLA provides for strict (objective) liability, but has a slightly narrower scope than the traditional regimes of contract and tort. The PLA sets stricter limits on recoverable damages as well as on the group of liable persons, and it also does not apply to post-marketing failures.

1.2 Does the state operate any schemes of compensation for particular products?

The Walloon Decree of 27 June 1996 and a Walloon Government Order of 5 November 1998 set up a fund for damage sustained in the Walloon region caused by waste.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the PLA, the producer is primarily responsible for a defect. ‘Producer’ means the manufacturer of a finished product or of a component of the ‘finished product’, the producer of raw material or the ‘own-brander’. Liability of the ‘own-brander’ does not preclude liability of the ‘actual’ producer (although this appears to be controversial). ‘Producer’ also includes any person who imports the product into the EC/EEA. Any other supplier may be liable only where the producer cannot be identified. A supplier can exonerate himself by informing the injured person, within a reasonable time, of the identity of the producer or of any other person who supplied him (provided this person is located in the EC/EEA). The same applies if the importer cannot be identified, even if the identity of the producer is known.

The responsible persons in contract are the seller and any person higher up in the chain of supply, including the producer (action directe, see answer to question 1.1 above). The guardian of a particular item is responsible under Article 1384 C.C., and, under the fault based system of Articles 1382 and 1383 C.C., the person who is under the duty of care in question is responsible. This means that suppliers may be liable even where the producer can be identified, as their duties are separate and also, in most cases, of a different nature.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Post-marketing duties concerning the safety of products are primarily extra-contractual. The Products and Services Safety Act helps to define post-marketing duties. This Act obliges manufacturers to monitor products that are already on the market and to take appropriate steps in the event that defects become apparent. Appropriate steps in such a case range from informing and warning consumers, suppliers and public authorities, to recalling the product in question as the ultimate step. Failure to comply with the duties set out in the Products and Services Safety Act will usually amount to fault and give the injured person a claim under Articles 1382 and 1383 C.C. (See answer to question 1.1 above).

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The burden of proving the existence of a defect is - under all regimes - on the claimant. In contract and under Article 1384 C.C., the ‘defect’ can be inferred from the uncharacteristic behaviour of the product, provided that any other cause (particularly mishandling by the victim) is ruled out.

In a similar vein, courts in Belgium tend to let it suffice that the victim, in order to prove defect under the PLA, demonstrates simply that the product failed, rather than requiring that the victim establishes the exact (technical) cause of the product’s failure. However, this should not be taken as a general rule. Consumer expectation depends on the nature and presentation of the product and on how it is handled (Article 5 PLA). Accordingly, it seems more appropriate to relieve the claimant from showing the cause of the failure only where the (proven) events themselves suggest that the product was unsafe (cf. S. Lenze, Proof of Defect, Lovells, European Product Liability Review, December 2002, pp. 40).

Liability under Articles 1382 and 1383 C.C. generally requires proof of fault. Breach of statutory or regulatory duty, however, is usually enough to prove fault. The courts also tend to relieve the claimant from the burden of proving fault where he can establish that the product was defective in its design or manufacture. In all other cases, it is generally for the claimant to show that the defendant did not exercise the care of a prudent and diligent professional.

It may also be noted that courts in Belgium have adopted the doctrine of ‘loss of opportunity’ (perte d’une chance), according to which the victim can claim for the loss of an opportunity that would have arisen had the defendant acted properly. This doctrine has been used in various fields, such as in medical negligence where the loss of opportunity to avoid injury can be considered. However, there seems to be no reason why it should not be applied to certain cases of product liability, as, for instance, in the case of an ineffective drug or a failure to warn.
2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The claimant must prove a causal relationship between the defect (or - where necessary - fault) and the damage: it must be shown that, had the product not been defective, there would have been no damage. As is the case with the defect, it is possible for circumstantial evidence to suffice. The Cour de Cassation seems to consider that fault only has a causal relationship with the damage if it constitutes a condition without which the damage would not have occurred in the way that it did in concreto. Conversely, if, without this fault, the damage would in any event have occurred as it did in concreto, there is no causal link. It is the theory of equivalent conditions (l’équivalence de conditions). However, the judges of the substance (juges du fond) often apply the theory of sufficient causation (causalité adéquate), under the guise of this theory. The theory of sufficient causation tends only to retain as causes of damage events which, in the natural order of things or according to general experience, must have caused it.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Cases in which the actual manufacturer of the (defective) product cannot be identified remain a source of legal uncertainty. However, it is clear that where several people as a group created a risk, which then manifested itself in an injury, all members of that group are jointly and severely liable. The victim may bring an action against any producer member of the group for the total amount of damages. The defendant will then be able to recover the difference from the other producers. Each individual member of the group can exonerate himself by proving that it was not he who actually caused the damage. One must doubt, however, whether this approach is capable of dealing with modern mass torts. Producers usually have no more in common than the manufacturing of similar products, which is hardly enough to render them a group. And even if it does, the risk to consumers does not arise from the availability of choice between different products, but from using them. The minimum requirement must therefore be that the claimant shows that he has used the products of the defendant.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure to inform can make a product defective and give rise to liability. Indeed, according to jurisprudence the producer-seller who knows or should have known that the products which he is producing contain hidden defects is required to inform the purchaser of these defects. However, if, before the sale, the producer-seller has warned the buyer that there is a defect in the product, the defect will be likened to an apparent defect, of which the buyer will therefore be aware. The Cour de Cassation does not require the seller’s declaration to be express and specific. Besides, Belgian doctrine and case law impose on the seller an obligation to give information as to the risks and dangers of the product for sale, both when the contract is being formed and performed. This duty to inform during the performance of the contract is the application of the principle of performance of agreements in good faith provided for in article 1134 of the Civil Code.

The following decisions concern the obligation to inform which, indirectly, lies with the producer.

In its judgment rendered on 14 November 1997, the Civil Court of Namur seemed to consider that the defect in a product - a weighing and dividing machine - can not be inferred from the failure to issue an instruction leaflet. In the case in question, a doubt nonetheless subsisted over the issue of whether an instruction leaflet had been delivered with the machine. In any event, the judge considered that the claimant could not put this argument forward since he had used the machine for several months and therefore knew how it worked (Civ. Namur, 14 novembre 1997, J.L.M.B., 1998, p. 664).

The Civil Court of Brussels had to give a ruling in a case where a person had hurt his hand whilst trying to change the height of a basket ball net. In the opinion of the court, "the lack of any comprehensible warning anywhere on the box, an instruction leaflet or advertising and the failure to supply an accessory, may be commonplace but is nevertheless indispensable” and may have been the cause of the defect in the product. In this case, the instruction leaflet drafted in English did not state that a special pole was needed to carry out the manoeuvre in question. On the other hand, the court stated that the failure to supply an instruction leaflet in French and/or in Dutch did not ipso facto bring about the producer’s liability (Civ Bruxelles, 23 January 2001, unpublished (RG 97/10865/A).

As regards liability of intermediaries, it should be noted that the manufacturer of a component part is not, in principle,
liable for a defect in the product in which the component part was incorporated, when this defect is attributable to the design of the finished product or the instructions given by the producer of the product. It should however be noted that the seller of a component could be forced to guarantee the latent defects affecting the assembled product if this component was unsuitable for the use to which, to the seller’s knowledge, the buyer (the manufacturer of the assembled product) was putting it.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer or supplier can, according to the Cour de Cassation, defend himself against a claim for latent defects (see question 1.1 above) only by showing that the defect was “totally undetectable”. The court, however, hesitates to define exactly what it means by that. It seems appropriate, though, to apply the standard of a prudent and diligent professional rather than the mere objective criteria of the development risks defence available under the PLA.

Similarly, the producer/supplier can, under Articles 1382 and 1383 C.C., exonerate himself by showing that he applied the care of a reasonable professional, although the defence does not relate only to the discoverability, but also to the avoidability of the defect in question. There is usually no defence with respect to fault, however, where the producer/supplier has breached a statutory duty (for example one arising under the Products and Services Safety Act).

Liability under the PLA is independent of fault and contains only a specified list of defences (Article 8). The producer (supplier) is therefore not liable if he proves:

- that he did not put the product into circulation;
- that it is likely that the product did not have the defect which caused the damage at the time when the producer put it into circulation or that this defect came into being afterwards;
- that the product was manufactured neither for sale nor for any other form of distribution for commercial purposes nor manufactured or distributed in the course of business;
- that the defect is due to compliance of the product with mandatory regulations issued by public authorities;
- that the state of scientific knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered; or
- in the case of the manufacturer of a component or a producer of raw material, that the defect is attributable to the design of the product in which the component or the raw material has been fitted or to the instructions given by the manufacturer of the product.

Fault on behalf of the claimant (contributory negligence) is a defence under all regimes. This is particularly relevant where the claimant knew more about the characteristics of a product than the typical consumer or where the claimant handled the product wrongly (both are also factors that - if strong enough - can render a product free of defects). Also available under all regimes is the defence of force majeure.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The PLA contains a development risks defence (Article 8 e). This defence only applies where the producer proves that the defect could not objectively have been discovered. The standard of care required is not that of a particular industry, nor is it a national one. To determine whether the defect could be discovered, one must take into account the most advanced state of scientific and technical knowledge that is accessible at the time the product was put into circulation.

Once the problem with a certain product is known, there is no longer scope for the development risks defence. The question then is whether the defect could have been avoided rather than whether it could have been discovered.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The manufacturer can escape liability only if compliance with regulatory or statutory requirements has unavoidably led to the damage (Article 8 PLA). This is not the case where regulatory or statutory requirements merely impose minimum standards.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Judgments in Belgian civil law usually have effect only between the parties to the proceedings. The same claimant is precluded from bringing the same cause of action twice (res judicata). A different claimant can bring a claim against the defendant, without restriction, even where it is based on more or less the same facts and/or involves the same legal issues. There is no form of “issue estoppel” or “collateral estoppel” that would prevent either party from re-litigating preliminary issues, such as defect, fault or causation. Third parties can neither make defensive use of the fact that certain issues were already dealt with in a prior action, nor rely on such a fact to prove their case. The only situations where preliminary issues may be determined are cases of third party intervention and third party notice. However, these happen primarily in recourse scenarios.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is led and decided by a judge only. There is no jury verdict on any question.
4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, the judge may appoint technical experts but the advice given will not be binding. The evidence is assessed by the judge only (see question 4.8 below).

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class actions, or similar means to bundle mass tort claims, prejudicing the rights of each member of the group, are not available under Belgian law. The courts can deal with several claims in the same hearing. If the claims are related, claimants can also bring a joint claim or request that the court combine their claims. However, this does not prejudice the rights of the individual claimants.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Certain associations can bring representative actions for injunctions under the Fair Commercial Practice Act 1991 as well as under the law of 12 January 1993 on the protection of the environment. However, these actions neither give the representative body a right to claim damages nor can they be used to force the producer to recall a product. Note also that Directive 98/27/EEC on injunctions for the protection of consumers’ interests does not apply in the area of product liability or product safety.

4.5 How long does it normally take to get to trial?

There is no formal pre-trial stage under Belgian procedural law. After the claim has been filed and written submissions have been exchanged, litigation moves straight on to trial. Delays before getting a judgment vary from one region to another. The courts in the Brussels region are presently overloaded, and it can therefore take several years before a judgment is adopted.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

It is common for the courts to rule on a preliminary issue, e.g. appointing an expert to assess the damage caused in a first judgment before ruling on the substance of a case in a second judgment after some of the factual issues have been resolved. The judge may decide to do so on his own motion or following a request by one or several parties to the case.

4.7 What appeal options are available?

Decisions of the court of first instance and the commercial court are open to appeal if the value of the case exceeds €1,860. The court of appeal has jurisdiction over all factual and legal aspects of the claim to the extent of the motion of appeal. A similar form of appeal is available for decisions of conciliatory tribunals (juge de paix) exceeding €1,240, although they are referred to the court of first instance. Final decisions and appeal decisions may be referred to the Cour de Cassation for revision on legal grounds only.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court can appoint experts to advise on technical or scientific issues. Alternatively, the claimant’s and the defendant’s own experts may try to find a common position on the controversial issues. If that proves to be impossible, they may try to agree to appoint an independent expert to provide an opinion. Note also that courts are not bound by expert opinions (see question 4.2 above).

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There is no pre-trial discovery in Belgium and thus no instrument comparable to pre-trial depositions. Prior to trial, however, the parties have to exchange all documents which they intend to submit to the court. It must also be noted that the taking of oral evidence is rare in Belgian litigation proceedings as Belgian courts prefer written statements.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

As there is no pre-trial stage, there is also no institutionalised initial disclosure procedure (apart from the requirement to exchange documents, see question 4.9 above). The court can, however, by itself or following an application from either party, order the disclosure of documents (if necessary from a third party when the document is in the hand of that third party). The judgement ordering the production of a document is not likely to be appealed. Such a judgment can be obtained before commencing the proceedings relating to the product liability case (for instance, in order to obtain documents necessary to this main claim) or pending the course of these proceedings.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

All claims are, in principle, subject to a limitation period of 30 years, unless a shorter period is provided for by law.
6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Where the claimant has suffered personal injury, he is entitled to claim both pecuniary and non-pecuniary damages. Pecuniary loss resulting from personal injury includes, for example, medical expenses and loss of income or earning capacity. Relatives (e.g. spouse and children) can claim pecuniary loss for the death of the (primary) victim. Note also that that the claimant may claim the ‘loss of a chance’ (see question 2.1 above).

Non-pecuniary loss includes pain and suffering as well as loss of amenity. Loss of amenity can be claimed even where the victim's personality is destroyed and the victim has lost his senses permanently.

Courts tend to compensate mental damage rather generously. Mental damage does not need to manifest itself in an injury to health, i.e. in a recognised psychological disorder. Mere distress and grief can suffice. Accordingly, relatives (and other ‘close people’) can claim damages for a ‘nervous shock’ as a reaction to the injury or death of the primary victim, even where it does not constitute post traumatic stress disorder. However, the quantum of awards for mental damages is relatively low compared to US and even UK standards.

Damage to property other than the defective product itself is recoverable under all regimes. However, the PLA requires that the damaged items are usually, and were largely, used for private purposes (Article 11 PLA). Also, property damage can only be claimed to the extent that it exceeds €500.

Damage to the product itself is covered by the law of contract. The PLA expressly excludes such damage (Article 11 (2) PLA), and tort law is usually not applicable as a consequence of the cumul limité principle (see question 1.1 above).

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

So far, such cases are unknown in Belgium. The basic legal position is that damages are recoverable only where they have occurred. The Cour de Cassation further allows the claimant to recover damages if it is certain that damage will occur in the future. However, it is not entirely inconceivable that expenses for medical monitoring may be recovered in certain circumstances. Exposure to a product in a way that is known to be likely to cause certain types of injuries can without doubt lead to severe mental disturbances and lead to genuine mental damage. The focus under Belgian law must be on causation. Medical monitoring expenses, freely paid by the claimant, may often be seen as not directly linked to a damage, which renders them unrecoverable. However, this may be different where the claimant has reasonable grounds to be seriously disturbed, e.g. where the product has already caused an injury to him which is closely related to the one he now fears.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, Belgium has not made use of the option provided for under Article 16 of the Directive to include damage caps.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party can recover the costs of court proceedings (e.g. court-appointed experts and common costs of the proceedings which are supposed to also cover legal fees; there is a very limited lump sum depending on the type of procedure). In principle each party bears its own legal costs of pursuing the claim, e.g. lawyers’ fees and expenses for amicable expert opinions (see question 4.8 above).

However, in a recent judgment dated 2 September 2004, the Cour de Cassation accepted the principle that, in certain circumstances, legal fees could be regarded as part of the damage and could therefore be fully recovered as damages. The Cour de Cassation ruled that, since Article 1382 C.C. obliges the liable person to fully remedy the damage, it does not exclude that damages can extend to the fees which the victim had to incur in order to ascertain the existence of the damage and/or its extent.

As a result of this judgment the minister of justice
announced that he hoped to introduce a legislative measure to remedy the inequality created between the parties to the proceedings as a result of the Cour de Cassation’s judgment. Indeed, the judgment only permits the victim of the fault to recover his legal costs.

In light of these developments, the French speaking Brussels Bar adopted on 15 November 2004 a recommendation which inter alia recommends a lawyer to inform his client of the possibility to recover from the other party compensation for the costs of preparing the defence.

7.2 Is public funding e.g. legal aid, available?

A party can apply for a waiver of court fees under Articles 664 et seq. of the Code judiciaire. It is also possible to ask for representation by a pro bono lawyer under Articles 446 bis and 508/1 to 505/53 of the Code judiciaire. Reference may also be made to the Council Directive 2003/8/EC to improve access to justice in cross-border disputes (which should have been implemented by 30 November 2004).

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is granted depending on the financial situation of the claimant. Persons earning less than €620 per month will generally be able to get legal aid. People with higher incomes can also qualify for legal aid if the costs of the action are particularly high (e.g. because it involves difficult expert opinions).

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Lawyers are prohibited from working on a ‘no win - no fee’ basis (Article 459 of the Code judiciaire). However, fixed fee scales were repealed in 1995, and the Ordre des avocats now only requires that fees be fair and moderate. It is thus possible to agree on higher fees conditional upon success. Success fees should however be fair and modest.

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Chapter 13

Bolivia

C.R. & F. Rojas - Abogados

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Product Liability is regulated by the Bolivian Civil Code (the “Civil Code”). The Civil Code's chapter entitled 'Illicit Acts' specifically deals with product liability. Illicit acts are referred to as extra-contractual responsibilities.

Article 984 of the Civil Code provides that a person shall be held liable for any willful or negligent act that causes damage. Accordingly product liability is based on intent and negligence.

1.2 Does the state operate any schemes of compensation for particular products?

The Bolivian state does not operate any schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

According to Article 999 of the Civil Code, joint liability shall apply if there is more than one person responsible. If one person has indemnified the total amount of damages, said person may thereafter recover from the other wrongdoers. If it is not possible to determine the amount of damages owed by each wrongdoer, the total amount of damages will be divided equally.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Any product that threatens health or life of individuals must be recalled from the market. If damage has been caused as a result of failure to recall a certain product, the affected party may file suit for damages incurred.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The burden of proof lies with the victim who has suffered damages as a result of a willful or negligent act.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The existence of causation between a person’s acts and the damage caused are necessary for responsibility to arise.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

According to Article 999 of the Civil Code, joint liability shall apply if there is more than one person responsible. If one person has indemnified the total amount of damages, said person may thereafter recover from the other wrongdoers. If it is not possible to determine the amount of damages owed by each wrongdoer, the total amount of damages will be divided equally.
2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Yes, failure to warn may give rise to responsibility.

3 Defences and Estoppel

3.1 What defences, if any, are available?

With regards to illicit acts as they would apply to product liability, the following defenses are available: force majeure; or acts of God.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Bolivian legislation does not contemplate a state of the art/development risk defence.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory or statutory requirements may help prove that there was no negligence involved.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Claimants may re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant.

4 Procedure

4.1 Is the trial by a judge or a jury?

Bolivian civil court system does not contemplate trial by jury. Victim of product liability must file suit before a Civil Court.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not have power to appoint expert assessors to sit with a judge.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class actions are contemplated by Bolivian law. Such claims, however, are not common.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Provided a power of attorney exists, claims may be brought by a representative body on behalf of a number of claimants.

4.5 How long does it normally take to get to trial?

Trial may take up to 3 years.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Preliminary issues may be dealt by a court so as to determine whether a certain trial should proceed. Said issues may relate to matter of law and fact.

4.7 What appeal options are available?

Regarding civil matters, appeals are granted before an Appeals Court, and thereafter the Supreme Court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Expert witnesses may be presented by the parties. The court may also appoint expert witnesses. There are no restrictions on the nature and extent of said evidence.
4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no requirement for factual or expert witnesses to present themselves for pre-trial deposition. Witness statements/expert reports are not exchanged prior to trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Documentary evidence must be presented at the time one files civil suit. All other forms of evidence are presented during the discovery period.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

There is a 5 year statute of limitation for bringing or issuing civil proceedings.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

There is a 5 year statute of limitation for bringing or issuing civil proceedings.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Issues of concealment or fraud do not affect the running of the 5 year statute of limitation.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under Bolivian law, damages include both the actual (damnun emergens) and future (lucrum cesans) loss, detriment, or injury the Plaintiff’s person, property, or rights suffer. Moreover, damages under Bolivian law must be direct and foreseeable. Accordingly, damages that are punitive, indirect, incidental or consequential are not contemplated by Bolivian law.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Not contemplated by Bolivian law.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not contemplated by Bolivian law.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable from one manufacturer.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Yes, a successful party may recover (a) court fees or other incidental expenses; and (b) their own legal costs of bringing the proceedings, from the losing party.

7.2 Is public funding e.g. legal aid, available?

There is no public funding that would apply to civil actions related to product liability.

7.3 If so, are there any restrictions on the availability of public funding?

Not applicable (see question 7.2).

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Not applicable (see question 7.2).
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Founded in 1900 by the late Casto Rojas, C.R. &F. Rojas - Abogados (the “Firm”) is the oldest law firm in Bolivia. The Firm is based in the capital city of La Paz, Bolivia. The Firm also has an office in Santa Cruz, and correspondent offices in all other major Bolivian Cities.

Beginning as a family firm that currently extends to four generations of lawyers, C.R. & F. Rojas - Abogados has grown to include first-rate attorneys from around the country. Now after more than 100 years of dedicated service to its clients, the Firm continues to grow, and has developed an extensive network of correspondents throughout the world.

C.R.&F. Rojas has 15 lawyers who advise and represent a diverse group of entities of different sizes. The firm works as Bolivian counsel to many foreign corporations and Embassies, and as regional counsel to a number of national clients.
Chapter 14

Brazil

Pinheiro Neto Advogados

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Legal consumer relations in Brazil are regulated by the Consumer Protection Code (“CDC”) and can be defined as all relations in connection with production and placement on the market of goods and services, and subsequent acquisition and use of them by the public. These relations are necessarily composed of purchasers and end users, on one side, and suppliers, on the other. Consumers are defined as any individual or legal entity that acquires or uses products or services as an end user.

On the other hand, supplier means any individual or legal entity, whether public or private, Brazilian or foreign, as well as any unincorporated entities, engaged in production, assembly, creation, construction, transformation, import, export distribution or marketing activities or in the provision of services.

The CDC distinguishes two types of liability, namely: liability as regards the product itself and liability for a flaw in the product.

Liability as regards the product itself is related to the concept of a consumption accident. Liability for the product itself is strict, i.e., it does not depend on the fault of the supplier. The existence of damage is sufficient, which must be remedied by the party connected thereto by the chain of causation.

Suppliers are also liable, in the civil sphere, for damages incurred by third parties, i.e., those who are not purchasers or owners of the products, but who suffer any type of damage the moment that the defect of the product is manifest.

Suppliers are only held harmless from liability if it is proven that (i) the product was not put on the market; (ii) that, although it put the product on the market, there was no defect; or (iii) that the accident occurred as a consequence of the exclusive fault of the consumer.

The consumer may file suit against all involved in the chain of production. Those who are not directly responsible will have right of recourse against the responsible party. Only under express cases set forth under the law is there exemption from liability.

As for liability arising from faulty product, this does not arise from any damage caused to the consumer. In this case, liability arises from faults which render the product improper or inadequate for consumption, or from a reduction in its value or quantity.

The ground for liability differs from that related to product liability. Liability for fault in quality or quantity involves supplier responsibility and is linked to contract default, given that the supplier must place the product or service on the market in perfect conditions for use.

In cases in which a consumer relationship does not exist, the recently enacted Civil Code shall apply. The Civil Code provides for indemnity against illicit acts and also for contract liability. The novelty introduced by this system is indemnity for damages irrespective of guilt, when the activity normally conducted by the author of the damage implies, by its very nature, a risk against the rights of third parties.

1.2 Does the state operate any schemes of compensation for particular products?

The State has no ancillary liability in relation to any kind of product, unless it is proven that it is directly responsible for the event which caused the damage.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The responsibility as regards the product itself is borne by the manufacturer, producer or builder, whether domestic or foreign, and by the importer. The importer is answerable in its capacity as presumed supplier, whilst the remaining are answerable in their capacity of effective supplier. The merchant (also a presumed supplier) has been excluded from the general rule, and is only answerable in a supplementary manner when the manufacturer cannot be identified or the product does not contain clear identification of the manufacturer, or when the merchant does not adequately store perishable products.

The CDC provides for the right of return of the person who has paid against all other joint holders of responsibility, given the solidarity which exists among such suppliers.

The liability for product fault/defect is jointly held by all suppliers, and here, differently for the case of consumer accident, the merchant receives no privileged treatment.
Should the consumer sue the merchant, the latter will hold a right of return against the party responsible for the fault/defect, and the same right is ensured to all other suppliers.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Products that are very harmful or hazardous cannot be placed on the market. However, both law and jurisprudence fail to conceptualise the meaning of “very harmful or hazardous”, so that the interpretation of this phrase is subject to a case-by-case evaluation.

If a supplier acknowledges the harmful and hazardous nature of the product only after it has been placed on the market, it is responsible for immediately informing both consumers and the proper authorities, by means of public media advertisements.

Ordinance 789/2001 establishes the obligation to communicate Departamento de Proteção e Defesa do Consumidor - DPDC and the State and/or City Consumer Protection Offices the harmful or hazardous nature of a product.

Failure to comply with the Law theoretically subjects the supplier to the administrative penalties. If DPDC (a) acknowledges a lack of communication that supplier was supposed to have carried out; or (b) decides that the communication is insufficient, it shall initiate administrative procedures to find out whether supplier has violated the Law, and, if so, the penalties shall apply.

On the other hand, a criminal investigation shall be started to ascertain criminal liability of anyone that contributed to the lack of the mandatory communication, for late communication or for insufficient mandatory communication.

The supplier may also be sued in a civil court, whether jointly or severally, for providing indemnity for any damages caused to consumers.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The burden of proof may be shifted to the supplier, at the court’s discretion, when (i) the claim brought by the consumer is found to be verisimil; or (ii) in the event the supplier is found to hold a stronger position in its relationship with the consumer. Whenever technical aspects are involved, the courts may order the suppliers in lieu of the consumer to submit proper evidence.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Expert, documentary and testimonial evidence are admitted to prove causation. Although suppliers are subject to strict liability, it is necessary to evidence the causal relation between the actual damage suffered and an unexpected injurious effect relating to the product.

The burden of proof may also rest on the defendant when there is verisimilitude in the allegations and when the consumer is the weaker party. Thus, if there is a relation between the damage suffered and the product, it will be incumbent on the supplier to evidence that the damage did not result from use of the product.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

There is no legal provision covering the referred hypothesis. Although liability for product defects is objective, proof of the cause-effect relationship will at all times be required. Thus, it is improbable that a given producer will be made answerable in the absence of proof that the damage was caused by a product of such producer. Although the reversion of the burden of proof is allowed, such reversion is inadmissible in the case of an impossible proof.

On the other hand, since solidarity cannot be presumed, it is therefore inconceivable to determine a joint liability among producers based on market share or similar criteria.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Once the law does not stipulate that proper information should be provided directly to consumers, it is possible to defend that if the necessary middleman (such as the physician in the case of restricted use drugs) has the proper information, the supplier will not be liable for the consumer’s absence of awareness of the underlying risk.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A supplier is only released from liability if it is evidenced that he did not place the product on the market or otherwise render the service; that the defect does not exist; or that the accident is exclusively attributable to the consumer. The risks reasonably inherent to a certain product or service, as
well as proper disclosure to consumers, must always be taken into account for liability purposes.

3.2 Is there a state of the art/development risk defence? i.e. is there a defense if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defense, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There is no statutory definition concerning the matter, and it will be dependent on the interpretation of legal doctrine and of case law.

Some jurists understand that the supplier’s good faith and its initial unawareness of the occult hazard shall not exempt it from liability for any damages that may arise. There are others who believe that the risk of development exempt supplier’s liability was adopted by the CDC, following a suggestion of the European Economic Community.

However, the CDC determines that a product shall not be deemed defective merely because another product, with a better quality, has been placed on the market.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

If a given company complies with all the rules and regulations determined by the State, it cannot be held liable for damages caused by a given product.

There are, however, opinions in the sense that, as liability for the product itself is strict, it is not dependent on any actual fault of the supplier.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Awards issued in similar or precedent individual suits are not binding on the Magistrate, who must review each specific case based on his own conviction.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial shall be issued by the judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Technical specialists may carry out the work involved for pursuing these purposes. Expert witnesses act as assistants to the magistrate, and it is the magistrate who appoints them for the purpose of conducting a bona fide review of the things and the facts and to submit, in the form of an expert opinion, a report on his conclusions which can be derived therefore.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Yes there is a specific procedure for multiple claims.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Civil Class Actions are special proceedings established by Law No. 7347 of September 24, 1985, which governs lawsuits involving liability for damages caused to (i) the environment; (ii) consumers (represented by the general public); (iii) assets and rights of artistic, historical, tourist or scenic value; (iv) any and all general public interest; and (v) violations of the economic order.

The CDC has expanded the scope of Law 7347/85, by creating a new category of collective rights or interests.

There is currently a vast case law in terms of class suits, covering a wide number of subject matters. It is a common procedure which is routinely brought to court.

4.5 How long does it normally take to get to trial?

It may extend over a period of five to seven years, on the average.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The magistrate must provide for the correctness of the suit as from the moment he receives the initial petition, and may dismiss it if it does not meet legal requirements. After the initial reply has been submitted, the magistrate will review issues related to matters of law. Once the proceedings have been cleared and put in due form, the magistrate can issue his award based on the state of the records or order finding of evidence.

4.7 What appeal options are available?

Brazilian procedure establishes a single judge in the first instance and a collegial tribunal of three judges in the second instance. In some cases, review by a court of the third or even fourth instance will be permitted.

There are the following types of appeals: (1) appeal; (2) bill of review (seeks review of interlocutory decisions); (3) request for a rehearing en banc; (4) request for clarification; (5) ordinary appeal (may be brought before the Supreme Federal Court or Superior Court of Justice as a last instance in case of writs of mandamus, habeas corpus, habeas data and injunctions which are awarded by the Higher Courts); (6) special appeal (may be brought before the Supreme Court of Justice as a last instance against an award which is contrary to a treaty or a Federal Law); (7) extraordinary
appeal (may be brought before the Supreme Federal Court if the challenged decision contravenes provisions of the Federal Constitution); and (8) special appeal for resolution of conflict in previous jurisprudence and extraordinary appeal.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Please refer to the reply to question 4.2.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements / expert reports exchanged prior to trial?

There is no pre-trial in the Brazilian procedural system. The judge has the power to interrogate the parties and the witnesses. The judge may take the deposition of any party at any stage of the proceedings, but ordinarily parties and witnesses testify only under the final public hearing.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Documentary evidence is introduced in the initial stage of ordinary proceedings by attachment to the pleadings. The judge will also admit documentary evidence at a later stage to support unforeseen facts or to refute evidence presented by opposing counsel.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

For apparent defects: 30 days for a non-durable product or service, and 90 days for durable products or services. The terms are calculated as from the delivery of the product or from the completion of the performance of the service.

For hidden defects: 30 and 90 days, as in the case of apparent defects, but the term is to be reckoned as from the time the hidden defect becomes apparent.

The CDC stipules that the right to demand indemnity for damages caused by the product or the service prescribes after a term of five years, to be calculated as from the time the damage and its authorship becomes known.

The magistrate does not have the power to interfere in the terms defined by the CDC. By the same token, the age or the conditions of the consumer do not interfere with the reckoning of the terms.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The limitation period starts running when consumers become aware of the injury. If there is any fraud concealing the injury, the period for claiming damages caused by the product or service will only start running when the damaging act is unveiled.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Losses and damages encompass (i) actual damages, which correspond to all losses incurred by the victim by virtue of the harmful event (including those of a material nature and for pain and suffering, i.e. moral damages); and (ii) loss of profits, which represents the legitimate and expected gains which the same failed to receive, due to the accident.

Specifically in terms of consumer rights, there are the following general indemnity obligations:

(i) indemnity of damages caused due to defects arising from design, manufacture, construction, assembly, formulae, handling, presentation or packaging of the products, as well as for insufficient or inadequate information concerning its use and risks;

(ii) indemnity for damages caused due to defects related to the rendering of the services, as well as to insufficient or inadequate information concerning the enjoyment and risks thereof;

(iii) indemnity for defects in quality or quantity which render the products improper or inadequate for the consumption or which reduce their value, as well as defects arising from inconsistency with information contained in the container, packaging, labels or advertisement, subject to the variations inherent to the nature of the product, the consumer being entitled to demand replacement of the defective parts;

(iv) indemnity for defects in product quantity whenever, and subject to variations inherent to the nature of the product, its net content is less that that indicated in the container, packaging, label or advertisement, the consumer being entitled to demand replacement of the defective parts;

(v) indemnity for defects in product quantity whenever, and subject to variations inherent to the nature of the product, its net content is less that that indicated in the container, packaging, label or advertisement, subject to variations inherent to the nature of the product, the consumer being entitled to demand replacement of the defective parts;
6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The indemnity will seek to restore the situation of the affected party to that prior to the injury. Therefore, the indemnity is to be calculated on losses actually borne by the aggrieved party.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

No. However, what has been accepted recently is the theory of discouragement, according to which the amount of the award for pain and suffering must be set at reasonable levels so as to discourage it repetition.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The actual number of claims arising from the same incident is irrelevant, since the main purpose of the Law is to ensure full recovery of all victims of the incident or accident.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The losing party shall pay all court costs, as well as the other side’s attorney’s fees. Attorney’s fees are normally fixed at 10 to 20 percent of the amount of the award. Recovery of the party’s own costs does not automatically arise from the winning award, and will at all times be subject to the reasonability criterion and to an effective proof that it represents a material damage.

7.2 Is public funding e.g. legal aid, available?

Yes public funding is available in Brazil.

7.3 If so, are there any restrictions on the availability of public funding?

Judicial Assistance will be granted to those who need it in the manner established by law. To secure legal aid, a person must file a petition declaring that he does not have sufficient assets to bear the expenses of the law suit. If the petition designates a lawyer who expressly declares that he is willing to accept appointment, the judge must have fair cause to refuse to appoint the indicated lawyer. If a judge decides to grant a legal aid petition that does not specifically designate a counsel, he will request a public legal aid agency to name a lawyer to represent the indigent. If there is no such legal aid service, the judge will ask the bar association to appoint a lawyer. In a municipality where there is no representative of the bar association, the judge himself will appoint a lawyer to take the case. The lawyer cannot refuse to take the assignment without reasonable excuse. An indigent receiving legal aid is excused from payment of all judicial costs.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

All charges are to be paid by the losing party whenever the beneficiary of legal aid prevails. If an attorney representing a person without sufficient means prevails, the attorney’s fee cannot exceed 15 percent of the recovery. The Minors’ and Juvenile Statute has assigned to the magistrate the power to set the fees, according to a pre-set schedule.

In the event the beneficiary of legal aid is the losing party in the suit, such party shall bear legal costs and attorney fees, provided he is able to do so without damages to his own support or to that of his family, within a period of up to five years as from the final award.

**Pinheiro Neto Advogados**

Pinheiro Neto Advogados was organized in 1942, and has steadily grown in size and importance ever since. It currently has over 1100 members, comprising 350 lawyers (57 of whom as partners), 180 trainees and 160 paralegal workers, backed up by other professionals and administrative staffs. The Firm provides full legal services on all fields of law, and is strongly committed to providing up-to-date and creative solutions within the utmost standards of quality expected by its clients.

The Firm has offices in São Paulo, Rio de Janeiro and Brasília, and also works with local correspondents throughout Brazil. Pinheiro Neto Advogados also maintains a representative office in London to assist clients that wish to do business on the European market. The Firm also fosters an international presence byseconding its associates to law firms outside Brazil.
Chapter 15

Bulgaria

Borislav Boyanov & Co.

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

In the last 20 years the legal doctrine and practice in Bulgaria, in terms of product liability, developed greatly due to the serious economic transformations leading to establishment and development of the free-market economy. In 1999 Bulgaria adopted the first Consumer Protection and Rules of Trade Act (the “CPA”) in line with the EU Directives. However the adoption of a new Consumer Protection Act by the Bulgarian Parliament is imminent. The new act is aimed to further and more accurately implement Directive 85/374/EEC, as well as a number of other EU directives.

In general, Bulgarian law recognises three legal grounds for product liability in the sphere of civil law and one in criminal law - general tort liability (delict), strict product liability, contractual liability and criminal liability.

Strict product liability, defined in Art. 14 of the CPA, is a specific liability which compared to tort liability is non-fault and is based on objective reasons. In order to successfully engage the strict liability under the CPA, consumers have to prove three main interrelated facts in corpus delicti: a defect, existing at the time of putting the product on the market, material damage and causal link between the defective product and the relevant damages. Unlike general tort liability this specific liability, being purely objective does not provide the liable person with opportunity to exculpate on subjective grounds by proving he was not acting intentionally or he was not negligent. Another characteristic feature is that the compensation may cover only material damages.

Strict liability as of the date hereof does not explicitly provide for liability in relation to defective services but only for liability related to defective products. As the rules of the CPA, related to the product liability, are considered lex specialis in relation to the general tort liability they could not be subject to interpretation thus extending the strict liability over cases that are not specifically provided for in the CPA. Thus, under the present regime in case liability arises from rendering of defective services by the manufacturer, importer or retailer the consumer may seek protection of his rights under tort law.

General tort, defined by Art. 45 and following of the Obligations and Contracts Act (the “OCA”), is applicable, inter alia, to matters regarding product liability. Tort under OCA is fault based either on intent or negligence on the side of the wrongdoer who in cases of product liability could potentially be manufacturer, importer or retailer. Fault under OCA, i.e. negligence, in the form of non-compliance with the objective test of due care, is presumed, thus shifting the burden of proof for a corpus delicti fact from the injured party to the wrongdoer and resulting in the procedural burden for the wrongdoer to prove that he indeed applied the due care when his behaviour was in objective breach of law. The consumer would have to prove that the wrongdoer acted or omitted to act; the act or omission to act caused, as a result, a breach of law; and there was damage and a direct causal link between unlawful result and the damage. In addition Art. 14 of CPA explicitly limits strict product liability of the manufacturer, importer or the retailer only to obligation for compensation for material damages.

Therefore, should a party injured by a defective product seek indemnification of non-material damages, the only existing legal solution would be to follow the general procedure by seeking damages in tort as set forth in Art. 52 and 45 of OCA, according to which the court based on equity resolves on the non-material damages resulting from tortious behaviour.

Contractual ground is another legal option for seeking relief for damages suffered from a defective product. Unlike the strict and tort liabilities, contractual liability may include obligation for compensation for damages arising only from the defective product itself and not from the death, personal injury or damage to other property of the consumer, caused by the defective product. Contractual liability is limited in respect of the persons it could be brought against. Under OCA any claims arising from a contract may be directed only towards a party thereto. Therefore in cases of product liability, based on contractual non-conformity (shortages, defects, incompliance with sizing etc.), besides claiming damages, the consumer may also claim:

- reimbursement of the money paid;
- replacement of the defective product with another (in case of generic goods);
- price discount; and
- free repair of the defective product.

The aforementioned legal grounds work on a concurrent basis i.e. the different forms of liability (strict, tort and
contractual) do not exclude but supplement each other as to provide the consumer with sufficient and efficient integral indemnification.

The Bulgarian Penal Code sanctions some acts or omissions to act which are of a nature to adversely and substantially affect the interests of the consumers and the society.

1.2 Does the state operate any schemes of compensation for particular products?

No such schemes exist in Bulgaria.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the strict liability regime the liability for the defect, respectively for the damages incurred, is born by the manufacturer. ‘Manufacturer’, according to the CPA, is any person who manufactures or renovates products or parts thereof or offers services, extracts or processes raw materials or represents himself as a manufacturer by using his trade name or distinctive sign.

In case the product is imported in Bulgaria than the importer may be hold liable under the strict regime of the CPA. An importer under the CPA is “any person who first acquires the ownership over imported products on the customs territory of Bulgaria or mediates such acquisition”.

If neither the manufacturer or the importer can be identified then the retailer should be hold liable. According to the CPA, ‘retailer’ is “any person that sells or offers for sale goods or provides services, as well as manufacturer or importer, which sells or offers for sale goods directly to the consumer”.

Provided that several persons qualify as liable manufacturer, importer or retailer they bear joint liability and may eventually seek within their internal relations distribution of the liability engaged.

In case of tort only the person in fault (manufacturer, importer or retailer) could be held liable. If an injury was caused by the act / omission to act of several wrongdoers they would bear joint liability. In cases of contractual breach joint liability exists only if explicitly stipulated in the contract, otherwise defaulting contractors may bear only several liability.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In order for a product to be recalled under the CPA first of all it has to fail an abstract safety test - a product is considered safe if under normal circumstances of use it does not generate any risk or generates minimal risk, deemed acceptable in terms of protection, and safety of the consumer. Whoever of the manufacturer, the importer or the retailer finds out that a product is unsafe he is under a duty to recall the products representing a threat to the life, health or property of the consumers. The responsible person should inform immediately in a suitable way the consumers and the controlling authority (The Trade and Consumer Protection Commission) for all risks, related to the exploitation of the products.

If the person under the duty to recall a product fails to do it then any consumer, group of consumers, consumer association or the Trade and Consumer Protection Commission would have legal interest and legitimacy to a claim under Art. 52 and 53 of the CPA establishment and suspension of the breach including obliging the liable person to recall the product in due time. Further to this judicial procedure the Trade and Consumer Protection Commission or the municipality administration could establish that the manufacturer, importer or retailer are not performing their duty to recall unsafe products and following the issue of a statement of findings either the Trade and Consumer Protection Commission or the mayor of the municipality could issue administrative act in the form of order for mandatory recall and destruction of all dangerous products of a certain type.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In general, according to Art. 127, par. 1 of the Civil Procedure Code, each party is to establish the facts which serve as grounds for its claim or objection. The above provision sets the general rule for the main burden of proof in the Bulgarian legal system (with the party making allegations based on existence of positive facts).

Particularly in case of strict product liability the burden of proof lies with the consumer. He has to prove the defect, the damage and the causal link between them. As stated below the allegedly liable person could not exculpate but could exonerate himself on exhaustively listed grounds for objection in Art. 16 and Art. 18, par. 2 of the CPA (see question 3.1 below).

In case of tort the law lays down a refutable presumption that the existence of fault (negligence) is assumed provided the other, objective components of the tort are present. In this hypothesis the burden of proof lays with the manufacturer / importer who may seek means of proving that he was not negligent and has applied the necessary professional effort thus satisfying the requirement of the abstract, objective and relative professional due care.

In relation to potential contractual liability - the party claiming damages as a result of non-performance has to prove the non-conformity of the product with the specifications as set out in the consumer agreement.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Causation could be investigated in two directions:

The first relates to the relationship between the behaviour defined as an act or omission to act of the allegedly liable person (cause) and the unlawful result of this behaviour expressed in the breach of consumer law or contract (effect). This particular causal link is very often considered second important to the other causal relationship - between the

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unlawful result of one’s behaviour and the relevant damages, caused by the same result, which may be compensated. Nevertheless it undoubtedly plays an important role in the construction of the civil liability as it is proving the existence of tort or contractual default and its author (ground for liability).

The second causal link is between the unlawful result of one’s behaviour (cause) and the damages incurred under the contract (effect). This second causal relationship relates to the recoverable damages sought by the victim, thus establishing the scope of the liability. In view particularly of the strict liability under the CPA, only the second causal link (between the unlawful result and the relevant damages) is to be investigated. The main argument for this conclusion is based on the fact that the product liability under the CPA excludes the behaviour of the liable person (disregarding whether lawful or unlawful) leading to the production, import or sale of the defective product as a legally relevant fact when engaging the strict product liability.

In order to identify the relevant damages two tests are usually applied, corresponding to two different causation theories. The first test is related to the condition sine qua non theory of causation, proving that there is factual causation between the defect, existing at the time of the passing of risk to the consumer, and the damages suffered. The defect is viewed as one of several preconditions which lead to the damage of the consumer. Would the damage still occur, if the defect of the product is imaginarily taken out? A negative answer leads to establishing a factual causal relationship. However, it has to be pointed out that not all actual damages are recoverable under the Bulgarian law. The legally relevant, direct damages are the limit of the civil liability. That is why in order to identify the direct damages we put the factual damages to a second test using the adequate causation theory. This test would isolate only damages which are: a typical, normally occurring and necessary result; a consequence from contractor’s default; or unlawful behaviour, which are characteristic and repeat under the same related conditions”.

In view of the aforesaid it is not sufficient to prove exposure to increased risk that might have led to or is usually associated with the damages of the bodily constitution or property of the injured person provided that the consumer cannot prove that the specific injury would not have arisen without such particular exposure.

2.3 What is the legal position if it cannot be established which of several possible manufacturers manufactured the defective product? Does any form of market-share liability apply?

If several manufacturers have taken part in the manufacturing of the defective product and it cannot be established which of them exactly manufactured the defective part of the product than they would bear joint liability. For details, please, see question 1.3.

There is no market-share liability system in Bulgaria.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The CPA explicitly grants to the consumer the right of information before acquiring a product, as the obligation for providing certain information lies with the retailer. The information would have to cover a minimal scope of characteristics of the product - contents, packaging, directions for use, price and quantity, impact on other goods, the risks associated to the use or maintenance, terms and conditions of the warranty and expiry date. The information needs to not only satisfy the requirements of a minimal scope, covering particular issues, but it has to be true, complete, accurate and clear. It has to also be in the Bulgarian language, as the measures should comply with the International System of Units (SI). At the request of the consumer and if the type of product allows the retailer should demonstrate the use of the product. The CPA specifically provides that the retailer could not exonerate his failure to perform the above obligations, arguing that he was not provided with the necessary information by the manufacturer or the importer. Moreover, the consumer is also entitled to obtain advance information if the offered goods are used or expired, have deviations from preliminary declared characteristics or are subject to clearance sale while the trader is obliged to designate special places in its commercial outlet for the sale of aforementioned goods, separately from the other goods.

Should the retailer fail to duly perform any or all of the above obligations any consumer, group of consumers, consumer associations, as well as the Trade and Consumer Protection Commission, could lodge a claim for establishment of breach of the CPA, for termination of and desisting from the established breach and/or for damages caused (Art. 51-54 of CPA).

Only the information provided directly to the injured party is taken into account.

Notwithstanding his professional qualifications, under Bulgarian law, the retailer being a contractual party should assess the suitability of a product to its intended use as stipulated in the contract between the retailer and the consumer. Otherwise if the product does not qualify for the intended contractual or normal use, thus rendering it defective in accordance with §1, p.9 of the CPA, this might consequentially provide grounds for product and contractual liability under the CPA.

In conclusion, the Bulgarian law does not apply the principle of “the learned intermediary” as it places the main burden for providing information to the consumer with the direct
retailer rather than the manufacturer or importer. In contrast, the obligations of the manufacturer or importer, which do not qualify as retailers, arise from their duty to abstain from marketing unsafe products, being therefore with a narrower scope compared to the obligation of the retailer. Hence, manufacturers or importers, excluding retailers, are under an obligation to provide information to the consumer allowing them to assess only the health- and life-threatening risks, related to the normal or foreseeable circumstances of use. That is why despite the fact that the manufacturer or importer might have provided some information to the retailer as an intermediary in the chain of supply to the consumer, the direct retailer is still under obligation to provide the consumer with particular information regarding the safety of the product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In case of the strict product liability there are 6 grounds under Art. 16 of the CPA for exclusion of the manufacturer’s liability:

- did not put the product on the market;
- the defect which caused the damage did not exist at the moment of the putting the product on the market;
- he did not produce or distribute the product with the objective/aim to put it on the market;
- the defect is due to compliance of the product with the mandatory requirements issued by the state authorities;
- the state of scientific and technical knowledge at the moment of the putting of the product on the market did not allow the detection of the defect; or
- he produced only a component part of the product and the defect is due either (i) to the design or the assembling of the product by another manufacturer; or (ii) to the compliance with the instructions of the other manufacturer for the transportation, storage or exploitation.

However, manufacturer’s liability may not be waived in a contract. The law stipulates that such contractual clause is deemed null and void ex lege.

In case of contract there are 4 grounds for exclusion of manufacturer’s liability - (a) there is no breach of contractual obligation; (b) that the breach of contract or non-conformity is not attributable to the manufacturer, i.e. it is due to force majeure or other circumstances beyond the control of the manufacturer which made the performance of his obligations objectively impossible; (c) there is no causal link between the particular damage and the breach of contract; or (d) the defect / damage is not covered by the terms and/or conditions of the applicable contractual warranty (e.g. it is time-barred).

In case of tort - it has to be proved that there is no fault (negligence) on the part of the manufacturer / importer, i.e. the burden of proof rests on the manufacturer to demonstrate that he did not breach his general duty of care / not to cause damages to third parties.

In all hypotheses the liability of the manufacturer may be fully excluded or reduced proportionally where the consumer has solely caused or has contributed by his own act or omission to act for the occurrence of the damages.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The state of the art/development risk defence is given in Art. 16, item 5 of the CPA as “state of scientific and technical knowledge”. The manufacturer / importer has to prove that the defect was not discoverable at the time of the release of the product in question in circulation on the market, which is an objective test.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under Art. 16, item 4 of the CPA the manufacturer must prove that “the defect is due to compliance of the product with compulsory requirements issued by state authorities”. A stricter interpretation of this rule may lead to the conclusion that the defect should have been caused solely due to the compliance with the mandatory requirements (which were valid and in the form specified in the applicable normative act) issued by the competent state authority. However, the observance of the applicable minimum statutory standards and/or quality and safety requirements will not be sufficient per se to exclude the liability of the manufacturer unless he can prove that compulsory instructions of a state authority had been issued and complied with.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

After judgements enter into force they have the effect of res judicata between the parties to the solved court case. As an exception the same parties can “re-litigate” on the same matter only if (i) the legal ground for the claim is different (tort instead of contract liability); or (ii) the facts justifying the claim occurred after the date of the last hearing of the case.

In addition an interested party may request the revocation of a judgement after its entry into force in certain hypotheses including inter alia new facts or new documentary evidence of significant importance for the case are found or it is established that witness statements or expert opinions on which the court had based its judgement were false.

If the Supreme Court of Cassation, being competent to review the request, finds that the request is justified it may revoke entirely or partially the contested judgement, reopen the case and return it to the issuing court for a new review. Clearly, in such case, the court to which the case has been returned can, taking into account the specific revocation
grounds, reconsider the issues of fault, defect or capability of a product to cause a certain type of damage.

A different claimant (who is a third party to a solved court case) can lodge identical claim against the same manufacturer, and thus, “re-litigate” issues of fault, defect or causation already adjudicated on the solved case.

4 Procedure

4.1 Is the trial by a judge or a jury?

A jury system does not exist in Bulgaria. Regional Courts are the first instance courts with general jurisdiction to adjudicate on civil, including product liability, cases. District Courts have special jurisdiction to hear as first instance court product liability cases where the value of the claim exceeds BGN 10,000 (approximately €5,100). All first instance courts comprise of a single professional judge. Alternative dispute resolution methods are also available but have not yet become common in product liability cases. The CPA provides for conciliation commissions assisting in the resolution of disputes related to warranty liability, right of claims for goods and services and unfair contractual terms. Pursuant to the Mediation Act, effective as of December 21, 2004, product liability disputes may be referred to mediation by the parties. In such case the dispute may be settled amicably with the help of mediators, by entry into a binding settlement agreement. Monetary claims regarding product liability disputes may also be referred to arbitration if the parties agree so.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Law stipulates that experts are to be appointed by the court if the judge possesses no specific scientific or technical knowledge. In cases involving product liability, experts are appointed either ex officio or upon request of a party whenever the case contains issues of a technical or medicinal nature which require special knowledge and experience. Such experts, however, do not sit with the court and do not take part in the decision-making process. Experts are required by the law to be non-biased and their opinions are true and impartial (otherwise they can be subjected to criminal liability). A party may request dismissal of an expert appointed by the court in case of a reasonable doubt as to his impartiality. Generally, the scope of the expert opinion is determined by the parties by the tasks and questions specified by the latter and recorded in the court ruling for appointment. Expert opinions must be filed in writing with the court at least 5 days prior to the court hearing, and presented again verbally at an open hearing where the parties and the court may interrogate the expert and request extension of the scope of the opinion or a more in-depth opinion or appointment of new expert/s. Expert opinions are non-binding upon the court. The court has the sole discretion whether to rely on the findings of the expert, assessing the opinion in the light of all other relevant evidence on the case.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

There are no group or class actions under the Bulgarian legal system.

In certain circumstances (in case of strict product liability and tort) several claimants can file a common claim based on the same legal grounds and set of circumstances (damage, defect, causal link) against one manufacturer / importer provided that the same court has jurisdiction to adjudicate on all those cases. Alternatively, in case of a number of claims filed with the same court the latter can ex officio decide to consolidate all claims into one single case if the above conditions are satisfied. However, in both situations the consolidated cases will be resolved by the court by means of separate decisions (which may be incorporated by the court in a single judgement) reflecting the different circumstances in each case which shall be binding exclusively ex parte. It is generally accepted that in the above hypothesis the court decisions have to be absolutely identical with respect to the so-called “common facts”, i.e. the facts which have the same legal or evidential importance for all claimants in the consolidated case.

In general, the court has the sole discretion to decide whether to consolidate the claims which have sufficient connection with each other into one case.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

CPA provides for certain claims for “collective defence of the consumers” which, however, cannot be used in the context of the liability of the manufacturer for damages suffered by an individual consumer, even in case of multiple claims of individual consumers resulting from the same type of defect and damage, from the same product and directed against the same manufacturer. Pursuant to the law every individual consumer, group of consumers, consumer association or the Consumer Protection Commission is entitled to file:

- a claim for imposition of appropriate measures for termination of the infringements under the CPA or other applicable laws directly or indirectly protecting consumer rights; and
- (only the consumer associations) a claim for compensation of the damage caused to the collective consumer interest as a result of an infringement of CPA or other applicable laws directly or indirectly protecting consumer rights. If the court grants the claim, it adjudicates the compensation to all claimants for joint disposal.

4.5 How long does it normally take to get to trial?

There is no pre-trial procedure in Bulgaria. A case is considered opened at the moment when the claim is lodged with the competent first instance court conditional on its acceptance as admissible by the latter. Depending on the workload of the competent court first court hearing is normally scheduled within 1 to 3 months from the filing of the claim.
4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

No. First instance courts are only empowered to assess the admissibility of the statement of the claim. In case the judge finds certain insufficiencies he can request their remedy within a 7-day term and if the claimant fails to provide adequate remedy, the court refuses to open a case. The court refusal is subject to appeal before a higher court instance.

4.7 What appeal options are available?

The decisions of the Regional Courts are subject to appeal before the District Court within the judicial territory of the respective Regional Court. The first instance decisions of the District Courts are subject to appeal before the Courts of Appeal. The time limit for appeal of a first instance judgement is 14 days as of the date of announcement of the judgement and the motives thereto for the parties present or represented at the hearing or as of date of receipt of the court notice that the judgement and the motives are issued - for the parties absent. District Courts and Courts of Appeal sit in panels of three professional judges.

The Supreme Court of Cassation is the third and final instance on civil cases with respect to decisions of the Courts of Appeal and the second instance decisions of the District Courts. However, decisions of the Courts of Appeal and second instance decisions of the District Courts on cases where the value of the claim is below BGN 5,000 (approximately €2,550) are final and are excluded from cassation appeal. The time limit for appeal of a second instance judgement is 30 days as of the date of the announcement of the motivated judgement at a court hearing or as of date of receipt of the notice that the judgement is issued. The Supreme Court of Cassation sits in panels of three professional judges. The parties cannot present new evidence at the cassation instance and can only argue that the parties absent. District Courts and Courts of Appeal sit in panels of three professional judges.

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4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

See answer to question 4.2. Experts are chosen solely by the court from official public lists of experts from a particular field of science, profession or practice. The lists are adopted by a special magistrates’ commission and are updated annually.

The parties may present written expert opinions prepared by experts of their own but the opinions will be considered as private statements originating from an interested party.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

No. As an exception, witnesses can be interrogated before the trial only in case there is danger that the collection of their statements would be hindered or prevented at the time of the trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

It is only required that the claimant attach to his claim all supporting documentary evidence at his possession. In case the claim is found admissible by the court copies of the claim and the supporting documentary evidence are sent to the defendant.

Only in the specific hypothesis where there is danger of destruction or loss of evidence or that its collection would be hindered or prevented, a party may request from the court to order certain preventive measures in order to collect such evidence.

A party may also request the court to order a third party to present a specific document in its possession which is of relevance to the subject matter of the case.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have discretion to disapply time limits?

A general remark: the lapse of the time limit specified in the law only precludes the right to file a claim and does not extinguish the substantive right to compensation for the damages suffered - any payment made by the manufacturer to the injured person after the lapse of the time limit shall not constitute unjustified enrichment and shall not be subject to reimbursement.

In case of strict liability the claim for compensation has to be filed with the court within 5 years from the date on which the injured person became or should have become aware about the damage, the defect and the identity of the manufacturer but in all cases not later than 10 years from the date on which the defective product was put on the market.

In case of tort - within 5 years starting from the date when the manufacturer of the defective product, has become known to the injured person.

In case of contract the time limit for filing of a claim for compensation for damages caused by a non-performance of contract is set at 3 years from the date on which the receivable has become due and payable.

In principle, age or condition of the claimant does not affect the calculation of the time limits. However, the OCA
stipulates that the running of the time limit shall be suspended in respect of minors (under the age of 18 years) or judicially disabled individuals for the period during which they do not have a duly appointed statutory representative or guardian and for 6 months after the appointment of such or, respectively, after the end of the judicial incapacity. The court has no discretion to disapply time limits, but they cannot be applied ex officio - such defence must be explicitly raised by the defendant.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment and fraud are not among the exhaustively listed grounds for suspension or discontinuance of the running of time limits under the OCA.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

As explained above under the strict product liability system only material damages, both actual damages (damnum emergens) and lost profits (lucrum cessans), resulting in personal injury, death or damage to objects, other than the defective product itself, in the property of the injured person are recoverable. The consumer would have legal interest to claim compensation under the special strict liability regime provided the defective product has damaged other goods to the extent of more than two minimal monthly salaries, as established by the Council of Ministers, at the time of causing the damages - this limit at present is at BGN 300 (€150). In cases of personal injury no such limitation is set.

The moral damages (pain and suffering), resulting from caused death, disability, health deterioration etc., may be compensated on the grounds of tort liability as set in Art. 52 and Art. 45 of OCA. In those cases the court would rule on the moral damages based on equity and deliberating not only on the scope of the compensation and the types of sufferings for which such compensation is awarded, but also on the line of persons that may have legitimate claim for such damages incurred. According to the jurisprudence as unified by the mandatory interpretative resolutions of the Supreme Court, presumably interested parties, that may initiate such a claim, could be: the closest relatives and the persons in factual relationships resembling those of adoption and marriage. All other persons claiming damages from death, disabilities etc. of another person would have to prove how the loss / injury incurred to another person has affected them.

The general rules of tort are applicable in cases where pursuant to Art. 15, par. 4 of the CPA, the claim for compensation of material damages (strict product liability) was not granted. In such cases the consumer may choose to claim the same compensation in accordance with the general rules of tort as set in Art. 45 - 54 of the OCA.

The damage to the product itself is recoverable based on the contractual relationship between the seller (in most cases retailer) and the consumer.

Under all forms of civil liability only direct damages are recoverable - the obligation for compensation is set as the top limitation of the civil liability. Direct damages are result of the causation as explained in question 2.2 hereto. Under contractual liability, however, a lower limit of the damages is set if the defaulting contractual party is being only negligent, failing the professional due care test. In that case only foreseeable at the time of the formation of contract damages may be compensated. Foreseeable are damages whose occurrence is foreseeable if the debtor applies the standard pater familias care.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

So far the Bulgarian jurisprudence has been very consistent that in order for a compensation to be awarded there has to be actual damage incurred. The case of medical monitoring relates to potential damages, normally associated to certain risk factors. Given the present legal standards in Bulgaria, only medical expenses following and in direct relation to the damage could be recovered.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

The civil liability in Bulgaria, including the strict product liability, has only compensatory, no punitive function. The principle is that civil liability distributes the damages arising from a contractual default, tort or strict product liability, relieving the suffering party and providing the wrongdoer, manufacturer, importer or retailer (for strict liability) with additional obligation for compensation. As mentioned above direct damages represent limitation of the civil liability in any form. The only exception is the case where the parties to a contract explicitly stipulate punitive forfeit which may exceed several times the actual scope of the damages potentially incurred.

Notwithstanding the above, the CPA provides for the legal solution of administrative penalties - fines which in certain cases could reach a maximum of BGN 30,000 (approximately €15,300).

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The CPA aims at balancing the consumer interests with the interests of manufacturers, importers and retailers, because the public interest of an efficient, productive and growing economy would not be satisfied if strict product liability, favouring the consumer, is unlimited with respect to identical incidents related to defective products, produced by one and the same manufacturer. As per Art. 17 of the CPA the accumulative amount of compensations that a manufacturer may be obliged to pay for death or personal injury of several injured persons, caused by one and the same defect of identical products, is set at BGN 100 million (approximately €51 million). As for the claims based on general tort liability no maximum limit set in the form of a fixed amount exists.
7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In principle, the losing party must bear the legal costs to the extent established by the law. However, the costs awarded by the court to the successful party are in practice lower than the actual costs incurred on the case.

In cases of litigation related to product liability issues the general rules in the Bulgarian legislation regarding litigation expenses apply. Court fees and litigation expenses paid by the claimant, as well as the remuneration for one advocate should be recovered in relation to the award on the claim. If the award is partial then the consumer would bear the respective part of the expenses incurred.

Other legal costs and expenses related to the litigation are subject to the general rules of indemnification and accordingly would have to be proved to become direct damages as explained in questions 2.2 and 6.1 hereto.

7.2 Is public funding e.g. legal aid, available?

Yes. Legal aid, financed by the state budget, is available to individuals in difficult material situation. Such individuals are entitled to file a request for waiver of the court fees to the chairman of the competent District Court or to the regional court judge. There are no specific criteria or thresholds as to the persons eligible to such legal aid specified in the law. In addition to that advocates are permitted to represent pro bono individuals in difficult material situation.

7.3 If so, are there any restrictions on the availability of public funding?

The law does not provide for any requirements or restrictions on the availability of legal aid. The judges have discretion to apply the court fees waiver on a case-by-case basis.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The new Advocacy Act (2004) introduced contingency fees with the rule that advocate’s remuneration may be agreed in the contract between the advocate and the client as a lump sum and/or percent of certain proprietary interest depending upon the outcome of the trial. The applicability of the above provision is only excluded in respect of criminal cases and civil cases with non-material interest.

In all cases with regard to the advocate’s remuneration the Advocacy Act stipulates that it has to be specified in a written contract and its amount must be fair and justified, not less than the minimum thresholds laid down in a regulation of the Supreme Bar Council.

Acknowledgment

This chapter was prepared jointly by Borislav Bozhidarov, Pavel Hristov and Violeta Hristova of Borislav Boyanov & Co.

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Product liability is available in respect of damage to persons or property resulting from the supply of products found to be defective or faulty, and in respect of “pure economic losses” in more limited circumstances. Liability is primarily fault based, in the absence of contractual privity or warranty, although consumer protection statutes in some provinces create implied warranties between manufacturers or distributors on the one hand and users of products on the other, where privity of contract does not otherwise exist. Where there are implied warranties or contractual privity, liability is, in effect, strict where a product is found to be defective. Where an injured person sues the party that sold a defective product in contract, and each of the other parties in the contractual chain of distribution are brought into the lawsuit, contractual liability can play a prominent role.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Certain statutory obligations to recall products exist in Canada for specific products. For example, there is a right in the Minister of Agriculture to order a recall under the Canadian Food Inspection Agency Act. In the prescription medicines and medical devices context, there is no legal obligation to recall; however, if a recall occurs, there are reporting obligations. A claim for “failure to recall” would be brought by an injured person as a claim in negligence for failure to exercise a reasonable standard of care in the “putting up” of the product. The claim may be asserted as a claim for negligence in the design or manufacture of the product (the recall could be evidence of a defect, although not of negligence in the manufacture or design). It may also be asserted as a claim for failure to warn of dangers inherent in the use of the product. The duty to warn in negligence continues after the product is sold and includes a duty to warn of dangers discovered after the product is sold. (See for example, Hollis v. Dow Corning, [1995] 4 S.C.R. 634; Nicholson v. John Deere (1986), 58 O.R. (2d) 53 (H.C.); Willar v. Ford Motor Co. of Canada Ltd., [1991] N.B.J. No. 843 (Q.B); Can-Arc Helicopters Ltd V. Textron Inc., (1991) 86 D.L.R. (4th) 404 (B.C.S.C.).)
However, with respect to manufacturing defects, if the plaintiff can establish that the product came off the manufacturing line in a manner not intended (i.e. inconsistent with the design specifications), the court will assume negligence (either by an employee or in the production process) and will not require a plaintiff to establish where in the production process the negligence occurred. In the context of a contractual or warranty claim, the claimant has the burden of proving a defect in the product. The claimant also has the burden of proving that the negligence or defect caused or materially contributed to damage.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The test for proof of causation is “caused or materially contributed to” the injury or loss (see Athey v. Leonati, [1986] 3 S.C.R. 458 (Q.L.) at para. 18; Mizzi v. Hopkins (2003), 64 O.R. (3d) 365 (C.A.).) Proof of exposure to increased risk of a type of injury that the claimant ultimately experienced will not alone be sufficient as a matter of law to find causation, although the court can draw inferences of causation from all of the evidence including evidence of an increased risk of the very injury the claimant suffered (see Snell v. Farrell, [1990] 72 D.L.R. (4th) 289 (S.C.C.)).

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The plaintiff must prove on a balance of probabilities which of the several possible producers manufactured the defective product, unless products of all of the manufacturers were defective, were used by the claimant and increased the risk of the injury the claimant suffered. (See Cook v. Lewis, [1951] S.C.R. 830; and Fairchild v. Glenhaven Funeral Services Ltd., [2002] 3 All ER 305 (H.L.) - although a UK case, it may well be considered persuasive in Canada). Market share product liability has not been recognised in Canada.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Manufacturers have a duty to warn users of their products of dangers inherent in their use, and their foreseeable misuse. Ordinarily, the warnings that will be considered are those provided directly to the injured party. However, a “learned intermediary” exception to the manufacturer’s duty to warn will be recognised where the product is highly technical in nature and intended only to be used under the supervision of experts or the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using the product, and where an intermediate inspection of the product is anticipated or where a consumer is placing primary reliance on the judgement of the learned intermediary and not the manufacturer. The “learned intermediary” exception applies where the intermediary has been fully apprised of the risks by the manufacturer and the manufacturer has taken adequate steps to ensure that the intermediaries’ knowledge of the risks approximates its own. (See Hollis v. Dow Corning, supra.) The “learned intermediary” exception has been applied by Canadian courts for prescription medicines and implanted medical devices.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defences available may include absence of a duty to the injured person (depending on proximity and foreseeability), although this defence is not typically available where the claimant is the direct user of the product; absence of negligence (no breach of the applicable standard of care) in the context of allegations of design defect or failure to warn; absence of defect; lack of causation; and voluntary assumption of risk (where the plaintiff knows of the defect and continues to use the product). In the context of a failure to warn allegation, defences include the “learned intermediary” exception described in question 2.4 above, that the warning was adequate, and that, subjectively, a warning would not have changed the user’s behaviour. Concepts of voluntary assumption of risk, intervening act and intermediate inspection in the context of a manufacturing or design defect claim will often not absolve a manufacturer of all liability because Canadian provinces typically have a “joint and several liability” regime - a manufacturer may need to plead contributory negligence, or
There is no “state of the art/development risk” defence in Canada, although evidence of the state of the art is admissible to assist in proving that a reasonable standard of care was used in the design or development of the product (see Rentway Canada Inc. v. Laidlaw Transport Ltd., [1989] O.J. No. 786 (H.C.J.); aff’d [1994] O.J. No. 50 (C.A.)). Evidence that a design deficiency in the product or a danger inherent in its use was not discoverable at the time of supply will be admitted as part of the proof that a reasonable standard of care was exercised in the design and warnings of the product. However, there is a continuing duty to warn of the danger once it is known or ought to be known. In all respects, the burden is on the plaintiff to establish negligence, including breach of a reasonable standard of care, on a balance of probabilities.

Canadian courts have held that it is not a defence to show compliance with regulatory and/or statutory requirements relating to the product (see R v. Saskatchewan Wheat Pool [1983] 1 S.C.R. 205), although, if it can be established that a statute or regulation required the product to be manufactured, designed or labelled in the specific way in which it is alleged to be faulty, and in no other way, a defence of statutory compliance may be available (see Ryan v. Victoria (City), [1999] 1 S.C.R. 201). (Likewise statutory non-compliance is not a cause of action, although it may be evidence of negligence - failure to exercise a reasonable standard of care.)

It has generally been held in Canada that issue estoppel only arises between the same parties and will not prevent a non-party from re-litigating issues in separate proceedings. However, this question is the matter of some debate in Canada and the possibility that non-mutual issue estoppel will be recognised exists.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court in most provinces has the power to appoint technical specialists who assist the judge, but the power is infrequently, if ever, used. Expert evidence is presented by the parties.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class actions are permitted in all provinces in Canada, with most having specific class action legislation. In the provinces other than Quebec, an action can be certified as a class action if the claim asserts a sustainable cause of action (which will be assessed based on the pleadings alone), there are two or more persons in the proposed class, the claims of those persons have substantial issues of fact or law in common, it is preferable to resolve the common issues in a class action having regard to the objectives of the legislation - access to justice, judicial economy and behaviour modification, and the proposed representative plaintiff can adequately represent the interests of the class. (See for example the Ontario Class Proceedings Act, S.O. 1992, c.6, sections 5 (test for certification), 11 (stages of class proceedings), and 29 (approval of settlement); Western Shopping Centres Inc. v Dutton, [2001] 25 S.C.R. 534)).

In Quebec, the threshold is even lower than in the other Canadian provinces. Quebec actions will be allowed to proceed as a class action if: the recourses of the members raise identical, similar or related questions of law or fact; the facts alleged seem to justify the conclusions sought; the composition of the group makes the application of article 59 or 67 of the Quebec Civil Code difficult or impractical; and the member to whom the court intends to ascribe the status of representative is in a position to represent the members adequately. Where a class action is certified, discovery and a trial of the common issues will be held first, and then a procedure ordered for resolution of any individual issues (such as causation and damages). Court approval is required for any settlement of a class action. Class actions have been certified in Canada on a national basis. Class actions are commonly brought, and with increasing frequency, in Canada. Representative actions are also permitted in most provinces in very limited circumstances. For example, in Ontario, the court may grant a representation order where the proceeding concerns certain estate or trust issues or the approval of a sale, purchase, settlement or other transaction and there are persons who may have an interest in or be affected by the proceeding who cannot be readily ascertained, found or served.
4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

In most provinces, claims generally not be brought by a representative group such as a consumer association on behalf of a number of claimants, although consumer associations have been known to fund a class action brought by an individual representative plaintiff. However, class action claims can be brought by a representative group in Quebec.

4.5 How long does it normally take to get to trial?

Time to trial varies from province to province, and courthouse to courthouse within each province. Normally, it would take anywhere from two to five years to get to trial.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Preliminary dispositive issues can be determined by judge alone. In most provinces, the court can determine a question of law, based solely on the pleadings, and can also be asked to grant summary judgment where there is no genuine issue of fact for trial. However, summary judgment is not available in Quebec. In addition, some provinces (for example Alberta) have a summary trial procedure available in certain circumstances, whereby the court can determine summarily all or part of the action even if material facts are in dispute and there is a genuine issue for trial. Some provinces also have simplified procedures for smaller claims.

4.7 What appeal options are available?

Appeal options vary from province to province, often depending on whether an issue is final or interlocutory. In all jurisdictions, appeals are generally available, either with leave or as of right. They are typically as of right on final dispositive decisions, to the highest appellate court in the province. Appeals to the Supreme Court of Canada are only granted with leave on questions of national importance.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court does not typically appoint experts to assist in considering technical issues. The parties present expert evidence. Unlike lay witnesses, experts are permitted to give opinion evidence within the sphere of their expertise. The evidence an expert gives must be information that is likely to be outside the experience and knowledge of a judge or jury (see Sopinka on Evidence at 12.27 citing the Supreme Court of Canada in R. v. Abbey, [1982] 2 S.C.R. 24 at 42). To be admitted, expert evidence must be relevant, necessary and given by a properly qualified expert and it must not violate any exclusionary evidence rules. (See R. v. Mohan, [1994] 2 S.C.R. 9; Sopinka supra at 12.30). Novel scientific evidence is subject to special scrutiny to determine its reliability and whether it is essential (see R. v. J.J., [2000] S.C.R. 600).

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Factual witnesses other than the parties themselves and expert witnesses are not typically required to present themselves for pre-trial deposition, although there are exceptions in a few provinces. Information about what witnesses know related to the matters in issue can be obtained through the discovery of the parties to the litigation in advance of trial. In most provinces leave can be given to examine fact witnesses in exceptional circumstances where material evidence is otherwise unavailable to the parties before trial. Experts are required to serve reports of their findings, opinions and conclusions in advance of trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

In most provinces, parties to the litigation are required to disclose all documents relating to any matter in issue in the action that are in their possession, power or control as part of the pre-trial procedures. Relevance is broadly construed and in some jurisdictions, documents must be produced that contain information that may lead to a train of inquiry with respect to the issues. “Documents” are broadly defined and include such items as electronically stored information. In Quebec, however, parties are only obligated to disclose those documents upon which they intend to rely.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

There are statutes of limitation limiting the time for bringing or issuing proceedings which vary from province to province.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

In the product liability context, as a general rule, they range from two years to six years from the day on which the cause of action arose, with the possibility of the period being extended if a reasonable person could not have known of the material facts giving rise to the cause of action through the exercise of reasonable diligence until some time after the events in question occurred. If a government body is being sued, the limitation period may be much shorter. The limitation period generally does not run while a person is a minor or is incapable of commencing a proceeding in...
respect of the claim because of his or her physical, mental or psychological condition.

Within the parameters of the statutes of limitations, the court may have some discretion to determine when a limitation period begins to run. For example, under Ontario’s recent legislation, the court may consider the fact that a notice of possible claim has been served in determining when the limitation period can run.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

If the person against whom a claim is made wilfully conceals the claim from or misleads the person with the claim, the limitation period may not run during that time. The person with the claim has the burden of proving any such concealment.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damages for bodily injury and damage to property are recoverable. Damages for mental distress generally have been held not to be recoverable in the absence of a diagnosable physical or mental illness or at least a “scar on the mind” (see Graham v. MacMillan [2003] B.C.J. No. 334 (C.A.)). However, some provincial courts have held that this issue should be reconsidered following a full trial (see Anderson v. Wilson (1999), 44 O.R. (3d) 673 (C.A.)).

Pure economic loss is often recoverable, particularly where the economic losses were incurred as a result of a failure to warn or misrepresentation, or to remedy a condition that was dangerous to person or property (see Winnipeg Condominium Corporation No. 36 v. Bird Construction Co., [1995] 1 S.C.R. 85). Recovery for damage to the product itself may be available in contract or warranty subject to the terms thereof.

General damages for pain and suffering alone are capped in Canada by common law at today’s equivalent value of $100,000 in 1978 dollars adjusted for inflation according to the Consumer Price Index. As of April 2005, the cap is approximately $290,000.00.

Family members may be able to recover damages for loss of care, guidance and companionship, loss of contribution to the family income and loss of household services. The extent of recovery and circumstances under which recovery is available vary from province to province.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Medical costs are often paid by provincial government health insurers, which, in most provinces, have a statutory right to sue to recover costs from a tortfeasor. Canadian courts have not yet determined whether the costs of medical monitoring are recoverable in circumstances where the product has not yet malfunctioned and caused injury, but they may do so in the near future. The issue has been determined to be one that can proceed to trial in a number of the recent class action cases. (See Nantais v. Telectronics (1995), 25 O.R. (3d) 331 (Gen. Div.); Servier v. Wilson (2000), 50 O.R. (3d) 219 (S.C.J.); Andersen v. St. Jude Medical (2003), 67 O.R. (3d) 136 (S.C.J.).)

6.3 Are punitive damages recoverable? If so, are there any restrictions?

In general, punitive damages are recoverable only where there has been high-handed, malicious, arbitrary or highly reprehensible misconduct that departs to a marked degree from ordinary standards of decent behaviour. Their purpose is not to compensate the plaintiff but to achieve the goals of retribution, deterrence and denunciation of the behaviour (see Whiten v. Pilot Insurance, [2002] 1 S.C.R. 595). In Vorvis v. Insurance Corp. of British Columbia, [1989] 1 S.C.R. 1085, the Supreme Court of Canada also held that, for punitive damages to be awarded in a claim for breach of contract, there must also have been a separate actionable wrong in addition to the breach.

Punitive damages are not recoverable in product liability claims in Quebec. For the other provinces in Canada, awards of punitive damages in product liability cases are extremely rare. The authors are only aware of one product liability case where punitive damages were awarded (see Van Oirschot v. Dow Chemical Canada Inc., [1995] A.J. No. 611 (C.A.) where the plaintiff recovered $10,000.00). In another Canadian case, the court refused to strike out a claim for punitive damages (see Vichek v. Koshel, [1988] B.C.J. No. 2345 (C.A.); S.M. Waddams, Product Liability, 4th ed. (Toronto: Carswell, 2002) at 72) but stated that, for such damages to be awarded, the act must be malicious or reckless to such a degree as to indicate complete indifference to the consequences that might flow therefrom, including the welfare and safety of others. Accordingly, awards of punitive damages will only be made in product liability claims in very limited circumstances.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on damages recoverable from one manufacturer.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As a general rule, most provinces have a “loser pays” costs system whereby the successful party can recover a portion of its own legal costs and disbursements from the losing party. For example, in Ontario, a successful party can recover costs on a “partial indemnity” scale, which, depending on the level of counsel’s billing rates, often approximates from 30 to 50% of the party’s actual legal costs. With the use of offers to settle, a successful plaintiff may be able to recover “substantial indemnity” costs, which are often between 1.5
7.2 Is public funding e.g. legal aid, available?

The availability of legal aid varies from province to province. In Ontario, for example, legal aid would not typically be available for an individual product liability claim. Public funding is, however, available in a number of provinces, including Ontario, for plaintiffs seeking to commence class actions.

7.3 If so, are there any restrictions on the availability of public funding?

Restrictions on the availability of public funding vary from province to province, and depend also on the type of case. For example, in Ontario, where funding is available for class proceedings, the committee reviewing applications for funding may have regard to: the extent to which the issue affects the public interest; the likelihood of certification; and the amount of money in the fund created for that purpose.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are permissible in all provinces in Canada. The conditions vary from province to province. Some provinces require contingency fees to be court-approved.
Chapter 17

Chile

Claro y Cía.

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Chilean Law establishes liability for defective products, for dangerous products, for unreasonable discrimination by suppliers, for false or delayed information, for deceptive publicity, for unconscionable clauses in pre-drafted agreements and for breach of contract with consumers. In the case of defective products, the consumer can claim, not only damages compensation, but also request that the good be fixed, replaced or that the price be reimbursed. Where damages are claimed the Law assumes the fault of the provider of the good, but she has the chance to prove her due diligence. In the rest of the cases, strict liability operates. Compensation shall include damage to property as well as to persons and material as well as psychological or “moral” damage.

1.2 Does the state operate any schemes of compensation for particular products?

The State does not operate any system of compensation for consumers.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The retail supplier and the importer are severally liable for damage compensation. However, in the case of dangerous products, the retail supplier, the distributor, the importer and the manufacturer are severally liable for damages. On the other hand, the obligations to repair the product or reimburse the price can be claimed from the retail supplier, the manufacturer or the importer.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

There is no rule holding the obligation to recall defective products, but the failure to recall such products if the defendant was aware of the defects can be construed as proof of negligence. In the case of dangerous products, there is an obligation to communicate such circumstance (i) to the authorities so that proper measures can be taken, including the recall of the product; and (ii) to the consumers. If no communication was delivered, a fine will be imposed (also with damages compensation).

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The consumer has to prove that the product is defective and that damages were caused and the defendant has the burden of proving its diligence.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The test of causation is a ‘reasonability test’ so the claimant must prove that damages are reasonably, although not necessarily, traced to the defective or dangerous product. Evidence of an undue exposure to a risk or damage associated to the product may be enough to conclude causation. However, the conclusion about causation is largely at the discretion of the court.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Chilean Law does not establish any rule providing for collective liability, allocating liability among several possible agents or attributing liability where there is no sufficient proof of causation.
2.4 **Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?**

The supplier of hazardous products has the obligation to provide the consumer with warnings and instructions required to its proper use. If such obligation is not properly performed, liability may arise where the damage was caused by the lack of information or its wrongfulness. There is no principle of “learned intermediary” under Chilean Law.

### 3 Defences and Estoppel

**3.1 What defences, if any, are available?**

Where damages are claimed, the defendant may raise the same defences available under general tort or contract law. However, where reimbursement of the price or restoration of the product is claimed no defence can be raised, not even force majeure. However, in this case, the retail supplier can claim reimbursement from the manufacturer, importer or distributor.

**3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?**

The supplier of hazardous products will not be liable if she provides evidence that she undertook (i) the preventive measures provided by specific laws; and (ii) other measures that are required by the nature of the product. Under the latter, a state of the art risk defence may be raised. Defendant can also raise as a defence the unforeseeability of the risk or damage; but the supplier has the burden of proof of the unforeseeability.

**3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?**

The supplier of hazardous products is authorised by the law to raise such defence as explained in question 3.2 above.

**3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?**

The same claimant cannot re-litigate the same issues in a new proceeding once there has been a final decision on the case. In such case, the defendant can raise a ‘res judicata’ defence.

### 4 Procedure

**4.1 Is the trial by a judge or a jury?**

The trial is by a judge. Chile does not have any jury courts.

**4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?**

The judge can appoint an expert so to receive a report from a specialist on the technical issues raised in the case. But, it is the judge who issues the final decision and is not limited by the conclusions of the expert.

**4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?**

There is a class action available for consumers and consumer organisations under which they can claim (i) the imposition of fines to the supplier; (ii) the nullification of unconscionable clauses contained in pre-drafted agreements; (iii) performance of agreements with consumers; (iv) an injunction against violations of the Consumers Act; and (v) compensation of damages. To bring a collective suit before a court, five requirements must be met: (a) a violation of the Consumers Act must be denounced; (b) that the number of potential consumers affected by the violation makes it reasonable, under a cost-benefit analysis, to hear the case under the proceeding of a collective action, (c) the claimant must have standing to bring the suit; (d) that the denounced violation affects the collective interest of the consumers; and (e) that the claim is clearly drafted.

Once the claim is presented to the court, the judge will hear the defendant on the issue of admissibility of the class action and issue a decision. If the class action is admitted, notices will be published in newspapers so that every consumer may participate in the case or request that the results of the case do not affect her. Then, the claim will be answered by the defendant and a term of eight days will be opened so to receive evidence. Finally, the court will issue a decision, only on the issue of liability and on the amount of the compensation for each group of affected consumers.

After the decision of the court is issued, every individual consumer will have the right to appear before the court to present evidence that she is among the group of affected consumers described in the decision of the court so to receive compensation.

At any time the parties may reach an agreement, but it must be approved by the court.
Class actions have not been frequent in Chile.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, a consumer association may bring a collective suit on behalf of any consumers, not only the members of the association.

4.5 How long does it normally take to get to trial?

As class actions were recently incorporated in Chilean Law (July, 2004), it is not clear how long will judges take to handle these cases.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The only instance where the court will be able to determine whether the case shall continue is at the beginning of the proceedings when the court shall decide if the class action is admissible under the law.

4.7 What appeal options are available?

Parties can appeal the decision of the court regarding the admissibility of the class action and of the final decision on the case.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As explained above, the judge can appoint an expert so to receive a report from a specialist on the technical issues raised in the case. But, it is the judge who issues the final decision and the court is not limited by the conclusions of the expert. Parties can also present particular expert reports, but these have much less weight.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Generally, Chilean Law does not provide for pre-trial evidence exchange or discovery.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Parties to a proceeding may request the other party or a third party to present specific documents, duly identified, that are in the possession of the other party or the third party, as evidenced, that are not confidential and that are relevant to the issued of the case. Wide discovery, as authorised in other countries, is not allowed in Chile.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, there are limits.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Unless otherwise provided in the parties’ agreement, the consumer has a term of three months to claim the replacement or reparation of the product or the reimbursement of the price. Any action for the imposition of fines expires after six months. Claims for damages are subject to a statute of limitations of five years. These terms do not depend on the condition of the claimant or the discretion of tribunals.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Those issues do not affect the time limits.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Every direct damage is recoverable.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

It may be possible to claim such damages should the consumer provide conclusive evidence that the medical monitoring is necessary to adequately treat and supervise the consequences of the defective product.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Chilean law does not allow punitive damages.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable from a manufacturer.
7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Although it is possible that the court orders the losing party to reimburse the costs and expenses of the other party, generally the amounts fixed by the courts in such cases are insignificant.

7.2 Is public funding e.g. legal aid, available?

The National Consumer Service supports consumers with advice and may bring actions before the courts. Also, public funding is available to consumers associations. Finally, the

State provides with free lawyers for parties that do not have the means to provide one for themselves.

7.3 If so, are there any restrictions on the availability of public funding?

Consumer Associations shall apply for public funding in an open and competitive bidding procedure. There are no special restrictions for free legal aid.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

There is no rule forbidding a private party to retain a lawyer on a contingency fee basis. Lawyers provided by the State do not charge the parties.

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Chapter 18

Denmark

Kromann Reumert

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?


The producer’s liability for defective products was based on the principles of the Law of Tort until the Product Liability Directive was implemented into Danish law. In Denmark the Law of Tort is not set out in any Act, but has been developed over the years in the courts.

It has previously been held that the Act is a supplement to existing Danish law on product liability and not a replacement. Thus, even in cases of bodily injury and non-commercial property damage, the claimant may also use the ordinary Danish rules. After the judgments of 25 April 2002 of the European Court of Justice in the cases C-52/00, C-154/00 and C-183/00, it is doubtful whether this is still the case; and the Act is rather a replacement of existing rules in case of personal injury or damage to non-commercial goods.

Product liability has generally been defined as a producer’s liability for damage caused by a defect in his product. According to ordinary Danish rules on product liability it is a condition for liability that the defect in the product is due to negligence on the part of the producer. The burden of proving negligence is not onerous.

The main difference between contract law and tort in relation to product liability is the limitation period for bringing claims. According to the Sale of Goods Act the limitation period is 2 years from delivery of the goods.

Although product liability is not governed by the Sale of Goods Act of 1906, the existence of a contract between the parties can be of relevance. If the contract is entered into between professionals it may regulate, limit or eliminate product liability. The contract may state certain obligations of the professional purchaser to check the product. Danish courts will not accept limitation of liability for product damage in case of personal injury and, as a main rule, limitation of liability will not be accepted if the seller has shown gross negligence. Danish courts tend to be critical in their interpretation of limitation on liability using the in dubio contra stipulatorem rule of interpretation.

Under the Product Liability Act it is not possible to limit or eliminate product liability.

1.2 Does the state operate any schemes of compensation for particular products?

Patients who suffer damage from drugs may claim damages from the Government according to Act No. 1120 of 20 December 1995 with later amendments on Damage from Use of Drugs. The Act gives the Government the right of recourse against the producer according to product liability rules, cf. section 16, subsection 1.

Existing acts on liability for nuclear plants, vaccine damage and damage occurring during military service deal with product liability in these specific areas.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

According to ordinary Danish rules on product liability the producer bears responsibility for the fault/defect. According to the Product Liability Act (produktansvarsloven) the producer - as defined in the directive art. 3 - bears responsibility for the defect.

Since the 1930’s it has been held that the supplier is immediately liable for defects in the product delivered by the producer even though the supplier has not acted negligently himself (the supplier then has a right of recourse against the producer). Thus, the injured party can choose to hold either
the producer or the supplier or both liable in case of damage. According to the Danish Product Liability Act, section 10, the supplier is immediately liable to the claimant and any other suppliers in the chain of distribution for any product liability incurred by the producer, also in case of personal injury or damage to non-commercial goods regardless of whether the supplier has acted negligently. After the judgment of 25 April 2002 of the European Court of Justice in the case C-52/00, The EU Commission against The French Republic, it is doubtful whether section 10 of the Product Liability Act can be upheld in cases involving personal injury or damage to consumer goods. On 20 January 2005, the Advocate General of the European Court of Justice rendered an opinion in the case C-402/03, Skov æg v. Bilka Lavprisvarehus A/S and Bilka Lavprisvarehus A/S v. Jette Mikkelsen and Michael Due Nielsen, which concluded that Denmark has incorrectly implemented the Product Liability Act. According to the Advocate General, Denmark did so by providing in section 10 of the Product Liability Act that the supplier is immediately liable to the claimant and/or other suppliers lower down the chain of distribution.

A customer suffering injury or damage from a defective product will still be able to sue the supplier under ordinary Danish rules, if the supplier has acted negligently.

### 1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Obligations to recall products are governed by the Act on Products Safety (produktsikkerhedsloven), which implements the Product Safety Directives 92/59 and 2001/95. A failure to recall under the obligations of the Product Safety Act may lead to product liability or even criminal sanctions.

Even if recall cannot be required according to the Product Safety Act a producer may be under an obligation to warn relevant parties about possible dangers of the product. A failure to warn may lead to liability according to ordinary rules on product liability.

### 2 Causation

#### 2.1 Who has the burden of proving fault/defect and damage?

Under Tort Law it is for the claimant to prove that the product is defective, that the producer has shown negligence, that a loss has been suffered and that there is causation between the defective product and the loss suffered.

No particular rules exist as to what standard of proof must be met by a claimant or defendant in order to lift his burden of proof. The court is free to evaluate the evidence in the particular case and on the basis of this concrete evaluation the court will determine whether the burden of proof has been lifted or not.

Under the Directive it follows from Article 4 that the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

#### 2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The basic rule of Danish law is that the claimant must prove a causal relationship between his/her particular injury and the defect. There are no rules under Danish law stipulating the standard of proof. The principle of the courts’ freedom to assess evidence applies. The standard of proof is set by the courts in each particular case from an overall assessment of the claimant’s possibilities of providing evidence, the defendant’s situation, the nature of the defect and the situation in general. Danish law does not provide rules on how the court is to assess the evidence. Section 344 of the Danish Administration of Justice Act (retspløjeloven) stipulates that the court, on the basis of what has been presented to the court during the trial and the production of evidence, decides on which facts of the case to base its decision.

The courts’ freedom to assess evidence applies to all evidence, both direct evidence, e.g. witnesses or technical equipment (cameras, measuring devices, etc.) having observed a particular event, and indirect evidence where the court from the circumstances of the case decides on what fact to base its decision.

It is not impossible that a court of law on the basis of strong statistical evidence could find that it is enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product. Even if it cannot be proved by the claimant that the injury would not have arisen without such exposure. It is, however, a prerequisite that the statistical evidence with a very high degree of certainty must exclude that the particular injury could have other causes.

#### 2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If it cannot be established which of several possible producers have manufactured the defective product, the claimant has not lifted his burden of proving who the producer/responsible party is. It is for the courts to decide how onerous the burden of proof is in the particular situation. No form of market-share liability applies.
2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure to warn can give rise to a liability. The producer has an obligation to warn anyone who the producer knows or should have known is in possession or will be in possession of the particular product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

See the answer to question 3.2.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Under tort law and under the Product Liability Act (which implements the Product Liability Directive), the producer is not liable, if he can prove state of the art defence or prove that the damage suffered is a so-called system damage i.e. a case of damage from a product with known but unavoidable defects (e.g. tobacco). As examples from court practice concerning system damage, reference is made to the Danish Supreme Court case, UfR 1931.1044 H (the Danish weekly law reports), where a coat collar was coloured with paraphenylendiamin which caused eczema. The particular dyestuff was commonly used in the entire world and only caused eczema in very few cases. As the use of the dyestuff was not prohibited the producer was not held liable. Another example is the Danish Eastern High Court case, UfR 1947.656 Ø, where a consumer reacted to formaldehyde, which had a known but acceptable adverse effect on a few people.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

It is not necessarily a defence for the producer that he has complied with regulatory or statutory requirements, but it will be a strong argument when assessing whether the product is defective.

The producer is not liable if he proves that the defect is caused by the product having to conform to mandatory statutory requirements, cf. the Product Liability Act, section 7. This also applies to product liability according to Tort Law.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A claimant can litigate issues of fault, defect or the capability of the product to cause damage even though another claimant has litigated regarding the same issues. However, the first trial may have a substantial effect on the second trial.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is by a judge, never a jury.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The parties can ask for a court-appointed expert to answer questions formulated by the parties and accepted by the court with regard to factual or scientific issues. The expert is appointed by the court and the rules on judges’ impartiality apply to these experts as well. The expert will give written answers to the questions raised, and can be heard as a witness.

A case before the Maritime and Commercial Court in Copenhagen will be heard by one judge with a legal background and two or four lay judges with either a maritime or commercial background, i.e. experts within a particular field.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

A class action system does not exist and there are no rules in the Danish Administration of Justice Act regarding representative actions or other representative procedures.

There are provisions in the Administration of Justice Act, which make it possible for different claimants to consolidate their claims against the same defendant, if the claims concern the same issue. Thus, in case of a series of damage it has happened that a number of claimants - usually represented by the same lawyer - have consolidated their claims in one single action against the defendant, producer or distributor.
4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

See the answer to question 4.3 above.

A representative body can intervene in an existing trial or can litigate on behalf of a claimant.

4.5 How long does it normally take to get to trial?

Court cases generally progress slowly and, depending on its complexity, a product liability case will invariably last 1-3 years in the first instance. In the second instance it will usually take less time to pursue the claim.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court can try preliminary issues, the result of which determines whether the remainder of the trial should proceed.

Thus questions of jurisdiction, capacity to sue and time limits may be dealt with on a preliminary basis. If there is an advantage to it, the court may decide that the question of liability should be dealt with before the question of damages is handled.

4.7 What appeal options are available?

The ordinary courts in Denmark are organised in a 3-tier system: City Courts, High Courts and a Supreme Court. Denmark is divided into 82 city court districts with 1 judge dealing with civil and criminal matters.

The second tier consists of 2 courts of appeal, Eastern High Court (Østre Landsret) seated in Copenhagen and Western High Court (Vestre Landsret) seated in Viborg. At present there are 64 judges at The Eastern High Court and 39 judges at The Western High Court. Three judges will participate in a case.

With status as a high court The Maritime and Commercial Court is seated in Copenhagen. This court will sit with one judge with a legal background and two or four lay judges with either a maritime or a commercial background.

The Supreme Court is situated in Copenhagen and consists of 19 judges, one of whom is the president. The Supreme Court is an appeal court for judgments rendered by the two regional High Courts of Appeal and by The Maritime and Commercial Court in Copenhagen. At least 5 judges will participate in a case.

All cases with a value of less than DKK1,000,000 are heard by the city court on first instance. Cases with a value of more than DKK1,000,000 can at the request of one of the parties be heard at one of the two high courts on the first instance.

The judicial system is based on the principle that a case may be tried at two instances, and that further appeal requires permission. Judgments of less than DKK10,000 cannot be appealed.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

A court of appeal may try questions of fact as well as questions of law. New evidence may be submitted by the parties, but new claims and allegations may only be introduced with the consent of the other party or the court.

As will be seen from the answer to question 4.2 above, experts may be appointed by the court to answer questions of fact or science. An expert opinion unilaterally obtained by a party before legal proceedings have been instituted is usually not admitted as evidence.

To a very limited extent the parties can present expert evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There are no pre-trial depositions under Danish procedural rules.

The expert’s written answers are exchanged prior to trial and may give rise to supplementary questions.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Documentary evidence must be disclosed before written proceedings have been finalised and in advance of trial. Only in very special circumstances will the court admit new evidence during trial.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

In product liability cases involving personal injury or damage to non-commercial goods the time bar is 3 years calculated from the date the injured party knew or ought to have knowledge of the damage, defect and the relevant producer’s name and address. The requirement is that the injured party must be able to identify his claim and the producer. The time bar is interrupted by acknowledgement or commencement of litigation.

Under the Product Liability Act, the 20-year limitation has been replaced by a 10-year limitation calculated from the date when the producer placed the product into commerce and is interrupted by acknowledgement or litigation.

The limitation period for bringing claims for product liability to commercial goods is according to most scholars 5 years calculated from the date on which the claim fell due.

In other words, from the day of the incident causing the damage or from the day the injured person had or ought to have knowledge of the incident. The 5-year time bar is interrupted by acknowledgement of the claim or by commencement of litigation. A 20-year limitation also applies running from the time at which the claim was
founded - that is the time at which the damage occurred. The 20-year time bar is interrupted by a reminder from the claimant. There are, however, legal scholars who are of the opinion that the 3-year time bar applies to all product liability. No judgments have been rendered on the issue.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

See answer to question 5.1.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

To the extent that the producer is liable for product damage due to serious criminal behaviour, e.g. fraud, then the applicable time limit is 20 years.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In case of total loss of or damage to property, the replacement cost, less a deduction for depreciation due to age, wear and tear and reduced applicability, determines the amount of damages payable.

In case of partial loss or damage to property, damages payable equal the cost of repair. If repair does not fully restore the utilisation value or commercial value of the damage to property, compensation may also be claimed for the remaining loss.

In addition to the above the claimant can recover consequential damages.

In case of personal injury the Danish Act on Liabilities and Damages applies. In general, compensation for personal injury in Denmark is low, when compared to other Western European countries and the US. For damage that occurs after 1 July 2002 the level of compensation has been increased to a certain extent.

The following types of damages are recognised: medical expenses, temporary loss of earnings, pain and suffering, permanent injury, permanent loss of earning capacity and compensation for loss of support.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

If at a later stage the product malfunctions or causes injury then previously incurred costs of investigations or tests may be recoverable if the court finds that the costs incurred have been relevant.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

No, punitive damages are not recoverable.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No such limit exists in Denmark.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

A successful party can recover legal costs, including court fees, from the unsuccessful party. The amount recoverable, however, is determined by the court and the amount seldom covers all costs. The court may approve legal costs if for example a party wins some, but not all, points in issue in the case.

7.2 Is public funding e.g. legal aid, available?

Denmark has a system of legal aid, which is governed by the Administration of Justice Act. The County Authority can grant legal aid. If legal aid is refused the applicant can appeal to the Ministry of Justice. It is a requirement that the applicant is of moderate financial means, however, a substantial number of Danish families will meet the conditions. As of 2005 the annual income for a single person must not exceed DKK236,000, for a married person the household income must not exceed DKK300,000 with DKK41,000 added per child. It is a condition of obtaining legal aid that the chances of winning the case in court are reasonably good. The local municipality grants legal aid and they will evaluate whether chances of winning are good. Their evaluation is discretionary, but the decision can be appealed to the Ministry of Justice. In certain cases legal aid may be granted even though the financial criteria are not met or the chances of winning are not reasonably good, if the case involves issues that are of fundamental interest.

Many families have a limited access to legal aid according to their private insurance, usually limited to a moderate sum.

7.3 If so, are there any restrictions on the availability of public funding?

See answer to question 7.2.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

There is no tradition for contingency fee arrangements in Denmark.
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### 1 Liability Systems

#### 1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Product liability claims may be made under the Consumer Protection Act 1987 ("CPA"), in negligence or in respect of breach of contract.

The CPA, which implements the Product Liability Directive, 85/374/EEC, in the UK, imposes liability on the producer of defective products for damage caused by the defect. A product is defective if it is not as “safe as persons generally are entitled to expect” taking account of a number of factors including any instructions or warnings provided with the product and the manner in which it has been marketed. Liability is strict: it is not necessary to prove that the manufacturer was at fault in causing the defect. The Claimant need only prove a defect and a causal relationship between the defect and the injury.

Claims may only be brought under the CPA in respect of products put into circulation (i.e. entering the distribution chain) after 1 March 1988. Claims relating to products supplied before this date must be brought in negligence or for breach of contract.

In order to establish negligence, it is necessary to prove that the Defendant owed a duty of care to the Claimant, that he breached that duty by failing to take reasonable care, and that the breach caused the damage complained of. Such claims are commonly brought against the manufacturer of a defective product, although they may also be brought against other parties in the supply chain, if fault can be established.

Claims for breach of contract may only be brought against the immediate supplier of the defective product to the person injured. Liability is strict where the contract has been breached and will depend upon the terms of the contract agreed between the parties or implied into the contract. Under the Sale of Goods Act 1979 (as amended) and the Supply of Goods and Services Act 1982 standard terms are implied into all contracts for the sale of goods, unless the parties agree to exclude them. Products sold in the course of business must be:
- of satisfactory quality;
- reasonably fit for their stated purpose made known by
- comply with the description applied to them or a sample supplied.

The seller will not be liable for faults drawn to the buyer’s attention prior to the contract, or which should have been revealed by the buyer’s examination of the goods.

Additional obligations apply to contracts between a business and a consumer ("consumer contracts"). There is a presumption that goods that malfunction during the first 6 months after delivery were in breach of contract at the time of supply. Public statements made by manufacturers, importers, distributors and retailers of the product, for example in labelling and advertising, must also be factually correct and form part of the retailer’s contract with the consumer.

There are also restrictions on the extent to which manufacturers, retailers and others in the supply chain can exclude or limit their liability. Under the Unfair Contract Terms Act 1977 the implied terms of satisfactory quality and fitness for purpose cannot be excluded in consumer contracts (and they may only be excluded in business contracts if the exclusion is reasonable). Liability under the CPA and for death or personal injury resulting from negligence can never be excluded. Other liability for negligence may only be excluded if the restriction is reasonable. Additional rights apply in respect of standard terms not individually negotiated with consumers.

In practice, claims for breach of contract are rarely brought in respect of the supply of defective medicines. Where medicines are supplied on prescription by the National Health Service there is no contract between the patient and the prescribing doctor or the pharmacist dispensing the drugs. In general contractual claims will therefore only arise where medicines are supplied privately.

#### 1.2 Does the state operate any schemes of compensation for particular products?

Yes. Under the Vaccines Damage Payments Act 1979 fixed compensation is paid to persons suffering severe disablement as a result of certain vaccinations. Compensation schemes are also sometimes set up to resolve specific claims e.g. the schemes relating to HIV and Hepatitis C contamination of blood products.
1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under section 2 of the CPA liability principally rests on the ‘producer’ (the manufacturer), or the importer of the product into the EU, or an own brander (i.e. any person who, by labelling or the use of trademarks, holds himself out as being the producer of the product). The supplier (whether the retailer, distributor or a wholesaler) may be liable in place of the manufacturer if, in response to a request by the Claimant, he fails to identify the producer or at least the person who supplied the product to him. The issue of whether a request by the Claimant is necessary on a true interpretation of the Directive, or whether the supplier has an automatic obligation to name the producer or his immediate supplier, has arisen in the context of a pending reference to the European Court of Justice from the English Court. In negligence fault rests on the party found to be negligent; this can be any person or organisation in the supply chain. Contractual liability may be passed down the supply chain through a series of contractual agreements between the manufacturer, distributor, retail supplier, customer and others, depending on proof of breach of the contractual terms in each case and subject to any exclusion clauses.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Claims for a failure to recall may be brought under the CPA, in negligence and in contract. A duty to withdraw unsafe products underpins the CPA as this imposes strict liability for defective products. Manufacturers/retailers may owe a duty of care in negligence to institute a recall or product withdrawal in appropriate cases. They owe a duty to keep the products they produce/supply under review and to warn of risks that come to light after the product has been supplied. If warnings are not adequate to manage the risk the product may need to be modified or withdrawn. Under the General Product Safety Regulations 1994 producers must ensure that they only place safe products on the market, and must take measures to manage any risks that are identified including, in appropriate cases, issuing warnings or withdrawing the product from the market. Although the regulations impose criminal penalties, breach of the requirements may be of evidential value in supporting the product may need to be modified or withdrawn. Under the General Product Safety Regulations 1994 producers must ensure that they only place safe products on the market, and must take measures to manage any risks that are identified including, in appropriate cases, issuing warnings or withdrawing the product from the market. Although the regulations impose criminal penalties, breach of the requirements may be of evidential value in supporting the product may need to be modified or withdrawn.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The Claimant has the burden of proving his/her case on the ‘balance of probabilities’:

- Under the CPA, the Claimant must prove that the product is defective, and that the defect caused damage to the Claimant. However, where the producer relies on defences under the CPA, including the development risks defence, the producer has the burden of proving that defence: see the answers to questions 3.1 and 3.2 below.
- In negligence, the Claimant must prove that the Defendant breached the duty of care he owed to the Claimant, and that this negligence caused damage to the Claimant.
- In contract, the Claimant must establish that the Defendant breached his contract with the Claimant by supplying product(s) that did not meet the terms and conditions of the contract, and that such breach damaged the Claimant. The burden of proving breach of contract is reversed in the case of consumer contracts if the product malfunctions in the first 6 months after delivery; the product is presumed not to conform to the contract at the time of supply.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The Claimant has the burden of proving on the balance of probabilities that the Defendant’s product caused the Claimant’s injuries. The traditional test of causation is the ‘but-for test’; the Claimant must prove that, but for the Defendant’s negligence, or (as the case may be) supply of a defective product, the Claimant would not have sustained the injury. However, this rule has recently been relaxed by the House of Lords in Fairchild v Glenhaven Funeral Services Ltd and Others [2002] 3 All ER 305 in the context of workplace injuries involving negligent exposure to asbestos. The court held that where the state of scientific knowledge means it is impossible to prove by whose negligent act the injury was caused, but the probable cause is the Defendant’s breach of duty or a similar wrongful act or omission by another party (the injury could not have been caused by an innocent act or omission), it is sufficient for the Claimant to show that the Defendant’s wrongdoing materially increased the risk of injury. It is uncertain whether the courts will extend this approach - which was declared to be responsive to very particular factual circumstances - to product liability cases. It is also difficult to see how this approach has any application to a case in which the capability of the product to cause damage is not well established.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

At present the position remains that, where it cannot be established which of several possible producers manufactured the defective product, the Claimant’s evidential burden cannot be met and the claim will be dismissed. The English courts have not adopted so called
2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure to warn may give rise to liability under both the CPA and in negligence.

The CPA provides that the “get up” of the product and any instructions or warnings relating to its use form part of the circumstances to be taken into account in assessing if the product is defective. Whilst it seems clear that warnings provided directly to consumers with the product must be taken into account in assessing liability under the CPA, the relevance of warnings provided to intermediaries, such as doctors, is uncertain and has not yet been decided by the English courts. In the so-called “Hepatitis C” case (A and Others v The National Blood Authority and Others [2001] 3 All ER 298) the Court ruled that that the medical profession’s knowledge of the possible risk of infection with Hepatitis C virus arising from use of blood products was irrelevant in assessing whether those products were defective. Defect was assessed by reference to the legitimate expectations of the public at large. The fact that physicians were aware of the risks of infection was irrelevant as they did not generally inform patients of those risks and the risks were therefore not known and accepted by patients. It remains uncertain how the English courts would approach this issue if there was evidence that the intermediary generally provided warnings to consumers.

In negligence manufacturers and suppliers owe a duty to take reasonable care to provide adequate warnings and instructions with their products. There is no duty to warn of dangers that are obvious or a matter of common knowledge (see for example, Bogle and others v McDonalds Restaurants Ltd [2002] All ER (D) 436 where the court found that McDonalds were not negligent in supplying cups of hot tea and coffee without a warning as consumers generally knew that there was a risk of scalding if hot drinks were spilled). Manufacturers owe a duty to warn of dangers identified after the product was first supplied.

In some circumstances warnings provided to learned or responsible intermediaries may be sufficient to discharge the manufacturer’s duty of care in negligence. Whether such a warning is sufficient will depend on factors including the likelihood and gravity of the risk and the practicality of providing a personal warning to the ultimate consumer. The learned intermediary doctrine has become less important in cases involving medicinal products as manufacturers of medicines are now required to provide patient information leaflets with their medicines unless the warnings and information can be provided on the container or outer packaging of the product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the CPA the following defences are available:

- the defect is due to compliance with legal obligations imposed by UK or EU law;
- the defective product was not supplied by the Defendant;
- the product was not supplied for profit and in the course of business;
- the defect did not exist at the time the product was supplied;
- the so-called “development risks defence” applies: the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the allegedly defective product might be expected to have discovered the defect if it had existed in his products while they were under his control; and
- if the product was a component used in another product, the producer of the component will not be liable if he can show that the defect was due to the design of the final product, or to defective specifications provided to the component producer by the producer of the final product.

The Defendant has the burden of proving each of these defences. Liability may also be limited by the principles of contributory negligence, if the Claimant’s negligence contributed to the damage. This applies both to claims in negligence and under the CPA.

In negligence it is a defence if the Claimant freely and voluntarily agreed to run the risk of injury in full knowledge of the nature and extent of the risk (volenti). Otherwise, the Defendant will defeat the claim if the Claimant cannot establish each of the elements of negligence. Thus if the Defendant can show that no duty was owed, or his conduct was reasonable, or the negligent act or omission was not causally related to the damage, he will escape liability. Proof that the fault in the product was not discoverable based on the state of scientific knowledge at the time of supply is often described as the ‘state of the art’ defence (see the answer to question 3.2 below). In contract no specific defences arise, but the claim will fail if the Claimant cannot establish the breach of contract and damage due to that breach.
3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes. The UK Government opted to include the development risks defence in the CPA; see the answer to question 3.1 above. Under the CPA the Defendant has the burden of proving the defence.

The defence has recently been considered by the English courts in the “Hepatitis C” case, which found that its scope is limited. Based on current authority the defence applies if the defect was not discoverable in the light of the scientific and technical knowledge at the time the product was supplied. The Defendant’s conduct is irrelevant. The court found that the defence was not available if the existence of the defect in the product was, or should have been, known. It was irrelevant whether or not the defect could be avoided because measures to identify and rectify the defect were impractical or impossible.

In negligence, whether the Defendant exercised reasonable care in relation to the design/development, manufacture, supply, marketing and, in appropriate cases, licensing of the product, will be assessed in the light of the state of scientific and technical knowledge at the time these activities were carried out. Manufacturers also owe a continuing duty to warn of any faults identified after the product has been supplied and, where a warning is not sufficient, to modify or withdraw the product. If the Defendant manufacturer is able to show that he acted in the way that a reasonable manufacturer would have done, this is often described as the “state of the art” defence. It is significantly wider than the development risks defence outlined above, because the Court must assess the Defendant’s conduct; not just whether the defect was discoverable. Factors such as whether the defect could be avoided, and compliance with statutory obligations are relevant.

These issues are not relevant to claims for breach of contract.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

It is a defence to proceedings under the CPA if the manufacturer can show that the defect is due to compliance with UK or EU laws. Otherwise there is no general defence under the CPA, in negligence, or in contract, in circumstances where the manufacturer is able to demonstrate compliance with regulatory and statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product.

Such compliance is, however, of evidential value, and may help in the defence of negligence claims by demonstrating that the manufacturer exercised reasonable care. Although the Defendant’s conduct is irrelevant for the purpose of proceedings under the CPA, evidence that the Defendant had in place appropriate systems to detect any defects in the product and for post marketing surveillance may also be relevant to the question of whether a defect was “discoverable” for the purpose of establishing that the development risks defence is applicable. Such systems are commonly mandated by statute, for example, in the field of medicines and medical devices.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

In general, a final judgment or order is conclusive as between the parties to the proceedings and their successors (save where the judgment can be set aside, for example because of fraud, or because the decision was not based on the merits). An estoppel arises that prevents the parties from re-litigating in subsequent proceedings the decision or any issues that were an essential part of the legal basis of the judgment.

In principle, an estoppel cannot arise in proceedings involving non-parties. However, in certain circumstances it may be possible to defeat a challenge to a prior decision by a party to that decision on grounds of abuse of process. For example, it may be an abuse of process in group litigation to seek to re-litigate in the individual proceedings generic issues decided in the lead actions. Even if the doctrines of estoppel and abuse of process do not apply, the prior findings of another court based on similar facts are likely to be persuasive.
procedural rules for the conduct of proceedings in England and Wales, the parties to any proceedings must be notified of the appointment of the proposed assessor and can raise objections.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Yes. Where claims give rise to common or related issues of fact or law the court has power to make a group litigation order (GLO) enabling it to manage the claims covered by the Order in a co-ordinated way. Many group claims have been brought over the last 30 years in relation to defective products and medicines, cases of industrial disease and sudden accidents or disasters.

Once a GLO has been made a group register will be established on which details of the individual claims to be managed under the GLO are entered. A managing judge will also be appointed with overall responsibility for case management of the litigation. He may be assisted by a Master or District Judge appointed to deal with procedural matters.

Co-ordinating judges have an extremely wide discretion to manage the litigation as they see fit. The court will usually make directions, including directing the transfer of claims to the court that will manage the litigation, giving directions to publicise the GLO so that Claimants may join the group register, and imposing a cut-off date during which claims proceeding under the GLO must be issued. The court often also appoints lead solicitors to act on behalf of the Claimants and Defendants.

There is no equivalent to the US class action procedure: claims managed under a GLO remain individual actions in their own right. However, the court will usually order that one or more actions that are representative of the rest of the claims cohort are tried as lead cases. The outcome of the lead actions is not determinative of the remaining cohort of claims, but those actions will lay down principles of law and fact that may simplify the subsequent actions allowing the parties to compromise the litigation or bring further proceedings clarifying any remaining points of principle.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No - not in the product liability field. Proceedings must be brought by the person/body that has suffered the damage/injury. Following public consultation the UK Government (Lord Chancellor’s Department) rejected calls for the introduction of a general right to bring representative civil claims.

4.5 How long does it normally take to get to trial?

This depends on the complexity of the case and the value of the claim. According to the 2003 Judicial Statistics published by the Lord Chancellor’s Department unitary actions proceeding in the High Court, on average, took between 2½ and 3½ years from the issue of proceedings until trial. Cases brought in the County Court generally proceed more rapidly and in 2003 took approximately 14 months. Complex group actions may take many years to come to trial. For example, in the third generation oral contraceptives litigation it took approximately 6½ years from the issue of the first proceedings until judgment. In all cases, delay is largely a result of the conduct of the parties and is not inherent in the court system.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes. In accordance with his general case management powers the Judge can order the trial of preliminary issues of law and fact in separate proceedings prior to the main trial, and can decide the order in which issues are to be tried in the main trial.

4.7 What appeal options are available?

An appeal may only be made with the permission of the court (either the appeal court or the lower court that made the decision subject to appeal) and such permission will only be granted if the appeal appears to have a real prospect of success or there are other compelling reasons why it should be heard.

The appeal will usually be limited to a review of the lower court’s decision, but the court retains the power to order a re-hearing in the interests of justice. An appeal will be allowed where the decision of the lower court was wrong (because the court made an error of law, or of fact, or in the exercise of its discretion) or was unjust because of a serious procedural or other irregularity of the lower court. However, in practice, the courts will rarely disturb findings of fact made by the trial judge who had the benefit of hearing first hand the witness and expert evidence.

The appeal court may affirm, vary or set aside any order or judgment made by the lower court, order a new trial or hearing or make any other appropriate order.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Experts are generally appointed by the parties to litigation rather than by the courts. No expert may give evidence, whether written or oral, without the court’s permission and the court may, in appropriate cases, dispense with expert evidence or require that evidence on a particular issue be given by a single joint expert. (The court will select a joint expert from a list prepared the parties if they cannot agree who should be instructed).

The extent of the expert evidence that is permitted will depend on the type and value of the claim, with more extensive evidence permitted in complex cases. In all personal injury cases, the Claimant must serve a medical report with his or her Statement of Claim substantiating the injuries alleged in the claim.

Expert evidence should be independent and comprehensive. An expert owes an overriding duty to assist the court on
matters falling within his expertise; and this duty overrides any obligation to the party instructing the expert. Experts can only give evidence on matters of opinion falling within their expertise.

Evidence must be provided in the form of a report disclosed to the other parties. The Court Rules give the parties a right to put written questions to an expert about his or her report in order to clarify the report. Where several experts are instructed it is usual for experts in particular disciplines to meet on a “without prejudice” basis, after the exchange of reports and before giving oral evidence, in order to explore areas of agreement and narrow the matters in dispute.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

The factual and expert evidence that the parties intend to rely upon at trial must be provided in the form of witness statements and expert reports that are disclosed by the parties prior to the trial. Evidence is usually exchanged, but the court may, in appropriate circumstances, direct that it is served sequentially. Factual and expert witnesses are required to give oral evidence at the trial unless the court orders otherwise. However, the witness can only amplify the evidence given in his/her written statement or report with the court’s permission.

Witnesses are not generally required to present themselves for pre-trial deposition. However, the court may order evidence to be given by deposition if the witness is unable to attend the trial. The increased use of video conferencing facilities has reduced the use of depositions in proceedings in England and Wales.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

A party to an action is required to disclose the documents in his control on which he relies and which adversely affect his own case or support another party’s case. A document is in a party’s control if he has, or had, physical possession of it, a right to possession of it, or a right to inspect and take copies of it. The obligation may therefore extend to documents in the hands of a party’s professional advisers or an associated company provided control can be established.

Disclosable documents are identified in a List of Documents served on the opposing party. All disclosed documents can be inspected save for those which are privileged from inspection. Two of the most important types of privilege are “legal advice privilege”, which applies to confidential communications between a lawyer and his client made for the sole or dominant purpose of seeking or giving legal advice and assistance, and “litigation privilege”, which applies to documents between the potential party, his solicitor and any third party, created after litigation is contemplated or pending, for the sole or dominant purpose of seeking or giving advice in relation to the claim, or collecting evidence for use in the litigation. Legal advice privilege only applies to lawyer-client communications with company employees who are regarded as the “client” (generally senior managers or the in-house lawyer), not all employees. Litigation privilege will only apply if there is a real likelihood of litigation, rather than a mere possibility.

The obligation to give disclosure continues until the action is at an end and applies to documents created while the proceedings are underway.

The parties are required to conduct a reasonable and proportionate search for disclosable documents. The duty to disclose the existence of documents is a strict one and is enforced by the court. A party may not rely upon any documents that it does not disclose. Moreover, if a party withholds documentation that should have been disclosed, the court may impose cost penalties or draw an adverse inference.

Disclosure usually takes place after pleadings setting out the parties’ cases have been served. In addition, a party may also seek an order for disclosure of specific documents or classes of documents. However, the court also has power to order pre-action disclosure in appropriate cases in order to fairly dispose of the proceedings. Such disclosure may only be ordered in respect of specific documents or classes of documents that would have to be disclosed in any event once the proceedings are underway.

Any documents disclosed in accordance with these rules may only be used in connection with the proceedings in which they are disclosed until such time as they are referred to at a hearing held in public, or the parties agree, or the court otherwise gives permission.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, see our answer to question 5.2 below.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Under the Limitation Act 1980 the basic limitation period for tortious actions (including negligence claims) and for breach of contract is 6 years from the date on which the cause of action accrued. Additional requirements apply in the case of latent damage caused by negligence.

Special time limits apply to personal injury claims for damages in respect of negligence, nuisance or breach of duty. In such cases, the claim must be brought within 3 years from the date on which the cause of action accrued (i.e. the date of injury or death) or the date of knowledge by the Claimant of certain facts. The date of knowledge is when the Claimant is aware of the identity of the Defendant, that the injury was significant, and that it was attributable in whole or part to the alleged negligence, nuisance or breach of duty. The court has a discretionary power to disapply this time limit where it would be equitable to do so.

Where proceedings are brought under the CPA there is also a general long-stop provision. A right of action under the CPA is extinguished 10 years after the defective product was put into circulation and this applies irrespective of the other provisions of the Limitation Act (including the requirements relating to the date of knowledge set out above).
Special rules apply to persons under a disability, during such period as they are a minor or of unsound mind. In general time only begins to run for limitation purposes when the Claimant dies or ceases to be under a disability. However, the 10 year long-stop for CPA claims still applies.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Where an action is based on the Defendant’s fraud, or the Defendant has deliberately concealed any fact relevant to the Claimant’s right of action, the relevant limitation period does not begin to run until the Claimant has, or could with reasonable diligence have discovered the fraud or concealment.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the CPA, damage includes death or personal injury (including mental injury) or loss of, or damage to, property for private use and consumption (provided the damages recoverable in respect of property loss exceed the minimum threshold of £275). Damages are not recoverable in respect of damage to the defective product itself.

In negligence damages are awarded to put the injured party into the position he would have been if the negligent act had not occurred. Damages can be recovered for death or personal injury (including mental injuries), damage to property and damage to the product itself.

In contract, damages are intended to put the injured party into the position he would have been if the contract was performed. Damages are usually awarded for monetary loss (for example, in respect of damage to property and to the defective product itself), but they can include non-pecuniary losses, such as damages for death or personal injury (including mental injury) where this was within the parties’ contemplation as not unlikely to arise from the breach of contract.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Medical monitoring claims of the type pursued in the USA in recent years have not been litigated before the English courts. English law does not generally permit recovery of the cost of tests or investigations unless the product has actually malfunctioned and caused physical or psychiatric injury or damage. Such medical monitoring costs are usually treated as medical expenses consequential on the main injury.

However, the courts have ruled that in certain circumstances it is possible to recover damages for a recognised psychiatric injury sustained as a result of the Claimant becoming aware that he is at risk of sustaining a serious disease or injury. It does not matter that the Claimant may, in fact, never sustain the disease. In the Creutzfeldt-Jacob Disease Litigation, (Group B Plaintiffs v Medical Research Council and Another 4/1 BMLR 157), the court found that children who were at risk of contracting CJD (but who had not yet contracted the disease and might never do so) could recover damages for psychiatric injuries sustained as a result of knowledge of that risk. Liability was established because of the close relationship between the children and the Defendants who supplied the human growth hormone to them, the fact that they were minors and did not choose the treatment, there were only a limited number of claimants, and the seriousness of the potential illness.

If such liability can be established, medical expenses consequent on the psychiatric injury, such as tests to determine if the disease has been sustained, are recoverable. However, the English courts only permit recovery for recognised psychiatric injuries. Mere anxiety or distress are not actionable and are not, on their own, sufficient to ground a claim for damages (see AB and Others v Tameside & Glossop Health Authority and Others [1997] 8 Med LR 91).

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive or exemplary damages are rarely, if ever, awarded. They are not generally available in respect of claims for breach of contract. Although they are available in tort claims (see Kuddus (AP) v Chief Constable of Leicester Constabulary [2001] 2 WLR 1789), exemplary damages will only be awarded in the certain limited circumstances, including where the Defendant’s conduct was calculated to make a profit that exceeds the compensation recoverable by the Claimant.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no such limit.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The assessment of costs is a matter for the court’s discretion. The general rule is that the unsuccessful party pays the costs of the successful party (costs “follow the event”), including both court fees and legal costs (including incidental expenses). However, the court can make such orders as it considers appropriate reflecting matters such as the parties’ success or failure on particular issues in the proceedings (issue based cost orders) and the parties’ conduct.

Of particular importance in product liability actions are the rules relating to the recovery of costs from legally aided Claimants. (Most group litigation in the product liability field is funded by legal aid). Costs will only be enforced against a publicly funded Claimant in exceptional circumstances, as the Claimant may only be ordered to pay such amount as is reasonable taking account of all the circumstances, including the parties’ resources. Although
costs are generally awarded against a legally-aided party they cannot be enforced without the court’s permission and, in practice, this will not be granted unless the Claimant’s financial position improves significantly. In effect this means that Defendants are unlikely to recover their costs of defending unsuccessful proceedings brought by legally aided Claimants.

Although Defendants may seek costs against the Legal Services Commission (“LSC”), who are responsible for administering legal aid services, costs will only rarely be awarded at first instance, as it is necessary to prove the Defendant will suffer hardship unless the award is made. Costs awards are normally made if the LSC funds an appeal and this fails.

If the amount of costs cannot be agreed between the parties they will be assessed by the court to determine if the sums claimed are reasonable; costs are commonly discounted (sometimes by up to one third) on assessment. The court also has power to manage the costs incurred during the course of the litigation. For example, in group litigation it can impose a cap on the costs to be incurred by the parties in litigating generic or common issues (see AB and Others v Leeds Teaching Hospitals NHS Trust and in the matter of the Nationwide Organ Group Litigation [2003] Lloyds Law Reports 355.)

7.2 Is public funding e.g. legal aid, available?

Public funding is available in England and Wales.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is not available to fund personal injury claims arising from negligence or breach of a statutory or contractual duty equivalent to negligence. It will also be refused if alternative funding is available, for example, if the Claimant’s case can be pursued under a Conditional Fee Agreement (CFA). The combination of these rules means that the majority of product liability claims involving personal injury are unlikely to benefit from public funding. However, legal aid remains available for cases involving a ‘wider significant public interest’. In practice, the LSC continues to provide funding for group actions in the product liability field on this basis where the case is of great complexity and is unsuitable for a CFA. The recent group litigation in relation to Hepatitis C and contaminated blood products and third generation oral contraceptives was funded in this way. Even if the LSC determine that the proceedings have a significant wider public interest full funding will only be granted if the following requirements are met:

- means test - the applicant meets certain financial eligibility criteria; and
- cost-benefit test - the likely benefit of the proceedings to the applicant and others justifies the likely costs, having regard to the prospects of success.

These factors will be reassessed throughout the course of the litigation as new information becomes available. The Defendant may submit written representations to the LSC opposing funding or seeking discharge of the Claimant’s legal aid certificate.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Yes, through CFAs. There are broadly 2 types of CFA: “no win no fee” agreements and “less (or nothing) if you lose” agreements. The precise terms of the CFA are strictly regulated and agreements that fall outside the legal requirements are unenforceable.

In order to protect the Claimant/Defendant from the potential costs exposure of bringing or defending proceedings it is usual to combine a CFA with either insurance or membership of an organisation, such as a trade union, that will bring proceedings on behalf of its members and pay the costs of an unsuccessful action. The success fee and any premium paid to obtain legal expenses insurance will be recoverable in addition to legal costs, where a party with the benefit of a CFA successfully pursues or defends an action.

Acknowledgement

This chapter was prepared jointly by Alison Brown and Ian Dodds-Smith of Arnold & Porter, and Michael Spencer QC of Crown Office Chambers. Alison Brown’s profile can be found in Chapter 1, “Reform of Product Liability Legislation in Europe”. 
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Arnold & Porter LLP is an international law firm with 700 attorneys in seven offices in the U.S., London and Brussels. With more than 80 attorneys engaged in product liability matters, Arnold & Porter LLP is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.

The European product liability group is a recognised leader in the UK and Europe, with comprehensive experience in handling the defence of claims. It’s lawyers have been at the forefront of “group action” litigation, with experience derived from the successful defence of many major multi-claimant cases that have been brought in the UK and elsewhere in the EU over the last 30 years. In the US, the firm has acted both as national counsel for companies and as trial counsel in cases involving personal injury and property damage claims.

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Chapter 20

Estonia

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Pursuant to the norms of product liability (the Law of Obligations Act), the manufacturer is liable for:

a) damage to persons (bodily injuries and damage to health) caused by a defective product;

b) destruction or damage of an object caused by a defective product only in cases when:
   i) this type of thing is normally used outside economic or professional activities,
   ii) the injured person mainly used the product outside his economic or professional activities, and
   iii) the extent of the damage exceeds an amount equal to 500 euro.

The manufacturer is not responsible for the damage caused to the defective product itself.

The liability is strict, but the manufacturer may escape liability in certain cases stipulated by law. The manufacturer shall not be liable for damages if:

a) the manufacturer has not placed the product on the market;

b) circumstances exist on the basis of which it may be presumed that the product did not have the deficiency which caused the damage at the time that the product was placed on the market by the manufacturer;

c) the manufacturer did not manufacture the product for sale or for marketing in any other manner or didn’t produce or market it in the course of the manufacturer’s economic or professional activities;

d) the deficiency is caused by the compliance of the product with the mandatory requirements as at the time of placing the product on the market; or

e) due to the level of scientific and technical knowledge at the time of placing the product on the market, the deficiency could not have been detected.

The norms of product liability do not prevent the injured person from claiming damages on other legal grounds. However, if the damage results form the breach of contractual obligation, the damage may be demanded on the basis of product liability norms only if the objective of the violated contractual obligation was other than to prevent the damage for which compensation is claimed.

1.2 Does the state operate any schemes of compensation for particular products?

No such schemes exist in Estonia.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Pursuant to the Law of Obligations Act the manufacturer bears responsibility. However, each of the following persons may bear the responsibility for a defective product, because they are deemed as manufacturers:

a) a person who manufactures an end product, raw material or part of a product;

b) a person who claims to be the manufacturer of a product and indicates his name, trade mark or other distinctive mark on the product;

c) a person who brings a product into Estonia or into a Member State of the European Union in the course of his economic activities with the objective of selling, leasing or marketing of the product in any other manner; or

d) if the manufacturer cannot be identified, any person who has delivered the product to a injured person shall be deemed to be the manufacturer if such person does not disclose the identity of the manufacturer or the person who delivered the product to the person within a reasonable time after the injured person has made a corresponding request.

Also other legal acts define a manufacturer. Pursuant to the Product Safety Act, a manufacturer is a person whose activities may affect the safety properties of a product and a distributor is a person whose activity does not affect the safety properties of a product. Pursuant to the Product Safety Act, a manufacturer is:

a) the manufacturer of the product, when he is established in a Member State of the European Union, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person...
2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The injured person has to prove the existence of damage, the deficiency of a product, and a causal link between the deficiency of the product and the damage caused.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The causal link is established according to the principle that an earlier event is the cause of a later event if without the first event the second would not have occurred. The causal link does not have to incur as a direct link between the act and the consequence (damage) - it may also be established in the series of acts that were initiated by the unlawful act of a tortfeasor.

As the legislation does not specify the rules of establishing causal link in cases of product liability these rules shall be established by case law.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If several persons may be liable for damage caused and it has been established that any of the persons could have caused the damage, compensation for the damage may be claimed from all such persons. In this case compensation for damage may be claimed from each person to an extent in proportion to the probability that the damage was caused by the person concerned.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account; only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Pursuant to the Law of Obligations Act, a product is regarded defective if it is not safe to an extent which corresponds to the legitimate expectations of a person. When estimating, whether a product is safe, the information provided by the manufacturer is taken also into account. Therefore, the failure to warn affects the liability of the manufacturer in the aspect of whether the product is considered defective or not.

The Product Safety Act stipulates the obligations of a manufacturer to inform the consumers to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. The distributor is required to act with due care to help to ensure the compliance of products with the applicable safety requirements. Therefore, it should be concluded that the information is to be provided directly to the consumer/injured party.

However, the Law of Obligations Act stipulates that the manufacturer shall not be held responsible if the circumstances exist on the basis of which it may be presumed that the product did not have the deficiency which caused the damage at the time that the product was placed on the market by the manufacturer. Therefore, if information, advice or warning was provided with the product by the initial manufacturer, but the next person in the supply chain does not provide the information with the product, the initial manufacturer cannot probably be held responsible. Still it must be noted that, pursuant to the Law of Obligations Act, the liability of the producer shall not be reduced if the damage occurs due to both deficiency of the product and the behaviour of a third party.

The responsibility for damage caused by providers of health care services, particularly for errors in diagnosis and treatment, is separately regulated as damage arising out of contractual relationship.

Estonian law does not stipulate the principle of “learned intermediary”. Pursuant to the Law of Obligations Act, the manufacturer of a defective medicinal product is held liable...
on the basis of the same provisions of the Law of Obligations Act, unless otherwise provided by law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer may escape liability for damage in cases stipulated by law (see answer to question 1.1).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The manufacturer is not responsible for the damage caused by a defective product if he proves that due to the level of scientific and technical knowledge at the time of placing the product on the market the deficiency could not have been detected.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Pursuant to the Law of Obligations Act, the manufacturer is not responsible for the damage caused by a defective product if the deficiency is caused by the compliance of the product with the mandatory requirements as at the time of placing the product on the market.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

If a fact is established by a judgment in a civil matter and the judgement has entered into force, this fact cannot be contested in another civil matter in which the same parties participate. If these issues arise in separate proceedings brought by a different claimant, they are re-established in the context of the given case.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial in the court of first instance is before a judge. Upon the application of a party, two lay judges may be included in the panel of a court in addition to the judge. Estonian procedural laws do not stipulate a trial by a jury.

Trial in the appellate court is held before a panel of three judges.

In the Supreme Court, appeals are normally heard by a panel of three judges, but the full Chamber (either Civil, Criminal or Administrative Chamber) will be summoned if disagreements regarding interpretation or application of law arise or if the panel wishes to amend the most recent opinion of the respective Chamber of the Supreme Court. The law also determines the cases where an appeal shall be referred to the Supreme Court en banc (üldkogu) or to a Special Panel (erikogu).

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No (see question 4.8). A court may appoint an expert to give his/her expert opinion on the facts of the case. The expert is asked specific questions that he/she has to answer in the opinion. Expert opinion is assessed as one piece of evidence.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

No, there is no specific group or class action procedure for multiple claims. However several plaintiffs may file a joint claim.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

In principle, a court may commence a civil matter on the basis of a petition of a person who is seeking protection of the rights and freedoms of other persons if the right to protect the rights or freedoms of other persons has been granted to the person by law. At present, law does not stipulate any representative body who may bring a claim regarding product liability on behalf of a number of claimants.

4.5 How long does it normally take to get to trial?

It depends on the difficulty of the case. As product liability cases are probably complex with regard to evidence, the pre-trial procedures may take from six months to one year.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court has to resolve procedural issues upon the relevant application from a party or on its own initiative. For example, the court may decide that a certain piece of evidence is not relevant and shall not be accepted; the court may request some evidence to be presented; or the court may appoint experts to give opinions, etc.

The court may, if several separate related claims are combined in one proceeding, make a separate judgment on each claim if this expedites the hearing of the matter. The court will resume the proceeding with regard to the claims which have not been adjudicated.
4.7 What appeal options are available?

The decision of the court of first instance may be appealed to the appellate court. The appeal may be both on the facts and on legal issues.

The decision of appellate court can be appealed in the form of cassation (only the questions of law can be reviewed) to the Supreme Court of Estonia. The Supreme Court has discretion to decide whether to accept the appeal.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Upon the application of a party the court has the right to order an expert assessment in the cases where non-legal expertise is required to ascertain facts which are relevant to the matter. The parties themselves may submit an opinion of a competent person or agency which is evaluated by the court as a documentary evidence not as an expert opinion.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

The expert opinion ordered by the court is presented in written form to parties during pre-trial procedures. The experts giving the opinion are not heard as witnesses during the trial, but the parties may ask questions from them during the trial.

The witnesses are heard during trial and no written statements are presented in pre-trial procedures. However, the party applying for the calling of a witness has to indicate the facts relevant to the matter with regard to which the witness may give testimony.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

During the pre-trial procedures the parties have to name all the facts which they consider relevant to the adjudication of the matter and specify and present all the evidence which proves such facts. The opposite party cannot be surprised during the trial.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The Law of Obligations Act stipulates a limitation period for claims regarding producer’s liability - it is three years as of the date on which the injured person becomes aware or should reasonably become aware of the damage, the deficiency and the identity of the producer. Regardless of the aforementioned, claims which arise from the producer’s liability provisions shall terminate after 10 years have passed as of the date on which the product which causes damage is placed on the market, unless an action has been filed with a court by that time.

If a person with restricted active legal capacity has no legal representative, the limitation period for the claims of and against the person is suspended until the person acquires active legal capacity or a legal representative is appointed for him or her. These claims shall not expire earlier than six months after the person has acquired active legal capacity or a legal representative has been appointed for him or her.

If a claim is brought to the court after the limitation period has passed, the court shall, at the request of the defendant, take into account the limitation period and shall not satisfy the claim. The court does not have discretion to disapply the limitation if the defendant has requested it.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The issues of concealment or fraud may affect the time the injured person became aware or should have become aware of the damage, the deficiency and the identity of the producer.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The following types of damage are recoverable:

a) damage arising from bodily injuries and damage to health; and
b) damage to property, but not to the product itself.

The following types of the abovementioned damage are compensated:

i) material damage - direct material damage and loss of profit. In cases of bodily injuries and health damage the expenses arising from such damage or injury, including expenses arising from the increased needs of the aggrieved person, and damage arising from total or partial incapacity to work, including damage arising from a decrease in income or deterioration of the future economic potential of the aggrieved person, has to be compensated; and
ii) moral damage - physical and emotional distress and suffering caused to the aggrieved person.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Those expenses cannot be recovered pursuant to norms of product liability if damage by the product has not occurred yet.

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These expenses might be recoverable on some other grounds - for example if these expenses can be regarded as damage which has occurred because of an unlawful act committed by the manufacturer and the manufacturer is guilty of causing the damage.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

No, punitive damages are not recoverable. Pursuant to the Law of Obligations Act, the objective of compensating damage is to put the injured person into a position he/she would have been if the damage would not have occurred. The injured person cannot enrich at the expense of the compensation.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The legislation does not provide such limits and relevant case law has not yet been established.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

a) The court fees and other reasonable expenses related to the proceedings are recoverable by the successful party.

b) The legal costs in case of monetary claims are recoverable from the losing party in an amount up to five per cent of the value of the satisfied part of the claim in favour of the plaintiff or in an amount up to five per cent of the value of the dismissed part of the claim in favour of the defendant.

7.2 Is public funding e.g. legal aid, available?

Yes, state legal aid is available. Additionally, the claimant may be made exempt from paying the state fees if the court finds that he/she is insolvent.

7.3 If so, are there any restrictions on the availability of public funding?

State legal aid is available to a natural person, who is due to his or her financial situation unable to pay for competent legal services. State legal aid is also available to certain non-profit associations and foundations when they apply for state legal aid in the field of environmental protection or consumer protection, or there is other predominant public interest for the grant of state legal aid. State legal aid is given either entirely at the expense of the state or, dependent on the financial situation of the person receiving state legal aid, with the obligation to compensate legal aid expenses fully or partially.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

No. Lawyer’s fees for state legal aid are fixed by a regulation.
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- Real Estate development.
- E-commerce.
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# Finland

## Roschier Holmberg, Attorneys Ltd.

### 1 Liability Systems

#### 1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

There are two main systems of product liability: strict liability under the Product Liability Act (694/1990), and fault based liability under the Torts Act (412/1974), the Sale of Goods Act (355/1987), and the Consumer Act (38/1978). Liability under the Sale of Goods Act and the Consumer Act is limited to damage to property. Product liability can also be based on breach of an express or implied contractual term concerning the quality or safety of a product.

#### 1.2 Does the state operate any schemes of compensation for particular products?

The state operates compulsory insurance schemes under the Patient Injury Act (585/1986) for injuries caused by medical treatments and clinical trials, the Traffic Insurance Act (279/1959) for certain traffic-related injuries, the Accident Insurance Act (608/1948) and the Farmers’ Accident Insurance Act (1026/1981) for work-related injuries and occupational diseases. In addition, a private Pharmaceutical Insurance Scheme covers product liability for pharmaceutical products. These Acts and schemes apply as parallel sources of remedies along with product liability under the Product Liability Act.

#### 1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Liability under the Product Liability Act is imposed on the manufacturer, the importer, and the marketer (i.e. the party under whose trademark or other commercial identifier the product has been marketed). If the product’s manufacturer is not indicated on the product, any other supplier is liable as a manufacturer unless they, upon request, identify the manufacturer or the person from whom they have acquired the product. The same rule applies if the importer is not indicated on the product.

#### 1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

General Finnish product liability rules impose an obligation on the manufacturer to recall products upon becoming aware of their defective qualities, if such defects cannot be eliminated in other ways. In addition, pursuant to the Product Safety Act (914/1986) the Finnish Consumer Agency may order a recall of a product intended for general consumption if that product is deemed by the Agency to be defective or dangerous, subject to criminal penalties. Breach of the duty to recall products does not in itself establish grounds for a civil claim under Finnish law, but is rather treated as negligent conduct.

### 2 Causation

#### 2.1 Who has the burden of proving fault/defect and damage?

Under the Product Liability Act, the injured person has the burden of proof of the damage, the defect, and the causal relationship between the defect and the damage. Under general tort law rules, the injured person is further required to prove negligence. Under the Patient Injury Act and the Pharmaceutical Insurance Scheme, the claimant need only show that a causal connection between the product and the damage is probable.

#### 2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Case law indicates that courts will find that causation has been sufficiently proven if the claimant can show that the injury is typically associated with the product, unless the defendant is able to establish that causation is not medically possible or that another factor is the more probable cause of the injury.
2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability is not recognised in Finland. It is unclear what position a Finnish court would take if a claimant could not prove the identity of the defective product and of its manufacturer. As the Product Liability Act places the burden of proving a case with the plaintiff, it is unlikely that a court would e.g. assist the plaintiff by reversing the burden of proof so that each defendant would be required to disprove that the injury was caused by its product.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure to warn may give rise to liability if the insufficient safety of the product is attributable to the marketing of the product and/or instructions (or lack thereof) for its use. The Product Liability Act does not rule out that information provided by another source than the manufacturer can be taken into account. Therefore, information provided to the consumer by an intermediary such as a doctor could be considered relevant to an assessment of the safety of the product. There is, however, no principle of “learned intermediary” under which the manufacturer’s duty to inform would be completely discharged by supplying information to an intermediary rather than to the consumer.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Liability under the Product Liability Act may be excluded if the defendant proves that it did not manufacture or put the product into circulation, or that the defect is due to the product having to comply with regulatory requirements. Liability may also be excluded if the defendant presents prima facie evidence that the defect did not exist at the time the defendant put the product into circulation. The producer of a component part may exclude liability if it proves that the defect was attributable to the instructions given by the manufacturer of the product.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Development damage is not a defence under the Product Liability Act, and therefore applies only to products not covered by the Product Liability Act or products that have been put into circulation before the Act’s entry into force on 1 September 1991. Since development risk in fault-based liability goes to show negligence on the part of the manufacturer (by its not complying with the state of scientific and technical knowledge), the claimant has the burden of proving that the defect was discoverable.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Mere compliance with regulatory requirements or the fact that the product has been appropriately tested or licensed is not a defence, unless it can be shown that the defect was caused by or inevitably resulted from compliance with mandatory requirements.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A final judgment on issues of fault, defect or the capability of a product to cause a certain type of damage is an absolute bar to the same issues being raised in subsequent proceedings between the same parties, including their successors, if those issues were necessary to the first judgment. Finnish case law indicates that, in proceedings brought by a different claimant but arising out of the same event as the prior proceedings, the parties would be stopped from re-litigating issues establishing or excluding the defendant’s liability to the first claimant.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is by a judge. In civil litigation the District Courts, which are the courts of first instance, generally comprise one judge as chairman (in criminal cases an additional panel of three laypeople are also members of the court). Major cases or cases involving complex issues of law may at the request of a party be adjudicated by a three-judge panel.
4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not have the power to appoint expert members to sit with the judge in the assessment of evidence in a product liability case.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class action is not available in Finland. Finnish procedural rules on actions involving multiple claimants permit common claims only where the claims concern essentially the same legal relationship. Thus, multi-party product liability actions can be brought e.g. if the damages stem from the same act. The availability of class action is currently being discussed by politicians.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No. A representative body would under Product Liability legislation not have a right of action under Finnish procedural rules.

4.5 How long does it normally take to get to trial?

Civil litigation in the District Court begins with a preparatory stage followed by the main proceedings. In the preparatory stage, the parties exchange written pleadings (application for summons, response, and possibly subsequent written submissions). The preparatory stage usually takes 4-6 months but may stretch to over a year in complex cases.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court is required to try defence pleas made in connection with the defendant’s first response, concerning matters of procedure. During proceedings, the court may under certain preconditions also separately try an independent claim in a matter involving several claims, and, at the request of a party, an issue that determines how a claim will be decided. Such issues may relate to both issues of law and issues of fact.

4.7 What appeal options are available?

District Court judgments may be appealed to the Court of Appeal without restriction. An appeal to the Supreme Court requires a leave of appeal.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may, at its discretion, appoint an expert to give a statement on a particular technical issue or other issue requiring specialist knowledge. The court is required to appoint an additional expert if the parties agree on a particular person. The parties may appoint their own experts, which are heard as witnesses. A court-appointed expert is required to give a detailed report of his or her findings, and, based on such findings, a reasoned statement in response to the question presented by the court. The statement shall be in writing unless the court decides it necessary to have the statement delivered orally. Expert testimonies may also be given in the form of written statements.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There is no requirement for deposition of witnesses or exchange of statements or reports during the preparatory stage of proceedings. The court will review what witnesses the parties intend to hear during an oral hearing conducted before the main hearing.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

There is no obligation to disclose documentary evidence before proceedings commence or as part of pre-trial procedures. The parties are required to identify the evidence they intend to present in an oral hearing conducted before the main hearing. A party may request the court to order the other party to produce specific documentary evidence in its possession that can be assumed to have significance as evidence in the case, at the main hearing or outside the main hearing if presentation of the document in the main hearing would cause undue inconvenience.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Proceedings for strict liability under the Product Liability Act shall be instituted within three years from the date on which the claimant became aware of the damage and of the identity of the party liable for the damage. However, proceedings may not be instituted later than 10 years from the date the defective product was put into circulation by the party liable for the damage as a manufacturer, importer or
5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud do not in general affect the running of time limits as such, but may affect the determination of when the claimant should have become aware of the damage and the responsible party.

6 Damages

6.1 What types of damage are recoverable, e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The Product Liability Act provides for compensation for direct personal injury and damage to personal property worth at least 400 euros. Damages to the product itself and pure economic damage cannot be claimed under the Product Liability Act, but may be recoverable under contract or fault liability. In the case of fault-based liability, the Torts Act provides for compensation for personal injury and property damage, including consequential damages where the damage was caused by intentional or negligent conduct. Damages for personal injuries include compensation for medical expenses and other direct costs, loss of income or support, pain and suffering, impediment or other permanent disability or disfigurement, and reasonable funeral expenses. Mental damage as a result of bodily injury may also be recovered.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Finnish law permits the recovery of costs of precautionary measures, if such measures are taken to prevent or restrict damage and are prompted by the existence of a specific fault or defect. Although there is no case law on point, it is plausible that costs of medical monitoring undertaken to restrict damage that is subsequently caused by a known defect in a product would be recoverable, provided that a sufficiently direct link between the defect and the precautionary measures can be established.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Damages are exclusively compensatory under Finnish law. Punitive or aggravated damages are not recoverable.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer, e.g. for a series of claims arising from one incident or accident?

There is no maximum limit for damages either for fault based or strict liability.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The losing party usually has to pay court costs and the reasonable legal costs of the successful party. Where the court deems the case to have been so unclear that the plaintiff has had a reasonable cause of action, each party is ordered to bear its own costs.

7.2 Is public funding, e.g. legal aid, available?

Legal aid is available to a party who cannot without difficulty afford the cost of proceedings, including attorney’s fees.

7.3 Is there any restriction on the availability of public funding?

There are no fixed financial or other criteria for eligibility for legal aid; rather the court determines the party’s eligibility on the basis of the nature of the case and the court’s opinion on their ability to pay the estimated costs. The merits of the case have no bearing on the grant of legal aid.

7.4 Is funding allowed through conditional or contingency fees, and, if so, on what conditions?

Conditional or contingency fees are allowed without any particular restrictions, but rarely used.
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Chapter 22

France

August & Debouzy

1 Liability Systems

1.1 What systems of product liability are available (i.e., liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

To the two classical régimes of civil liability (contractual and tort) created by the French Civil Code (French acronym C.Civ.), Act no. 98-389 of May 19, 1998, transposing a 1985 EC Directive into the French Civil Code (articles 1386-1 through 1386-18) added a third régime specific to liability on account of defective products.

Tort liability

The first régime of liability under the classical summa divisio of French law (tort vs. contractual liability) was originally characterised by its simplicity and its universality: except where liability arose out of a contract, the rule was, as set forth by Article 1382 C.Civ., that “any act of man, which causes damage to another, shall oblige the person by whose fault it occurred to repair it”. In addition, Article 1383 C.Civ. sets forth that “One shall be liable not only by reason of one’s acts, but also by reason of one’s imprudence or negligence”. A fault may therefore result either from the commission of an act or from the omission to perform an act. In addition, case law added various régimes of strict liability to this liability for fault.

Liability for fault

The wording of Article 1382 C.Civ. clearly shows the three elements that are necessary to engage liability: (i) a fault, (ii) an injury and (iii) a causal link between the two. The burden of proof of all of these elements falls on the plaintiff.

Fault can be defined as the failure to behave as a level-headed paterfamilias (the Anglo-Saxon equivalent of which is the “reasonable man”). Furthermore, under French law, in order to commit a civil fault, one need not necessarily be conscious of the wrongful nature of one’s behaviour (contrary to what is the case under criminal law). In any case, fault is a largely subjective notion which the courts have wide latitude to appreciate, and in recent years they have adopted a markedly more plaintiff-friendly approach.

Two elements should be noted concerning the link between tort liability and other régimes. Firstly, failure by a party to comply with its contractual obligations does not only constitute a contractual fault towards its co-contractors, but may also be a tortious fault towards third parties. Such third parties can thus evidence a tortious fault on the part of a person by simply demonstrating that such person has failed a contractual obligation. Secondly, it should be noted that judgments by criminal courts have res judicata value over civil courts examining the civil consequences of an offence, except for judgments ruling in unintentional criminal faults pursuant to Article L. 4-1 of the French Criminal Procedure Code (French acronym CPP.).

Liability only arises from a fault if there is a direct causal relationship between such fault and an injury. What constitutes a direct causal relationship has not been precisely defined either by statute or case law. The courts therefore have wide latitude to appreciate whether such causal relationship exists.

In order to be compensable, an injury must be actual, direct and certain. The criterion of directness however does not imply that derivative injuries may not be compensated, due to an evolution of case law intended to better protect victims. Similarly, an injury may be considered as actual even if it is future, provided it is certain.

Under these conditions, a broad range of injuries may be compensated for: material and financial injuries, bodily injuries, moral injuries and, as developed by case law, “loss of an opportunity” (perte de chance).

Strict liability

Strict tort liability is provided for by Article 1384 C.Civ., which sets forth various cases thereof. More specifically concerning product liability, Article 1384-1 provides that “one shall be liable... for the things that one has under one’s custody”. The régime of liability provided for by this text is a strict one, where no fault is required: the victim must only prove that a thing caused him an injury. Under Article 1384-1 C.Civ., the liable person is the “custodian” of the thing. Custody is defined by case law as the powers for use, control and management of the thing. In theory, therefore, the custodian of a thing is its owner. However, case law has, along the time, introduced nuances and complexities in this relatively straightforward definition (the distinction made by the courts between custody over the “structure” of things and custody over their “behaviour”, before it was eventually ruled par the European Court of Justice incompatible with the 1985 EC Directive on liability for defective products, and thus practically void, being an example of it).

Contractual liability

Contrary to tort liability, contractual liability is not explicitly
defined in the Civil Code. Case law nevertheless developed this régime on the basis Article 1147 C.Civ., which provides that “the debtor shall be ordered, if appropriate, to pay damages, either by reason of the non-performance of his obligation, or of the delay in such performance, if he cannot justify that such non-performance results from an external cause that cannot be ascribed to him, although there is no bad faith on his part”.

The recent transposition in France of directive n°99/44/CE of May 25, 1999, on certain aspects of the sale of consumer goods and associated guarantees, has provided consumers with specific rights.

**Scope of application of contractual liability**

The principle is that contractual liability is applicable to claims arising (i) between parties to a valid contract (ii) in connection with the non-performance or ill-performance of such contract.

When a plaintiff alleges the ill-performance of a contractual obligation, such plaintiff must base its claim on contractual liability. Indeed, on the basis of the principle of the absence of plurality of liabilities, consistently affirmed by courts, a plaintiff in such situation is prohibited from resorting to tort liability or to invoke both liabilities at the same time.

**Conditions of contractual liability**

A contractor engages his liability when a failure to comply with his contractual obligations causes his co-contractor an injury. Three elements are thus required, two of which (existence of an injury and causal link between the wrongdoing and such injury) are not specific to contractual liability.

Contractual failure is assessed in different manners: French law distinguishes between “best-effort obligations” (obligations de moyens) and “performance obligations” (obligations de résultat). A best-effort obligation, also referred to as a general obligation of care and diligence, consists in an obligation to make use of all of one’s capacities in order to attempt to reach a specified goal. Example: obligation of a physician, who is only obliged to make his best efforts to cure the patient, but may not necessarily succeed (Cour de cassation, May 20, 1936).

Conversely, a performance obligation consists in the obligation to reach a pre-determined result. For example, in a sales contract, a party may be under a performance obligation to deliver the goods sold. Failure to comply with a performance obligation results from the sole fact that the sought result has not been reached. The criteria of distinction between best-effort and performance obligations are not always obvious, and largely depend on the common intent of parties.

**Specific provisions on the purchase of tangible movable goods by consumers**

France has recently transposed Directive 99/44/EC of May 25, 1999 on certain aspects of the sale of consumer goods and associated guarantees into the French Consumer Code (French acronym C.Cons., Articles L. 211-1 to L. 211-17), by way of an Ordinance of February 17, 2005 applying to any contracts signed after February 19, 2005. The rules apply to contractual relations between a seller acting in the scope of its trade, business or profession and a purchaser acting as a consumer (Article L. 211-3 C.Cons.).

The seller must deliver to the consumer goods which comply with the contract of sale. Therefore, it shall be directly liable to the consumer for any lack of conformity existing at the time the goods were delivered (Article L. 211-4 C.Cons.).

The application of the principle of conformity is accompanied (under Article L. 211-7 C.Cons.) by a presumption of non-conformity of the goods delivered. Therefore, the obligation to deliver goods which comply with the contract may be deemed an obligation of performance (obligation de résultat), as described above.

In case of a lack of conformity, the consumer may has the choice to demand that the seller repair the goods or replace them, free of charge in either case, unless this is impossible or disproportionate (Article L. 211-9 C.Cons.). If these remedies are unavailable, the consumer may demand an appropriate reduction of the price or have the contract rescinded, except in case of a trivial lack of conformity (Article L. 211-10 C.Cons.).

It is important to note that these rules supplement and do not replace the general principles of contractual liability, and particularly those set forth in Article 1147 C.Civ., as mentioned above.

**Liability on account of defective products**

Act no. 98-389 of May 19, 1998 transposing the 1985 EC Directive into the French Civil Code (the “1998 Product Liability Act”) established a specific régime dealing with defective products applicable “regardless of the existence or not of a contract between the manufacturer and the victim” (Article 1386-1 C.Civ.).

Under this special régime, the definition of the term “product” is an extensive one: it includes all movables including, under French law, electricity and primary agricultural products (Article 1386-3 C.Civ.).

A product is considered to be defective if “it does not provide the safety which a person is entitled to expect” (Article 1386-4 C.Civ.). In order to determine the level of safety which a person is entitled to expect, all circumstances must be taken into account, “including the presentation of the product, the use to which it could reasonably be expected that the product would be put, and the time when the product was put into circulation”. This provision actually is protective of manufacturers, especially for products subject to specific warnings displayed on the packaging of the products concerned and, even without warnings, when such products are widely known as being dangerous or entailing risks for health.

Liability on the account of defective products is strict: the victim need not prove any fault on the part of the manufacturer, but only “the injury, the defect, and the causal link between injury and defect” (Article 1386-9 C.Civ.). “The manufacturer shall [then] be strictly liable” (Article 1386-11 C.Civ.).


**Criminal liability**

To date, few product liability cases have given rise to criminal prosecution. However, cases have already been
brought before criminal courts (e.g. injuries resulting from HIV-contaminated blood transfusions), because of the wide powers of discovery of investigating magistrates and the very low cost of such proceedings for the plaintiffs. Several provisions may serve as a basis for criminal action concerning injuries caused by products. The first basis on which product liability cases may be brought before criminal courts is fraud, provided for by Article L. 213-1 of the Consumer Code (C.Cons.), which punishes the fact to deceive consumers concerning the quality, quantity or appropriateness of a product for a specified use. Fraud may be punished with up to two years of imprisonment and/or a fine up to EUR 37,500, these sanctions being doubled if fraud renders a product dangerous for health.

Secondly, pursuant to Article 221-6 of the Criminal Code (French acronym CP), “Causing the death of another person by clumsiness, negligence, carelessness, recklessness or breach of an obligation of safety or prudence imposed by statute or regulations, constitutes manslaughter and shall be punished by three years’ imprisonment and a fine of EUR 45,000”. Article 222-19 CP sets forth a similar offence where the victim has suffered a work incapacity superior to three months, punished with two years’ imprisonment and a fine of EUR 30,000. The application of these provisions thus requires evidence of a fault, an injury and a causal link between the two. Of note, where the fault on the part of the professional consists of the deliberate violation of a safety or prudence obligation imposed by statute or regulation, sanctions may be increased and the offence becomes punishable even where it did not cause a work incapacity superior to three months.

Lastly, Article 223-1 CP provides that “the direct exposure of another person to an immediate risk of death or injury likely to cause mutilation or permanent disability by the manifestly deliberate violation of a specific obligation of safety or prudence imposed by any statute or regulation shall be punished by one year’s imprisonment and a fine of EUR 15,000”. This offence may be punished even in the absence of any actual injury.

1.2 Does the State operate any schemes of compensation for particular products?

Following a social trend according to which someone must be held civilly or even criminally liable for every injury, case law has evolved in a direction that renders the engagement of product manufacturers’ liability easier. Partly with the same motivation as case law, and partly as a reaction to the sometimes controversial judicial decisions, public authorities reacted by creating various compensation schemes. Specific régimes may be cited, be they based upon a system of compulsory insurance (for example the régime concerning the liability of builders for defects of their buildings: Act 78-12 of January 4, 1978), upon a public indemnification fund (indemnification of HIV contaminations caused by blood transfusions: Act no. 91-1406 of December 31, 1991; indemnification of the victims of asbestoses: Act no. 2000-1257 of December 23, 2000) or a combination of the two (indemnification of the victims of medical injuries: Act no. 2002-303 of March 4, 2002). One may note that recent specific compensation régimes often were created because the liability of the State was asserted concerning various products: HIV-contaminated blood intended for transfusions had been provided by public transfusion centres (Conseil d’Etat, April 9, 1993, three cases), and the State has been held liable for its failure to prevent the injuries caused by asbestos by regulating its use earlier (Conseil d’Etat, March 3, 2004).

Once the victim has been indemnified, the specific régimes typically set forth the right of the person having paid the indemnity, be it an insurer or a public fund, to bring a subrogatory action against the liable person(s) or their insurer(s), in order to attempt to attribute the final burden of the indemnity to the actually liable person, without there being a need for the victim to bring action before the courts.

1.3 Who bears responsibility for the fault/defect: the manufacturer, the importer, the distributor, the “retail” supplier, or all of these?

(a) Under French law, the word “defect” itself is only used concerning the specific liability régime resulting from the 1998 Product Liability Act. Under this régime, a product is considered defective when it “does not provide the safety that one is legitimately entitled to expect”. The principle is that producers, defined by article 1386-6 C.Civ. as manufacturers of finished products, producers of any raw material, or manufacturers of components acting in a professional capacity are liable for the defect. In addition, any person who affixes its name, trademark or other distinguishing sign to the product and any person who imports the product from the EC is considered the producer. Contractual agreements suppressing or limiting liability on the account of defective products are in principle forbidden and nil, except when entered into between professionals concerning injuries caused to goods used professionally (Article 1386-15 C.Civ.).

(b) Concerning responsibility for fault, the person who bears responsibility depends on the régime of liability. Under tort liability, from the beginning of the 20th century, law as well as case law have developed an obligation incumbent on the manufacturer and/or the seller of a product to provide information concerning the product sold. The principle remains that there is no obligation to inform those who are already informed.

Under contractual liability, the seller would generally bear the responsibility for the fault. Indeed, pursuant to Article 1641 C.Civ., the seller of a thing having a hidden defect or vice is liable towards the buyer and must indemnify the buyer for the diminished value of the thing and indemnify the buyer for the injuries caused by the defect, if he was aware of its existence.

Case law has nonetheless acknowledged, besides the warranty for hidden defects, the existence of a safety performance obligation binding upon the seller (Cour d’ cassation, June 11, 1991, appeal no. 89-12748), and then upon the intermediary seller (Cour d’ cassation, January 27, 1993, appeal no. 90-19777), consisting of delivering the products free of any such vice or manufacturing defect as may create a risk for people or property. In this regard, the victim should initiate a contractual liability action.

Of note, case law considers that the successive buyers of a product all have a contractual relation with the initial seller. They thus may not assert the initial seller’s tort liability, but
only its contractual liability. Also, a person incurring a derivative injury by reason of the direct harm caused to the original victim of a wrongful act may bring a claim under Article 1382 et. seq., regardless of the nature of the claim (contractual or tort) of the originally injured person (parents of a killed or disabled person by reason of the injury incurred by them because of his loss of income or the necessity to take care of him).

As seen above, the French Criminal Code sets forth the criminal liability of a professional when there is a breaking of an obligation of safety or prudence imposed by statutes or regulations. For example, under Article 221-6 CP, case law had condemned manufacturers as well as sellers who did not respect such obligations.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Failure to provide the security that one may legitimately expect can lead professional producer and seller to be subjected to an obligation to follow-up their products, or even an obligation to recall them.

Article L. 221-1 C.Cons. sets forth a general safety principle: “Products and services shall, under normal conditions of use or under other circumstances that may reasonably be foreseen by the professional, offer the safety that can legitimately be expected and shall not be a danger to public health”. Ordonnance no. 2004-670 of July 9, 2004 amended the Consumption Code C.Cons. for the purposes of transposing Directive no. 2001-95 concerning general product safety.

Article L. 221-1-2 II C.Cons. now places the person responsible for putting a product on the market under a follow-up obligation consisting of taking the necessary measures to be kept informed of any risks that its products may create and, where necessary, in taking appropriate action to prevent such risks. Such actions can consist in adequately and sufficiently warning consumers, or even removing the products from the market. In any event, the professional operator must immediately notify the competent administrative authorities (DGCCRF, AFSSA) of the risk created by its products, and any prevention actions it may take (Article L. 221-1-3 C.Cons.).

Besides, the Consumption Code provides two kinds of checks depending on the degree of danger for consumers. Under the normal procedure, several kinds of civil servants are allowed, by Article L. 215-1 C.Cons., to monitor the products regulated: agents from the ministry of Economy and Finance (DGCCRF, DGDDI), from the ministry of Agriculture (DGA), among others. Then, pursuant to Article L.221-6 C.Cons., agents who have performed the checks send the local government representative (préfet) the results of their investigations together with their proposals regarding the measures to be taken. The latter sends, as soon as possible and in any case within no more than fifteen (15) days, the file to the interested minister and to the minister in charge of Consumer Affairs with his reasoned opinion, in order for them to take the appropriate measures.

In the event of serious or immediate danger, the minister in charge of Consumer Affairs and the interested minister, or ministers, are allowed to suspend, for a period which may not exceed one year, the manufacture, import, export and marketing of a product, to withdraw a product from all sites where it is located or have it destroyed where this constitutes the only means of putting an end to the danger (Article L. 221-5 C.Cons.). Likewise, the local State’s representative (préfet) concerned can take all such measures as may be required on a temporary basis, and the minister in charge of Consumer Affairs and the interested minister must issue their decision by way of an administrative order (arrêté) within fifteen (15) days (Article L. 221-6 C.Cons.). Lastly, anyone who, in contravention of the provisions of an order adopted in application of article L. 221-5 C.Cons., has not withdrawn the product can be punished with fines up EUR 1,500 (Article R. 223-1 C.Cons.) - this sum being calculated by unit of the product on the market.

Regarding pharmaceuticals, the French Code of Public Health (French acronym CSP), in its Article R. 5121-47, allows the Director of the French Agency for the Safety of Health Products (AFSSAPS) to modify, suspend or repeal, by way of a reasoned decision, a marketing authorisation. Except in case of emergency, the decision to withdraw a marketing authorisation can not be taken before the beneficiary of the authorisation has been invited to provide explanations. If its explanations do not convince AFSSAPS, the beneficiary of the marketing authorisation must recall his products.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Pursuant to Article 9 NCPC, each party must prove the facts necessary to the success of its claim. The burden of proof therefore normally lies with the plaintiff. However, in certain fields, legislation or case law establishes presumptions which transfer the burden of proof to the defendant. Lastly, where no such legal presumption exists, courts may only take into account serious, precise and concordant factual presumptions.

(a) Under contractual liability, the plaintiff must first prove that he had entered into a contract with the liable person. Secondly, the plaintiff must demonstrate a breach of contract (faute contractuelle); in the case of a performance obligation (obligation de résultat), as well as in the principle of conformity system (Article L. 211-1 to L. 211-17 C.Cons.), such breach results from the simple proof of the non-performance of the sought result, whereas in case of a best efforts obligation (obligation de moyens), the victim is required to demonstrate that its co-contractor did not take the appropriate measures or make the appropriate efforts in order to achieve the result. In any case, the plaintiff must besides prove the existence and quantum of his injury as well as the causal link between the breach of contract and his injury. However, in case of non-execution of a performance obligation, there exists a presumption of a causal link between the non-execution and the injury.

(b) Concerning tort liability, a distinction should be made between liability for fault and strict liability. Under Article 1382 C.Civ., the plaintiff must prove the fault, the injury (existence and quantum) and the causal link between fault and injury. Under Article 1384 C.Civ., the plaintiff must demonstrate the existence and quantum of his injury, and in all events the fact that a thing materially intervened in
the production of said injury.

c) Under the defective product liability régime, the plaintiff must prove the defect, the injury, and the causal link between the defect and the injury. He need not prove any fault on the part of the manufacturer (Article 1386-9 C.Civ.).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The burden to prove the causal link naturally lies with the plaintiff. However, law and case law have lessened this burden, depending on the status of scientific knowledge concerning the existence of a risk relating to the product at the time when the product was put on the market.

(a) Regarding the contractual liability régime, case law has lightened the burden to prove the causal link between the defect of a blood product and the injury by instituting a legal presumption. In a case concerning the post-transfusion infection with the hepatitis C virus, the Cour de cassation required the victim to prove only “firstly that her infection with the virus occurred following blood transfusions, secondly that she had no other specific modes of infection” (Cour de cassation, May 9, 2001, appeal no. 99-18514). Accordingly, the causal link can be proven on the sole basis of a temporal conjunction between the transfusion and the appearance of the illness, and a proof by elimination of the other causes. The lightened burden of proof of the causal link in cases regarding hepatitis C virus infections has been upheld by Article 102 of Act no. 2002-303 of March 4, 2002. Similarly, the Act no. 91-1406 of December 31, 1991 which instituted an indemnification fund for HIV-positive victims had also alleviated this burden of proof in proceedings initiated before the indemnification fund (Article L.3122-2 CSP).

(b) Regarding the defective product liability régime, the risk of injury is the very definition of the product’s defect. The plaintiff must, however, prove both the existence of a risk and the causal link between said risk and the injury. In this respect, scientific and technical knowledge on the date of the product’s circulation in the market can possibly exempt the professional litigant from liability regarding both the defect and the causal link (Article 1386-11 4° C.Civ.). Thus, in a decision rendered on September 23, 2003, with reference to Articles 1147 and 1382 C.Civ., the Cour de cassation construed these Articles on the basis of the July 25, 1985 Directive and refused to hold a pharmaceutical laboratory liable for manufacturing a vaccine against the hepatitis B virus, due in particular to the absence of a causal link between the vaccination and the plaintiff’s contracting multiple sclerosis. The Cour de cassation justified the rescission of the Court of Appeals’ decision by emphasising the fact that neither the experts’ reports nor the scientific studies evidenced the existence of a relation between the vaccination and the illness (Cour de cassation, September 23, 2003, appeal no. 01-13063).

Accordingly, a professional litigant’s liability is subject to scientific and technical knowledge of the relation between the product and the injury; and the existence of an injury, as well as the causal link, must in any event be proven.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

(a) Under the two classical liability régimes (tort and contractual), the principle is that “Joint and several liability may not be presumed: it must be expressly stipulated” (Article 1202 C.Civ.), except where joint and several liability exists as of right under a statutory provision. Consequently, tort liability does not allow, in principle, to condemn several possible producers jointly and severally whereas, under contractual liability involving professionals, case law presumes joint and several liability.

(b) Concerning defective product liability, since a law of December 10, 2004, Article 1386-7 C.Civ. only provides for the liability of the successive suppliers when the producer cannot be identified. (Before a judgment of April 25, 2002, of the ECJ, condemning its formulation, Article 1386-7 C.Civ. used to provide that the successive resellers of a product were liable under the same conditions as the producer or persons having a similar role). If their liability is asserted by the victim, resellers have a right of action against the producer under the same conditions as said victim, but only within one year of the action brought against them.

Besides, pursuant to Article 1386-8 C.Civ., the manufacturer of a component is jointly and severally liable towards the victim with the manufacturer of the whole product into which said component was integrated if the injury was caused by the component. However, the component’s manufacturer can be exonerated from liability if he proves that the defect was caused by the design of the product into which the component was integrated.

In principle, market-share liability does not exist in French system.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

In case of breach of an obligation to provide information, the manufacturer and/or seller can in principle be held liable. However, there is no obligation to provide information when the purchaser is already informed.

(a) Under tort liability, from the beginning of the 20th century, law as well as case law developed an obligation incumbent on the manufacturer and/or the seller of a product to provide information concerning the product sold. Such an
and to protect himself from these risks, where these risks are circulating the product in the market to provide all useful information. This information is intended to allow consumers to concern, and of the main conditions of the contemplated goods and the provider of services to inform consumers of the “essential characteristics” of the good or service legal provisions. Thus, Articles L. 111-1 through L. 111-3 provide for an obligation incumbent on the seller of the creditor of such an obligation, asserting one’s ignorance does not suffice. Such ignorance must also be legitimate. This obligation to provide information does not apply, however, when the purchaser could easily have found out the information. As a consequence, it may be upheld that the legitimate ignorance requirement, which stems from the duty to inform oneself, defines the limitation of the pre-contractual obligation to seek out information. In order to be the creditor of such an obligation, asserting one’s ignorance does not suffice. Such ignorance must also be legitimate. This obligation to provide information does not apply, however, when the purchaser could easily have found out the information. Still, an obligation to provide information may arise from legal provisions. Thus, Articles L. 111-1 through L. 111-3 provide for an obligation incumbent on the seller of the goods and the provider of services to inform consumers of the “essential characteristics” of the good or service concerned, and of the main conditions of the contemplated contract. This information is intended to allow consumers to decide whether to enter into the contract or not. Article L. 221-1-2 (inserted by Ordonnance no. 2004-670 of July 9, 2004) also requires the person responsible for circulating the product in the market to provide all useful information for the consumer to assess the risk inherent to a product during its normal or reasonably foreseeable lifespan and to protect himself from these risks, where these risks are not readily perceivable by consumers without appropriate warning. Thus, pursuant to Article L. 221-1-2 C.Cons., it would seem that consumers can no longer take court action on the basis of the breach of an obligation to provide information, at least when the professional litigant indicated before entering into the agreement the existence of the risk which eventually materialised. It should be noted that an increasing number of legal provisions specifically provide for mandatory information to be affixed on products’ packaging (such is the case for pharmaceuticals, certain toxic products, cigarettes, etc.). In cases where legal provisions expressly set forth the nature and extent of the information to be provided, courts now generally rule that the producer may not be reproached with not having provided more information than what is required by law. Case law has not laid down any “learned intermediary” principle as the information taken into account by the courts is that provided to the end purchaser or circulated to the general public.

(b) Concerning defective product liability, Article 1386-4 C.Civ. sets forth that, for the purposes of assessing the safety that one can legitimately expect, it is necessary to take account of all circumstances, including in particular the product’s presentation. In this respect, the assessment of a defect in the product must be weighed against the information provided by the manufacturer in the product’s presentation. A contrario, the indication of a risk of injury cannot in itself be used as a substitute for the plaintiff’s offering proof of a defect in the product and a causual link. Indeed, the Cour de cassation refused to uphold the liability of a pharmaceutical laboratory which produced a vaccine against the hepatitis C virus, as the plaintiff suffered from multiple sclerosis and alleged that this disease had been caused by his vaccination, although the instructions for use indicated the existence of a low risk, considering that the plaintiff did not offer proof of a defect or of a causual link (Cour de cassation, September 23, 2003, appeal no. 01-13063).

Regarding defective product liability, there is no such principle as that of “learned intermediary”. In fact, further to the ECJ’s decision of April 25, 2002, successive suppliers can only be held liable when the producer cannot be identified.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Defendants in civil liability lawsuits may assert several causes of exoneration or limitation of their liability.

(a) The first cause of exoneration of liability under all liability régimes is force majeure. The traditional definition of force majeure is an event that is both unpredictable, irresistible and exterior (this condition of exteriority includes both natural events and events caused by third parties). Of note, the 1998 Product Liability Act does not specifically sets forth such cause of exoneration. However, in light of the French case law concerning civil liability, and considering that the recognition of liability on the account of a defective product requires proof of a causal link between the defect and the injury, it should be considered that force majeure constitutes an applicable defence, even in the absence of a specific text, although this issue has not yet
been adjudicated upon by the courts. The principle here is that force majeure results in a total exoneration of liability. Of note, in a contract between professionals, parties may provide that force majeure shall have no exonerating role.

(b) The second defence, also applicable under all liability régimes, is the fault of the victim (also known as contributory negligence) or of any person the victim is liable for. Such contributory negligence results either in shared liability, or in a complete exoneration of the defendant from any liability. When liability is shared, the apportioning is theoretically calculated on the basis of the seriousness of the faults committed by the respective defendants: partial causation, as a concept, does not exist under French law (Cour de cassation, December 4, 1990, appeal no. 89-17174). In practice however, this question very much depends on the first-level and appeals courts’ appreciation and is not subject to a strict legal control by the Cour de cassation. In the case of defective product liability, this defence has been expressly provided for by Article 1386-13 C.Civ.

(c) The third classical defence is the act of a third party, although it is less frequently invoked. If it presents the characters of force majeure, it results in a complete exoneration from liability. If it does not have such nature, the act of a third party does not, in principle, exonerate the liable party from liability towards the victim. It only allows said liable party to exercise a recursory action against the concerned third party, if its act was faulty, in order to recover some of the damages it had to pay. The 1998 Product Liability Act for instance sets forth, in Article 1386-14 C.Civ., that the act of a third party does not play any exonerating role; however, as mentioned above, according to our reading of these provisions, the act of a third party constituting force majeure should result in a complete exoneration of the defendant concerned.

(d) The 1998 Product Liability Act in addition sets forth specific causes of exoneration. Pursuant to Article 1386-11 C.Civ.: “The manufacturer shall be strictly liable except if he proves that:

- he did not put the product into circulation;
- the defect did not exist when he put the product into circulation;
- the product was not intended for sale or any form of distribution;
- the state of scientific and technical knowledge did not allow, at the time when the product was put into circulation, to detect the existence of a defect; or,
- the defect results from to compliance with legislative or regulatory mandatory rules”.

However, Article 1386-12 C.Civ. sets forth that: “A producer may not invoke the exonerating circumstance provided for in Article 1386-11, 4°, where damage was caused by an element of the human body or by products thereof”. The second paragraph of this text, which used to restrict the application of the exonerating circumstances set forth in Article 1386-11, 4° and 5°, was suppressed by a law of December 10, 2004, after being declared illegal by the ECJ (Article 7 of the 1985 EC Directive provides that the grounds of exemption from producer’s liability are unconditional).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

As mentioned in the precedent answer, Article 1386-11 C.Civ. sets forth that the manufacturer may be exonerated of its liability if it proves that, at the time when the product was put into circulation, the state of scientific and technical knowledge did not allow to detect the existence of a defect. The Cour de cassation has judged that the judges’ evaluation must be in abstracto (Cour de cassation, September 23, 2000, appeal no. 01-13063). Objective evaluation must be made on the basis of the most advanced knowledge available, irrespective of the area concerned (ECJ, May 29, 1997, Case C-300/95). Of note, the “state-of-the-art/risk-of-development” defence is inapplicable when the product concerned is a part or product of the human body (Article 1386-12 C.Cons.).

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under Article 1386-11 5° C.Civ., compliance with legislative or regulatory mandatory rules exonerates manufacturers from liability or mitigates it.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The principle of the relative effects of judgments (the res inter alios judicata alius neque nocet neque prodest principle) precludes the possibility of extending the effects of a judgment to other potential plaintiffs in the same legal situation as the party to a lawsuit insofar as these persons were not parties to the original lawsuit (Article 1351 C.Civ.). Thus, a different plaintiff can re-litigate issues of fault, defect or the capability of a product to cause a certain type of injury. Moreover, it is still possible for the original plaintiff to re-litigate the case if a new fact arises.

4 Procedure

4.1 Is the trial by a judge or a jury?

There are no juries in civil, labour, and commercial courts. In criminal matters, there are juries only in the Cours d’assises, which have jurisdiction over felonies, but not, however, in misdemeanour courts (tribunaux correctionnels). Most first-instance civil liability cases are therefore tried by one or three judges. Judges sitting in civil cases are civil servants.
4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e., expert assessors)?

The French Code of Civil Procedure does not allow courts to appoint technical specialists to sit with the judge(s). Only magistrates sit on the bench. Courts however have the option to appoint technical specialists as masters with a factual mission.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Pursuant to Article 31 of the Code of Civil Procedure (French acronym NCPC), a lawsuit is admissible only if the plaintiff has standing and an interest to act. Standing to act consists in the legal right to bring or oppose a claim and to defend a specific interest in court. Natural persons bringing a civil action in liability generally are presumed to have standing to act. It is, however, more problematic when a legal person - an association, for example - purports to defend the collective interest of a category of persons or a “social cause”. Indeed, one of the major principles of French law is that “No one shall plead by proxy” (Nul ne plaide par procureur).

Because of principles of the relative effects of judgments and “No one shall plead by proxy”, individual interests may not be aggregated and, even if they are grouped together in a single lawsuit, each plaintiff will have to formulate his own claims, which are evaluated and adjudicated upon separately. As a result, class actions as such do not exist under French law.

There are few legislative exceptions to this rule. Pursuant to the Consumer Code (C.Cons.), consumer associations may bring collective civil actions under specific conditions (see infra).

In addition, defence by an association of a general collective interest before the courts is already possible for labour unions and professional associations (ordres professionnels) of the professions, which are recognised by law as having the right to go to court by taking action against perpetrators of acts directly injuring the interests of these specific groups. Labour unions may, pursuant to Article L. 411-11 of the Labour Code (C.Trav.), bring actions to defend the collective interest of the employees they represent. Furthermore, pursuant to Article L. 321-15 C.Trav., they may bring actions in the interest of individual employees that are in specifically listed situations. This exception to the principle “no one shall plead by proxy” is however limited by the obligation, incumbent on the labour union, to inform the employees whose interests are at stake of the lawsuit they plan to bring, and by the possibility for one employee to prevent the union from doing so.

Nevertheless, the above-mentioned exceptions do not consist in permission to aggregate various individual claims, but rather in the recognition of a specific, “moral”, injury incurred by various associations defending “social causes”. Consequently, the damages awarded in litigation are often very low or even symbolic. The legislative exceptions to the principle have hitherto seldom been used.

In his New Year speech to the economic forces of the nation on January 4, 2005, the President of the Republic, Mr. Chirac, notably said he would ask the government to propose a modification of the legislation in order to allow groups of consumers and their associations to bring collective actions against the abusive practices seen in some markets. An administrative working group comprising representatives of consumer associations, of professional organisations, of plaintiffs’ lawyers and “qualified personalities” has been set up, and should submit on October 1, 2005 to the Ministers of Justice and of Economy and Finance its recommendations on how to amend the Civil Code, the Code of Civil Procedure and the Consumer Code in order to allow “group actions”, i.e., actions by groups of individual plaintiffs represented by one of them, or by associations representing a “class” of plaintiffs in the same situation (similar situation, similar injury allegedly resulting from the same fault). A bill should be finalised by the end of 2005 and be discussed in Parliament at the beginning of 2006.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g., by a consumer association?

As seen above, the French principle is that “No one shall plead by proxy”. However, as said above, one of the few legislative exceptions deals with consumer associations. Pursuant to Article L. 421-1 C.Cons., consumer associations may bring civil suits on behalf of either several consumers, or the collective interest of consumers as a whole. Article L. 421-1 C.Cons. sets forth that “Associations... having for their explicit statutory purpose the defence of consumer interests may, if they are authorised to this effect, exercise the rights of civil parties in connection with acts that directly or indirectly impair the collective interest of consumers”. It further provides that: “Where two or more identified consumers, natural persons, have personally sustained damage due to the acts of a same professional and having a common origin, any authorised [consumer] association that is recognised to be representative on a national level [...] may, if it has been mandated by at least two of the consumers concerned, bring a claim in compensation before any court in the name of these consumers”. This last provision has hitherto very rarely been used.

Indeed, associations can inform consumers of the existence of an action only through the press. Also, powers-of-attorney must be obtained before the action is initiated.

4.5 How long does it normally take to get to trial?

Having been filed, cases usually reach the trial stage between 12 and 36 months later. This duration may however vary depending notably on the complexity of the case. Of note, summary proceedings allow plaintiffs, under specific conditions, to obtain an interim judgment (ordonnance de référé) within short periods of time (weeks or even days). Interim judgments can be appealed before the competent Court of Appeals, and in cassation, but these appeals, although scheduled more quickly than those on the merits, can still take up to one year.

Judgments are usually rendered a few months after the trial hearing (generally 6 weeks to four months).
4.6 Can the court try preliminary issues, the result of which determines whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The French Code of Civil Procedure provides that judges can try different kinds of preliminary issues.

First, as said above, summary proceedings allow plaintiffs, under specific conditions, to obtain an interim judgment (ordonnance de référé) within short periods of time. This judgment often is, however, followed by proceedings on the merits. Interim judgments can be appealed before the competent Court of Appeals.

Second, during the pre-trial phase it is possible for one of the parties to raise what is called an “incident” on the lack of jurisdiction of the court or on other procedural issues (for instance, the inadmissibility of the plaintiff’s claim). These incidents may result in the Juge de la Mise en État (a magistrate designated by the President of the Civil Court to supervise the pre-trial phase of the proceedings) hearing the parties plead specifically on the points raised in the incidents, and to adjudicate on these incidents, or order that they be joined to the merits of the case for a global review by the full court. The interim judgments rendered by the Juges de la Mise en État can be appealed before the competent Court of Appeals and before the Cour de cassation. They cannot, however, be appealed separately from the judgment on the merits, which means that, in order to have a court rule a case inadmissible, it is necessary for the defendant’s counsel to submit briefs and evidence responding to all the claims raised in the writ of summons, and argue the case in its entirety before the court.

4.7 What appeal options are available?

Court of appeals are the normal second-level Courts which adjudicate upon appeals brought against first-level judgments of all civil, commercial, labour and misdemeanour courts. Each party has the right to a review of a first-instance judgment by appeal both on the facts and the law, except if the amount of the claim brought before the courts is less or equal to EUR 3,800. In such a case, the claim is tried by a tribunal d’instance (justice of peace), and cannot be appealed, except before the Cour de cassation.

The Cour de cassation is the judicial Supreme Court and reviews issues of law (not of fact) referred by the Courts of appeal. It has jurisdiction on civil, commercial, labour and criminal law matters. The Cour de cassation must compulsorily examine any appeal brought before it, and may not, like in the United States, refuse to hear a case by denying it certiorari.

The time periods to appeal civil judgments (generally 1 to 2 months) are calculated from the day when the judgment is served on the losing party.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Masters may be appointed by the court. Masters’ appointment is solely a faculty for the courts; in other words, there is no obligation for them to appoint masters, even when requested to by the parties. The masters’ mission is defined by the court through the formulation of a mandate; parties can file briefs with the court on the scope of the master’s investigation and may formulate the questions they would like to see addressed, although the court is not bound by these suggestions. In practice, the debate on the master’s (or masters’) mandate is crucial, because its outcome conditions the scope, the details and the orientation of the master’s (or masters’) mission. Masters are given by the court a deadline to submit their findings. They hold master’s sessions with the parties, their counsel and experts, and file reports on issues/facts on which the court has requested their contribution. Masters are usually chosen from a list of official experts but they may also be appointed by special selection.

The nature of expert evidence depends on their mission. Of note, courts are not bound by the findings of the master(s) either, although such is generally the case, especially on technical issues where courts rarely take the risk of contradicting masters’ conclusions in their judgments.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Under French civil procedure system, there is no obligation incumbent on factual or expert witnesses to present themselves for pre-trial depositions. However, Article 16 of the Civil Procedure Code (acronym NCPC) provides that “judges shall, at any event, cause to comply, and shall themselves comply, with the adversary principle”. Pursuant to this article, court-appointed masters’ reports and expert witnesses’ statements must exchanged prior to trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

The basic principle of French civil procedure is that each party freely decides what evidence it chooses to file. Discovery proceedings, in the US sense, thus do not exist under French law. The above-mentioned adversary principle implies that the parties shall be held to make known to each other in due time the items of evidence they shall produce so that each of them is in a position to prepare his case (Article 15 NCPC).

In addition, under French civil procedure system, an obligation to disclose documentary evidence can arise either before proceedings are commenced or as part of the pre-trial procedures. Concerning the first hypothesis, Article 145 NCPC provides that “Where there is a legitimate reason to preserve or to establish, before any proceedings, the means of proving the factual circumstances upon which the resolution of the dispute shall depend, directions legally permissible may be given at the request of any party further to a petition or by way of a summary interlocutory procedure”. In the second hypothesis, a party may request the production of some specific evidence not mentioned by the other party in its briefs but nevertheless in its possession. If the requested party refuses to submit to such request, the party having requested production of the evidence may try to
resort to forced production of evidence during the pre-trial phase, i.e., request the Juge de la Mise en Etat to order the opposing party to produce the evidence under financial penalties (astreintes). A party may also request the court, during the trial hearing, to order a third party to produce a specific document in its possession. It should however be noted that Juges de la Mise en Etat and courts rarely defer to these requests.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The two main types of civil liability (contractual and tort) are subjected to time limits on bringing or issuing proceedings. Moreover, the defective product liability system is specific on this particular point.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have discretion to disapply time limits?

The common principle applicable to any lawsuit is that proceedings must be brought within a period of thirty (30) years as from the manifestation of the injury or its aggravation (Article 2262 C.Civ.). However, liability régimes are subject to special time limits. Actions in tort liability are barred after ten (10) years from the manifestation of the injury or of its aggravation (Article 2270-1 C.Civ.) whereas, concerning contractual liability, the thirty years’ time limit would only apply if the law does not provide specific time limits.

Under the defective product liability régime, the manufacturer’s liability is extinguished ten years after the product was put into circulation (Article 1386-16 C.Civ.). Besides, the victim’s action is time-barred three (3) years after it has or should have knowledge of the injury, of the defect and of the identity of the manufacturer (Article 1386-17 C.Civ.).

Time limit does not run against non-emancipated minors and adults in guardianship, except in certain cases defined by law (Article 2252 C.Civ.). Moreover, the courts do not have discretionary power to disapply time limits (Article 2223 C.Civ.).

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In principle, the statute of limitations cannot be interrupted or suspended except in the cases set forth by law (Article 2219 et seq. C.Civ.). However, according to the principle “Fraus omnia corrupit” and case law, a party may not assert the statute of limitations when it is responsible for having prevented the claimant from acting within the time limit.

Also, concerning certain criminal offences, the statute of limitations only begins to run on the date when the wrongful acts are discovered by the victims.

Besides, issues of concealment and fraud can possibly give the right to initiate an extraordinary recourse action, i.e., a recours en révision (re-trial request) (Article 593 NCPC). Such recourse action allows a first-instance court to take back one of its final and res judicata decisions in a limited number of cases listed by law. In this regard, Article 595 NCPC provides four cases in which a recours en révision may be requested: (i) fraud, (ii) discovery, after the judgment, of decisive pieces of evidence withheld due to a third party, (iii) proof that the initial judgment was based on forged evidence. The time limit for initiating this recours en révision is two months as from the date on which the party initiating this recourse became aware of the reason it asserts for such re-trial (Article 596 NCPC). It may be noted that no recours en révision is available against judgments rendered by the Cour de cassation, since this recourse action is intended for the purpose of re-reviewing the case as a matter of both fact and law.

6 Damages

6.1 What types of damage are recoverable: damage to the product itself, bodily injury, mental damage, damage to property?

Under three conditions (an actual, direct and certain injury), the two main liability régimes allow the plaintiff to be compensated for a broad scope of injuries: material and financial injuries (including both actual losses and gains missed), bodily injuries, moral injuries (which include several aspects, and notably pain and suffering or pretium doloris et affectionis, loss of enjoyment - such as the impossibility to perform a trade - or aesthetic injuries - pretium pulchritudinis).

In order to further protect plaintiffs, case law developed in the last decades a specific injury called “loss of an opportunity” (perte de chance). This notion is used when the injury consists in the loss for the victim of an opportunity to realise a gain or avoid a loss (in the broad sense of these terms). For example, if a defective product injures a person who can thus not take an exam that he/she was preparing, or prevents him/her from taking up a job for which he/she had been recruited and results in his/her replacement by somebody else, the injury consists in the loss of an opportunity to pass the exam or to get the job.

The defective product liability is specific. It is applicable only to the compensation of bodily injuries or injuries to goods other than the defective product itself (Article 1386-2 C.Civ.). Of note, the 1985 EC Directive provided for a threshold of EUR 500 concerning non-bodily injuries, under which the specific régime set forth by is not applicable. Since a judgment of April 25, 2002, of the ECJ, and a law of December 10, 2004, the French transposition of this directive does now include a threshold.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g., covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Medical monitoring, insofar as it applies to injuries that are neither actual nor certain, does not meet the conditions to open right to indemnification of the plaintiffs claiming it.
Concerning future injuries, Article 1150 C.Civ. sets forth that solely those foreseeable at the time of the conclusion of the contract are compensable. However, this limitation has been interpreted by the courts as meaning that the nature of the injury, not its financial amount, must have been foreseeable. As a result, an injury that is certain but not yet actual can open the right to compensation.

There are neither legal provisions nor case law yet on this point but it has become a hot issue (for instance in the asbestos litigation) and developments may occur in the future.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

As said above, the principle of French liability law is that damages must correspond to the actual extent of the injury. In principle, damages are not limited by deductibles, thresholds or caps (except as set forth by law). The seriousness of the fault or, for corporate defendants, the wealth of the corporation, are thus in principle indifferent, the extent of the injury being the sole criterion of determination of damages.

Punitive damages therefore do not exist under French civil law. There however are voices in France - notably among academics and lawyers specialised in plaintiffs’ representation - advocating an evolution towards punitive damages; courts, however, have not (so far) accepted the legal reasoning supporting this idea.

Parties may, in a contract, set forth deductibles or caps. Of note, both the limits resulting from Article 1150 C.Civ. and those set forth by the parties are inapplicable if a party commits a breach of contract “of a particular gravity” or an intentional fault.

Compensation is in most cases financial, especially in liability cases. Other forms of reparation are also available in certain cases, such as the publication of a text or of the judgment itself in various newspapers.

Of note, concerning medical liability, the victim may refer the matter to special commissions, which must give an opinion on the liabilities incurred within six months, after which the insurer of the liable person must offer an indemnification within four months. Failure to do so may result in a fine equivalent to up to 15% of the amount of the injury being imposed on the concerned insurer (Articles L. 1142-14 and L. 1142-15 CSP). This fine is somewhat similar to punitive damages although it is not paid to the victim, but to the national indemnification fund.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Pursuant to the principle that damages must correspond to the actual extent of the injury, the only limit on the damages recoverable from one manufacturer for a series of claims arising from one incident or accident is the sum of the victims’ injuries.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Under the French civil procedure system, the successful party can recover different kinds of expenses from the losing party(ies).

Article 699 NCPC provides that, in principle, the losing party(ies) must bear the legal costs. These costs, as set forth by the courts in their judgments, are however generally very low (except where the court has appointed an expert), and do not include the attorneys’ fees, except for nominal amounts.

Article 700 NCPC allows the courts to order losing parties to pay their opponents an amount intended to compensate costs incurred by said opponents and not included in those covered by Article 699 (notably attorneys’ fees). Courts, however, generally tend to only allocate nominal amounts only on this basis as well.

Each party supports its own lawyers and experts’ fees.

7.2 Is public funding e.g. legal aid, available?

In principle, legal aid is available for any type of litigation and may be provided at any stage of the proceedings.

7.3 If so, are there any restrictions on the availability of public funding?

In order to obtain legal aid, an applicant must prove his or her lack of means to a special body consisting of various public officials and a lawyer. The legal aid application may be accepted in whole, in part or dismissed. Although amounts are reviewed annually, in order for applicants to be granted full legal aid, their income must currently be, for a single person, less than approximately EUR 844 per month. A person may receive partial legal aid if his income does not exceed approximately EUR 1,265 per month (for a single person). Legal aid may be denied to a person respecting these thresholds but whose claim is manifestly inadmissible or devoid of merit.

If a legal aid claim is rejected, Article 23 of Act no. 91-647, July 10, 1991 provides two types of recourse. First, the applicant may bring appeal to the President of the tribunal competent for the main claim when the dismissal is justified by the lack of seriousness of his/her main claim. The decision of the President cannot be appealed.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The Rules of the French Bar at present severely limit contingency or conditional fee arrangements. Contingency fees must be agreed upon in writing and prior to the launching of the action. They generally take the form of a “success fee” coming in addition to the lawyer’s fee. However, the Cour de cassation has admitted as lawful the
payment of additional fees for the successful service provided (Cour de cassation, February 17, 2005, appeal no. 02-14167). They may in no event constitute the exclusive or main remuneration of the lawyer (Article 11.3 of the Harmonised Rules of the Bar).

The prohibition on contingency fees is however less and less respected. In recent cases (most notably tobacco, environmental and asbestos litigation), plaintiff attorneys have almost exclusively been paid through the contingency system, which has resulted in much higher claims. Contingency fees will undoubtedly develop in the coming years, following the US and British examples.
1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

The law of product liability in Germany is based on three grounds: the law of contract; the traditional (fault based) law of torts; and strict liability law. These regimes form, according to a general principle of German law, concurrent legal bases. Article 13 of the European Directive 85/374/EEC on liability for defective products (‘the Directive’) preserves this juxtaposition.

The law of contract provides for compensation for damage caused by a product if, for example, it is not in conformity with the contract. These regimes form, according to a general principle of German law, concurrent legal bases. Article 13 of the European Directive 85/374/EEC on liability for defective products (‘the Directive’) preserves this juxtaposition.

The law of contract provides for compensation for damage caused by a product if, for example, it is not in conformity with the contract. Contract law, however, is only relevant where the injured person and the defendant have a contractual relationship, as the courts in Germany have not gone down the route of relaxing the principle of privity of contract in order to establish an effective legal basis for product liability claims for third parties to a contract.

The Federal Supreme Court established instead a distinctive concept of ‘producer liability’ under tort law, which, although in principle is based on fault, comes effectively very close to the non-fault system introduced by the Directive.

Most product liability claims in tort are based on negligence (section 823 subs. 1 of the Civil Code). This requires the breach of a duty of care (Verkehrspflicht). The Federal Supreme Court characterises putting a defective product on the market as indicative of a breach of duty (see also question 2.1). In this context, the Supreme Court has identified three types of defects: design defects, manufacturing defects and instruction defects (i.e. failure to warn/provide proper instructions).

Note that the producer’s duties do not end with the marketing of the product. He is still obliged to monitor the product and to take appropriate measures once the product is in circulation. (see question 1.4).

German tort law also encompasses liability for intentional or negligent breach of a statutory or regulatory provision meant to protect other persons (section 823 subs. 2 of the Civil Code). It does not matter whether the provisions are based on federal, state or EC law. Important examples of such provisions can be found in the Product Safety Act, the Food Act, the Drug Act, the Medical Devices Act and the Criminal Code.

Strict liability for products in Germany includes the Product Liability Act 1989 (‘PLA’), the Drug Act 1976 (the ‘Drug Act’) and the Genetic Engineering Act 1990 (the ‘Genetic Engineering Act’).

The PLA faithfully implements the Directive to introduce liability for defective products. Compared to tort law, the PLA sets stricter limits on recoverable damages as well as on the group of liable persons (see questions 1.3, 6.1 and 6.4); it also does not apply to post-marketing defects. Given the existence of an effective system under tort law, the PLA has rarely been applied. However, as it is now possible to recover non-material damages under strict liability regimes (as of 1 August 2002), this could change.

The Drug Act is an important strict liability regime for pharmaceutical products, which takes priority over the PLA. The Drug Act includes liability for development risks (see question 3.2) and renders insurance compulsory. Together with the novel rules on causation (see question 2.2) and a special - in German law unusual - claim for disclosure (see question 4.10), both of which were introduced in 2002, the German Drug Act is the most strict statutory product liability regime in Europe (see I. Brock, German parliament passes the Second Act to change the rules relating to damages, Lovells, European Product Liability Review, June 2002 at 16f.).

The Genetic Engineering Act provides for liability for damage caused by genetically manipulated organisms (GMO). This includes liability for development risks.

1.2 Does the state operate any schemes of compensation for particular products?

Thalidomide victims have a right to benefits provided by a public foundation established in 1971. Another public foundation has been set up to help patients who were infected with HIV through contaminated blood products before 1 January 1988. In both cases, the endowments are shared by the state and the relevant pharmaceutical companies. There is also financial aid available for a specific group of people who have been infected with the Hepatitis-C-Virus through particular batches of vaccine.
1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The PLA places the responsibility for the defect on the ‘producer’. The term producer includes the manufacturer of the product or a component, the producer of raw material, the ‘own-brand’er and the person importing into the EU (EEA). The supplier of the product is only liable if the producer cannot be identified. But the supplier can exonerate himself by informing the injured person within one month of the identity of the producer or any other person higher up in the chain of supply (provided this person is located within the EU/EEA). The same applies if the importer cannot be identified even if the identity of the producer is known.

The Drug Act assigns responsibility to anyone who, in his own name, puts the drug into circulation in Germany. The same goes for liability for products incorporating GMO under the Genetic Engineering Act.

A duty of care in tort (see question 1.1) can rest on all persons who are involved in the production and marketing of a product, although the characteristics of the duty may vary, depending on the role the individual person has in this process. In contrast to the situation under the PLA, the supplier can be liable in tort, regardless of whether the ‘producer’ can be identified. A duty of care can also rest on employees in their capacity as managers. Liability for breach of statutory or regulatory duty (see question 1.1) will fall on the person to whom the relevant provision assigns the duty (e.g. on producers and suppliers under sections 4 and 5 of the Product Safety Act).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Where a producer becomes aware of risks emanating from a product which is already on the market, he is under a duty of care to take appropriate measures to abate the risks. Often, it will be sufficient to issue warnings, but the producer is under a duty to recall the product where other measures are inadequate.

An obligation to recall products can also follow from an order by the relevant authority. Under the Product Safety Act amended in 2004, authorities can issue such a recall order if they have reasonable clues to that a product is not in conformity with the safety requirements under this Act and if the authority deems the recall to be the most appropriate measure to be taken.

The failure to issue warnings or to recall the product gives the injured person a claim in negligence or for breach of statutory/regulatory duty (see question 1.1). Furthermore, the courts now accept a claim in negligence or for breach of statutory/regulatory duty (see question 1.1).  Furthermore, the courts now accept a claim for mandatory injunction for warnings and even recalls.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Section 1 subs. 4 PLA puts the burden of proving defect on the injured person, who has to show that the product did not provide the safety that one is entitled to expect (section 3 PLA). As to the proof of manufacturing defects, this means the higher the expectations of safety to which the typical consumer is entitled, the lower the extent to which to which the claimant has to investigate the exact nature of events leading to the product’s failure - and vice versa (see S. Lenze, Proof of Defect, Lovells, European Product Liability Review, December 2002 at 40ff.). As far as design defects and warning defects are concerned, proof of defect effectively comes close to establishing corporate negligence.

Under section 84 of the Drug Act, the claimant must either prove that the risks of the drug in question outweigh its benefits (risk-benefit test) or that the information in the SPC (special product characteristics) or the PIL (package insert leaflet) did not comply with the medical knowledge available at the time.

While in tort the burden to prove fault is usually on the plaintiff, this rule is significantly modified in product liability cases. Where a breach of a pre-marketing duty of care is in question, it suffices that the consumer proves that the product was defective. The producer must then show that he did everything necessary and reasonable to discover and avoid the defect. Contrary to the PLA, it is also for the claimant to prove that the product was already defective when it was put into circulation. However, as to design and warning defects, this defect-focused approach is in practice hardly different from negligence. Finally, there is no shift in the burden of proof regarding the breach of a post-marketing duty (see question 1.4).

While the claimant also has to prove the breach of a statutory/regulatory duty, it will usually be for the defendant to show that this breach did not happen through fault.

It is also for the claimant to prove a causal relationship between the (pre-marketing) defect, or the (post-marketing) breach of duty and the injury.

Finally, it is for the claimant to prove, under all product liability regimes, his injury and consequential damages.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In order to prove a causal relationship, the claimant has to show that the damage would not have occurred but for the defect or the breach of duty, respectively (“condition sine qua non”). The claimant does, as a rule, not satisfy this test by demonstrating that the product created an increased risk (see also question 2.3). According to the rules of prima facie evidence (“Anscheinsbeweis”), the claimant can prove causation by establishing a typical course of events. This does not mean, however, that the claimant only needs to establish an increased risk or a certain probability of causation. It means that he can apply general common sense to persuade the court of a certain course of events.

Under the new rules of the Drug Act, the claimant no longer needs to prove that the drug in fact caused his injury. He only needs to prove that, under the circumstances of the individual case, the drug is “capable” of causing the damage.
Joint and several liability applies, according to section 830 subs. 1 of the Civil Code, “if it cannot be ascertained which of several participants caused the damage through his conduct”. The provision requires that all defendants contributed to the risk of injury. It might under certain circumstances apply in cases where the claimant cannot prove which of the products he had actually used in fact caused the damage. However, it will not apply where he cannot even say which products exactly he had used. The theory of market share liability is not used in Germany.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The 2002 amendments to the Drug Act add nothing to this rule. Although the claimant does not have to prove which of several defective drugs in fact caused his injury, provided he can show that the defective drugs in question were generally capable of doing so, he does have to establish that he actually took those drugs.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn constitutes a warning defect where, in the absence of warnings, the product does not provide the safety a person is entitled to expect (Article 6 (1) (a) of the Directive, section 3 (1) (a) PLA). The relevant test here is that of a “reasonably well informed and reasonably observant and circumspect consumer” (see S. Lenze, Proof of Defect, Lovells, European Product Liability Review, December 2002 at 42). Where a product is normally only used by professionals, the standard needs to be adapted accordingly. This means, for example, the information accompanying a medical device used by surgeons needs to contain instructions and warnings required by surgeons.

As to pharmaceuticals, Articles 11 and 59 of Directive 2001/83/EC (and the Drug Act) set out detailed labelling requirements for the summary product characteristics and the package insert leaflet. Accordingly, information on, amongst others, indications, contraindications, precautions for use, and possible undesirable effects has to be provided to doctors and patients respectively. Breach of these labelling requirements can constitute a product defect. There is normally no “learned intermediary rule” as to the issue of defect, i.e. warnings to doctors do not substitute direct warnings to patients. This may be different where the drug is not administered as “take-home medication” but during hospitalisation.

However, in the event that the information provided to the prescribing doctors contained instructions or warnings which were not part of the package leaflet, it will be difficult for the claimant to prove a causal link between the lack of warning and the damage. The claimant needs to show that - against the instructions of his doctor - he would not have taken the drug had the package leaflet contained this information. In other words, the learned intermediary defence can be used to contest causation.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In tort the defendant can argue that he was not at fault, which means he is not responsible if he is able to show that he did not breach a (pre-marketing) duty of care, or that the breach of statutory duty was not based on fault. Where there is no guarantee, absence of fault generally is also a defence in contractual damages claims.
Liability under the PLA is somewhat stricter, and so the producer is, according to section 1 subs. 2-4, not liable only if he proves:

- that he did not put the product into circulation;
- that it is to be assumed that the product did not have the defect which caused the damage at the time when the producer put it into circulation;
- that he manufactured the product neither for sale nor for any other form of distribution for economic purposes;
- that the defect is due to compliance of the product with mandatory regulations issued by public authorities;
- that the state of scientific knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered; or
- in the case of the manufacturer of a component, that the defect is due to the design of the finished product or that the component was made according to the instructions of the producer of the final product.

Finally, contributory negligence is a defence under all regimes.

3.2 Is there a state of the art/development risk defence?

Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

A defence for development risks is incorporated in the PLA (see question 3.1). However, the way in which this defence is read restricts its scope significantly. The producer of a defective product must prove that the defect could objectively not be discovered, taking into account the most advanced state of scientific and technical knowledge at the time the product was put into circulation (i.e. not just the knowledge of a certain industry). However, such knowledge must be accessible.

The same defence regarding the impossibility of discovering a defect is available under tort law.

The development risks defence can no longer apply once the problem with a certain product is known, as the issue becomes one of avoidability, which is solely a question of negligence. The producer is therefore in tort not liable for the one (unavoidable) “odd product” out of a series, which, despite all reasonable and necessary measures, contains a manufacturing defect. Given that the Supreme Court requires the producer to apply strict quality controls, it is difficult to raise this defence successfully in practice.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory (or statutory) requirements (see question 3.1) is only a defence where those requirements have necessarily led to the damage (section 1 subs. 2 PLA). Compliance with regulatory requirements is no automatic defence where they simply impose minimum standards. However, a product that complies with all regulatory requirements is not normally defective, so that a regulatory compliance defence exists as a practical matter.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The effect of a judgment in the German law of civil procedure is that a claimant cannot bring the same claim again based on the same set of facts (i.e. res judicata). “Claim” here refers to the relief sought by the claimant, regardless of the legal basis. Judgments will normally be determinative only of the rights of the parties to the proceedings (apart from third party intervention or notice under sections 66, 72 CCP, for example in a recourse scenario).

A different claimant can therefore litigate issues of fault, defect or causation against a producer who has already successfully defended a claim, on the same issues, brought by someone else.

The same claimant, on the other hand, cannot claim the same damage again, unless he comes up with a different set of facts (i.e. not only produces fresh scientific evidence). However, preliminary issues such as fault, defect or causation, are generally not subject to any form of issue estoppel. This means the same claimant can re-litigate issues of fault, defect or causation, provided they are based on different facts or appear in the context of a different claim (e.g. for a different head of damage).

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is led and decided by a judge (or judges). The judge in Germany has a much more active role than judges in common law systems do. He is the one who first and foremost interrogates the witnesses and selects the experts, with the lawyers free only to ask supplementary questions.

It is also for the judge to assess the evidence he has taken in order to find the facts (i.e. not only produces fresh scientific evidence). However, preliminary issues such as fault, defect or causation, are generally not subject to any form of issue estoppel. This means the same claimant can re-litigate issues of fault, defect or causation, provided they are based on different facts or appear in the context of a different claim (e.g. for a different head of damage).

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, it is only for the judge to assess the evidence (see also questions 4.1 and 4.8).
4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class actions, or similar means to bundle mass tort claims, which would prejudice the rights of each member of the group, are not available under German law.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Representative actions are not available in the areas of product liability and product safety.

4.5 How long does it normally take to get to trial?

There is no formal pre-trial stage in Germany. After the statement of defence has been made, the judge usually sets a date for the trial. This normally takes between four and eight months.

4.6 Can the court try preliminary issues, the results of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Given the role of the judge (question 4.1) there is no trial about preliminary issues. For example, at no time does the court decide on the admissibility of scientific evidence, for it simply appoints the experts itself (question 4.8). Furthermore, the court cannot split the trial to decide on certain preliminary issues (e.g. causation) in advance. What the court can do is turn to certain issues (e.g. causation) first, take evidence on them, and then ‘discuss’ the outcome with the parties. Courts may also take a decision on the merits first, reserving until later the assessment of damages (section 304 CCP).

A party itself can, in certain circumstances, before the claim is filed, request that the court appoint an expert to give an opinion on the cause of injury or defect (section 485 subs. 2 CCP). This may, depending on the opinion, prompt the claimant not to proceed with the litigation or may lead to a settlement. The claim for disclosure under the Drug Act can now request that the manufacturer (and the relevant authority) provide information on the known effects, side effects and interactions of a drug. This claim can be brought as of right where the amount of complaint exceeds €600. Otherwise, the party requires leave to appeal (section 511 CCP). The Federal Supreme Court revises the decision of the court of appeal on questions of law only (Revision) if either it or the court of appeal allows revision (sections 543, 545 CCP).

4.7 What appeal options are available?

Appeal from the decisions of the court of first instance (Berufung) may be taken as of right where the amount of complaint exceeds €600. Otherwise, the party requires leave to appeal (section 511 CCP). The Federal Supreme Court revises the decision of the court of appeal on questions of law only (Revision) if either it or the court of appeal allows revision (sections 543, 545 CCP).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court can, and must, appoint experts where it lacks the required technical or scientific knowledge itself. Experts usually give a written opinion on the technical and scientific issues, draw conclusions and may state a thesis. The parties can also obtain their own private expert opinions, although such an opinion will have minor probative value unless the other party agrees that it will be treated as an expert opinion. The main purpose of such private expert opinions is to influence the court-appointed experts in their findings.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no formal pre-trial deposition in Germany. The parties are free to exchange private expert opinions and similar documents before the trial, if they wish.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

German law has traditionally been fairly restrictive regarding document disclosure. There is no general pre-trial (or pre-action) discovery procedure and no general claim for disclosure that would help the claimant to establish liability. However, the recent reforms to the CCP and the Drug Act have introduced further-reaching rules for the disclosure of documents.

Under section 84a of the Drug Act, the injured person may now request that the manufacturer (and the relevant authority) provide information on the known effects, side effects and interactions of a drug. This claim can be brought prior to the damage action.

Procedural law now gives the court power to order the disclosure of documents in the possession of a party or a third person if a party makes a substantiated statement with respect to the content and implications of those documents (142 CCP). However, this does not mean a change of heart from the generally restrictive approach to the disclosure of documents in German law (see I. Brock, Does discovery find its way into the German rules of civil procedure?, Lovells, European Product Liability Review, December 2002 at 28f.).

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes time limits do exist.
5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The time limit for bringing compensation claims under tort law and under the strict liability regimes is generally three years. Broadly speaking, this period begins on the day on which the claimant became, or ought to have become, aware of the facts on which his claim is based. Time limits expire regardless of this knowledge 30 years after the incident in question occurred; claims for property damage, however, will be limited to only 10 years from the time when the damage manifests itself (subject to the 30-year limitation from the harmful event).

Rights under the PLA will be extinguished after 10 years from the day on which the producer put the product into circulation, unless the claimant has in the meantime instituted proceedings.

Contractual warranty claims are limited to two years from the delivery of the good.

All time limits (except the long stop in “Rights under the PLA” above) are suspended for the duration of negotiations between the parties.

The court generally does not have discretion to disapply time limits. But a time limit plea can be, in very limited circumstances, and following the intervention of the claimant, thrown out as being contrary to the principles of ‘loyalty and good faith’ (section 242 of the Civil Code).

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

As the time limit is three years from the day on which the claimant became aware of the facts, concealment or fraud will often delay the start of the time limit. An extension of the time limit may also be granted under the principles of ‘loyalty and good faith’.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

As of 1 August 2002, all product liability regimes cover, in principle, both pecuniary and non-pecuniary loss.

Pecuniary loss resulting from personal injury includes, for example, the costs of medical treatment and, usually in the form of an annuity, any loss of profit, income or maintenance.

Non-pecuniary loss includes pain and suffering as well as loss of amenity. Loss of amenity can usually be claimed even if the victim is unconscious. The highest amount so far awarded by a German court for pain, suffering and loss of amenity added up to the equivalent of €500,000.

Mental damage in the form of a recognised psychological disorder must be compensated, whether it manifests itself as pecuniary or non-pecuniary loss. Compensation for psychological disturbances of third persons, for example post traumatic stress disorder as a reaction to the injury or death of the primary victim, is subject to a number of restrictions. Damages in the absence of an injury (“fear of injury”, “loss of care and affection”) are not recoverable.

Damage to property is recoverable under all regimes, except for the Drug Act and the Genetic Engineering Act, but is subject to a number of restrictions. The PLA limits property damage to products other than the defective product (section 1). It further excludes damage to items that are usually, or that were largely, used for business purposes. Finally, €500 will be deducted from the damage (section 11).

Damage to the product itself is covered by the law of contract. Tort law allows the recovery of damage to the product itself only in exceptional circumstances, for example, where a separable part of the product causes damage to the rest of the product (so called creeping defects).

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Such cases have not yet come up in Germany. A claim for the expenses of medical monitoring would have no basis in negligence or under the PLA, as these regimes require an actual injury to body or health. It is hardly conceivable that the courts in Germany would follow the example of some state courts in the U.S. and give up this requirement. If at all, such claims would be brought for breach of statutory/regulatory duty (see question 1.1). However, it is unlikely that a court would hold that the relevant statutes and regulations serve the purpose of covering medical monitoring where the claimant is entirely asymptomatic.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable. Moreover, awards of punitive damages in foreign jurisdictions are regarded as being contrary to the German ordre public and are thus not enforceable in Germany.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The PLA limits the liability of the producer to a total of €85 million. The Drug Act sets a ceiling of €120 million and €7.2 million p.a. for annuities and cuts individual claims at a maximum of €600,000 (€36,000 p.a. for an annuity). The Genetic Engineering Act has a total limit of €85 million. There are no specified limits in tort or contract.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party can recover all necessary costs, including court fees and legal costs (section 91 CCP). The ‘necessary’ costs for a lawyer are reimbursed according to a
7.2 Is public funding e.g. legal aid, available?

The claimant can apply to the court for legal aid under section 114 CCP (see question 7.3.). Note also that legal insurance is comparatively common in Germany.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid will be awarded if the applicant does not have the financial resources to fund the claim and if the claim has sufficient prospect of being successful.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Lawyers in Germany are not allowed to work on a ‘no win - no fee’ basis or to agree on contingency fees. However, in the past few years, companies have emerged in Germany that offer to finance claims in return for a share of the profit.
1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Product Liability issues arising from the sale of products is regulated by the provisions of articles 534-558 of the Greek Civil Code (re: sale contracts) as recently amended by Law 3043/2002, which was introduced for the harmonisation of the national legislation to Directive 44/1999/EC for consumer products. Further, Law 2251/1994 which is a lex specialis “for the protection of consumers” regulates in more detail in its article 6 the issue of the manufacturers’ responsibility for defective products.

The Civil Code provisions are more strictly related to issues arising out of the sale of defective products, whilst Law 2251/1994 extends also to liability arising, inter alia, of abusive contractual terms, after-sale service, issues related to health and safety of consumers, responsibility of the provider of services etc. In both cases, i.e. pursuant to both the provisions of the Civil Code and the provisions of Law 2251/1994, liability is strict.

Contractual liability does play a role in the sense that, in addition to any liability arising out of the provisions of the law, the buyer or the consumer who purchased a defective product under a contract has also the possibility to file a complaint for breach of contract.

In general however, both the provisions of the Greek Civil Code, as well as the provisions of Law 2251/1994 provide adequate protection to lawful interests such as one’s life, health and property.

1.2 Does the state operate any schemes of compensation for particular products?

No. If a claimant considers that the State is responsible for damage incurred due to a particular defective product then, in order to be compensated, he will have to take action against the State before the administrative courts.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the aforementioned provisions of the Greek Civil Code on sale, the liability is with the seller and with the servants, agents etc., of the seller only. In this case, the claimant shall be always the purchaser of the goods in question.

However, under the special legislation on the protection of consumers (see art. 6 par 2(a), 3 and 4 of Law 2251/1994) the producer of the defective product is held liable for damages incurred to the consumer. Under certain circumstances (i.e. in case the producer is not known to the consumer etc.) the same liability is extended also to “importer” and to the “supplier” of the defective product who both are equated, by the law, to producer (quasi producers). According to the existing case law “importer” is anyone who imports goods from third (non EU) countries.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The obligation to recall products is a general obligation provided by article 540 par. 1(i) of the Greek Civil Code, as amended. More particularly, this article provides that in case of liability of the seller for a real defect in the product sold or if the product is not fit for the purpose or not fit by description, and in general when the product does not comply to the pre-agreed terms or the objective of the sale and purchase agreement between seller and buyer, the buyer has the right to request from the seller to recall the product and either repair its defect or replace it with a new one.

The main condition for the above article to apply is for the defect to exist at the time of the sale, namely at the moment when the ownership over the product passed from the seller to the buyer (art. 537 par.1 of the Greek Civil Code). In case the seller refuses to recall the product (or repair or replace it, as the case may be) the buyer has the right to have recourse to justice requesting from the court to order the seller to recall the product and to repair or replace it with a new one.

According to the general provisions on tort of the Greek Civil Code (see art. 914 sq.) an obligation is established for the producer to follow up and recall, if necessary, his product after it has been launched in the market. In case of failure to do so, then the producer is held liable as per the
aforementioned provisions on tort. Furthermore, article 7 par. 5 of Law 2251/1994 provides that products which even if used within the ordinary and foreseen circumstances may nonetheless entail serious and direct risks to the safety and health of consumers should be recalled by the producer or may be preventively confiscated by the authorities.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The claimant has the onus of proving that there is a defect in the product and that the defect is the cause of the injury or damage he has suffered.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The claimant must be able to establish a causal link between the damage he suffered and the defect in the product. It is not sufficient to prove (a) that the product was defective and (b) that he suffered damage or injury. The claimant also has the burden of proving that the defect in the product caused the specific injury or damage sustained.

If the claimant is only able to prove exposure to an increased risk of a type or injury known to be associated with the product, the seller and/or the producer may be released of any liability if they can produce evidence that the product was within accepted specifications when sold or launched in the market. However, if the claimant cannot establish a causal link between the defect and his damage or injury then the seller and/or producer cannot be held liable.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

According to art. 926 of the Greek Civil Code in case the damage is due to a joint action of several parties or in case there is a parallel liability on more than one parties (principal - servant etc.) for the same damage, then all the parties involved are liable in toto. The same principle applies also where several parties acted simultaneously or one after the other and the determination of who out of them is responsible for the damage provoked is impossible.

Following the above, if more than one producer manufactured a defective product, the claimant (buyer or consumer) may file a claim against all people involved.

Any manufacturer that ultimately pays to the claimant the amount awarded by the court has the right to take, in turn, action against the other co-defendants and request that they participate to the amount awarded to the claimant. The share of each one of them to the damages awarded shall be fixed by the court on the basis of the decree of each one’s fault or alternatively, it shall be shared proportionately amongst them.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn the public about the defects of a product does not in itself give rise to liability. The main element in any product liability case brought before the Greek justice is the existence or not of a loss or damage suffered and the causal link between the defect in the product and the damage incurred. However, the failure to warn may give rise to liability if the plaintiff can satisfactorily establish that had the defendant warned the public in time about the defect, the loss or damage would not have occurred. Further, failure to warn for defects that were known or became apparent to the defendant may be an aggravating element to be taken into consideration in the amount of damages awarded by the courts.

All kind of information will be taken into account. For instance, if the manufacturer or producer of a product becomes aware of a defect in his product, he can either inform directly the ultimate consumers or in case there is an intermediary in the chain of supply between him and the consumer he can ask the intermediary to inform the public about it. A classic example is the one of automobile manufacturer becomes aware of a defect in the gear boxes of a specific model he will inform his local representative and as a result the intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information.

In relation to who is responsible if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, then the issue is not one of “a defective product” but rather of “the wrong product”. In that case, the manufacturer (say a pharmaceutical company) has no liability towards the consumer (patient) because the choice of medical devise used in a surgery or medicine prescribed belongs to the surgeon / doctor who can be sued for malpractice.

There is no principle of “learned intermediary” under the Greek legal system in the sense that the manufacturer is completely discharged of any and all liability towards the
consumer if the product was defective and the defect caused the damage.

3 Defences and Estoppel

3.1 What defences, if any, are available?

According to the provisions of the Greek Civil Code on Sale of Products, the seller, besides the general defence of the claim, has the following particular defences: (a) to invite the buyer to proceed with the replacement of the product or to rescind from the contract within a reasonable period of time. If such time lapses inactive, the exercise of the respective right(s) of the buyer is time-barred (art. 546 of the Greek Civil Code); and (b) in case of consecutive sales, and therefore, liability of the end-seller towards the buyer, the end-seller has subrogate rights against the previous seller. As far as the defence of the producer against the consumer is concerned, same is analysed in the following paragraphs.

In any case, the liability of the producer/buyer (and its respective defence against the claimant) may be limited or eliminated in the event:

(a) of parallel liability with others; and

(b) of concurrent fault of the buyer/consumer (see article 300 of the Greek Civil Code).

In this latter case, the liability may be totally exhausted in case of an exclusive fault of the buyer/consumer (i.e. say in case of use of the product against the instructions for use, etc.).

3.2 Is there a state of the art/development risk defence?

Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The issue of defectiveness of products that fall within the category of “state of the art products” or within the category of “highly technologically advanced products” depends significantly on the scientific and technical knowledge available to the producer at the time of production of the specific product. The producer may be released if he produces sufficient evidence that at the time of placing its product in the market there was an objective lack, on the basis of the then existing standards of science and technology, of knowledge allowing him to diagnose the a posteriori defectiveness of the product. In this respect there is an obligation on the producer to strictly follow up the development of science and technology in his particular field of production and to adopt any developments accordingly. For the ignorance of a potential defect to be justified it is not sufficient for the producer to refer to his own capabilities. What matters is the international standard of scientific and technical knowledge existing at that particular point in time and in that particular field of production.

The burden of proof lies always with the consumer to prove the existence of a defect. However, in the case of technologically advanced products it is for the producer to prove the level of scientific and technical knowledge available at the time in his particular field of production.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Article 6 par. 8 and 9 of Law 2251/1994 provide the defences pursuant to which the producer of a defective product may be acquitted of his liability towards the consumer. More particularly, art. 6 par 8 (d) states that the producer is exempted of his liability if he can prove that the defect is due to the fact that the product was produced in accordance with the rules of ius cogens instituted by any public authority or pursuant to art. 6 par 8 (d) the producer is exempted of his liability if he can prove that when the product was placed into circulation the level of scientific and technical knowledge did not allow him to diagnose the existence of the defect.

Further, par. 9 of the same article provides that the producer of a component of a product is not liable if he can prove that the defect is due to the design of the product to which the component was embodied or to the guidelines provided by the producer of the product, in which case producer is considered to be the producer of the product in which the component was embodied.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

According to our procedural system any claimant (buyer/consumer) may file his claim either on the basis of tort or on the basis of breach of contract or on the basis of producer’s liability under law 2251/1994. The court shall issue its judgement which, after becoming final, creates res judicata which covers both the issues brought before the court for judgment and the litigant parties involved (and their successors, etc.).

Following the above, there is no possibility for a claimant to re-litigate on the same matter under the light of the outcome of another litigation even if this is between other litigants.

4 Procedure

4.1 Is the trial by a judge or a jury?

Pursuant to the Greek civil procedural system all trials are heard only by judges. A trial by jury in Greece will only be found in the criminal courts and only in serious cases (felonies).

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, there is no such possibility in the Greek legal system. As explained below the Greek courts may appoint experts
and technical specialists to testify as witnesses but they do not sit with the judges.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Article 10 of Law 2251/1994 introduced for the first time in Greece the institution of “Consumer Associations actions” for the protection of the general interests and welfare of consumers. Due to the peculiarities of the Greek procedural system the Greek legislator adopted the French version of class actions know as “Action Associationelle” and in German know as “Verbandsklage”.

Consumers Associations may act either independently or jointly provided that the total number of their registered active members exceeds the minimum number of 500 members.

In practice such claims are not very common and most of the times they are directed against banking institutions for the protection of consumers against unfair contractual terms.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

As explained above, Law 2251/1994 recognises the existence of consumers associations and regulates the way in which they can file claims against producers on behalf of consumers. A consumer association may file a claim or participate in a claim on behalf of any one of its members. Consumer Associations with more than 500 registered active members can bring claims for the protection of the interests and of the general welfare of consumers.

4.5 How long does it normally take to get to trial?

The length of time it takes for a case to get to trial depends firstly on the jurisdiction and secondly on the court before which the case is entered.

Although there are no official statistics, usually in Athens cases to be heard before the single-member Court of First Instance are scheduled for hearing approximately 10-12 months after filling of the lawsuit, whilst cases to be heard before the multi-member Court of First Instance are usually scheduled for hearing 14-20 months after the filling of the complaint. However, the length of time it takes for a case to get to trial in smaller jurisdictions (i.e. other than Athens and Thessalonica) are usually considerable lower.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Pursuant to the Greek procedural system, as amended, (through Laws 2915/2001, 3043/2002 and 3089/2002), the First Instance Courts do not any longer issue interim judgments but one judgment on both the procedural and substantial matters of the case. Such judgment is subject to appeal by the defeated litigant party before the Court of Appeal.

In making its decision, the First Instance Court will initially examine and decide on whether it has jurisdiction to judge over the case. After having responded positively to this question, the court will examine one-by-one all the procedural objections filed by the defendant(s) and pursuant to which the defendant(s) seek the rejection of the lawsuit, either on procedural grounds or on the substance of the case or on both. If it considers that an objection filed by the defendant is well substantiated and well founded, then such an objection will be sustained and the lawsuit will be rejected without further examination of the substance of the case.

However, in those cases where the court decides that it requires the services of an expert to provide his opinion on certain issues, then it will issue a preliminary judgment (“interim order”) determining the points and questions on which the expertise is sought and the time-limit within which the report must be submitted.

If on the other hand, the court rejects the defendants’ objections and does not require the services of an expert, it shall proceed with the examination of the substance of the case and the application of the facts of the case in the applicable provisions of the law, evaluating, at the same time, the evidential material submitted by the parties.

4.7 What appeal options are available?

The defeated party has the right to appeal to the Appeal Court. In those cases where the court accepted partially the claim and awarded to the plaintiff a smaller amount than the one claimed, both plaintiff and defendant are considered to be “defeated parties” and have the right to appeal against the judgment.

In this case, the plaintiff will appeal for the award of his entire claim and the defendant for the rejection of the partial amount awarded to the plaintiff by the First Instance Court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court has the right to appoint experts pursuant to the procedure outlined in articles 368 to 392 of the Greek Civil Procedural Code.

When the court appoints an expert, the only restriction on the nature and the extent of the evidence it seeks is that it determines specific questions to which the expert must answer in his respective report and to which he is appointed to provide his special knowledge and skills. Further, the court will impose on the expert a deadline by which he must prepare and submit with the court his report (which cannot exceed sixty days). Nonetheless, judges evaluate all kinds of evidence (even evidence presented by an expert), freely. This means that they are not bound to follow the conclusions of the expertise although certainly in practice an expert’s opinion has a special weight.

After his appointment by the court, the expert takes an oath that he will prepare his expert opinion-report with due diligence. The defeated party pays the expert’s fee. In case of the appointment of an expert, the litigant parties are entitled to appoint their technical advisors who cooperate...
with the expert. Irrespective whether the court has appointed any expert, the litigants are also free to either submit expert opinions prepared by experts of their own choice (as exhibits to their briefs), or to invite experts to execute affidavits or to testify in court and be cross examined as witnesses on the date of hearing. In this respect, there are no restrictions on the nature and the extent of the evidence presented to the court.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

In cases tried before the Multi-member Court of First Instance, the parties are obliged, as aforesaid, to file with the court secretariat their briefs and all documentary evidence (exhibits, affidavits, private expert opinions etc.), at least 20 days prior to the date of hearing. The purpose of this obligation is to enable the parties to review each other’s supporting documents and evidence and file, within five days thereafter, an addendum counter-arguing the allegations and arguments of the opponent. After that day the court secretariat delivers the files to the Reporting Judge for his preparation of the trial and no more fillings are permitted until the date of hearing.

However, in cases tried before the Magistrate Court or the Single-member Court of First Instance the parties file their briefs and all documentary evidence on the day of hearing and therefore, there is no possibility for the parties to examine each other’s documentary evidence prior to it. However, within 3 days after the date of hearing the parties are entitled to submit an addendum containing their counter arguments on the opponent’s briefs and commentary on the depositions of the witnesses before the court.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, all claims must be filed within the applicable time limits imposed by the statute of limitations.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The general principle is that all claims based on commercial disputes are statute-barred after the lapse of five years as of the date the claim was born.

However, claims based on the sale of goods provisions for defective products are statute-barred, after the lapse of two years for movable property, and after the lapse of five years for immovable property from the day of delivery of the product to the buyer, irrespective of whether the buyer discovered the defect immediately or sometime later.

The same above statute of limitations (five years) is also applicable for any claim based on tort (direct or indirect damages and moral damages) commencing as of the date the party who incurred the damage realised the existence of the damage and could also identify the liable party; in no case the party who incurred the damage could also identify the liable producer.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In case of wilful concealment or fraud, the defendant can...
also be sued before the criminal courts for their actions. The statute of limitations for criminal actions varies depending on the charges pronounced against the defendant (e.g. eight years for misdemeanour and up to twenty years for crimes). The criminal element, however, of the case cannot and does not affect at all the running of time limits in civil cases which remain as described above.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Pursuant to article 540 of the Greek Civil Code, the buyer has the right to take action against the seller of the defective product and request either the repair or the exchange of the product with a non-defective identical product, or the decrease of its value or even the retreat from the sale. Further, under the ordinary provisions of tort, the claimant can claim compensation for actual damages incurred (i.e. expenses incurred, damage to property) or for loss of profits under the condition that he can establish a causal link between the damage incurred and the defective product. These are strictly pecuniary damages that can be assessed.

Damages and/or compensation for bodily injury or mental damage suffered cannot be assessed in real money and therefore will fall under the broader category of “compensation for moral damages”. In this case again, the claimant will have to be able to prove the existence of a causal link between the moral damage suffered (i.e. due to the bodily or mental injury suffered) and the defective product.

The main difference however, between actual damages and moral damages is that the claimant does not have to assess and be able to prove the amount of moral damage suffered. Hence, there are no restrictions in claiming compensation for moral damages and claimants can estimate freely the amount of compensation they believe appropriate. Of course, the court in deciding whether to award or not moral damages and to what extent, will take into consideration not only the particular facts of the case but also the financial situation and wealth of both the claimant and the defendant and will award the amount it deems fair and appropriate given the circumstances of each particular case. Therefore, usually the amount of moral damages awarded by the court is lower than the amount sought by the claimant. In no case however, can the court award a larger amount of moral damages than those claimed by the claimant.

Damage to the product itself cannot be claimed under the provisions of the special law on the Consumer’s Protection but can only be claimed under the provisions of the Law on Contracts or Tort.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

As far as damages have been incurred and can be assessed and proved by the claimant, then they can also be recovered. Hence, under the provisions of Greek Law it is impossible for someone to claim compensation for future and not yet incurred damages. For instance, if a person had to undergo medical treatment or medical tests, examinations and monitoring due to the administration of a defective drug, which caused bodily damage, he would be entitled to claim compensation from the producer and the distributor of the drug and recover the damages incurred only if he was in a position to prove that the product was defective and that the defect caused the damage.

Namely, the claimant can only claim for damages incurred, however it is impossible to claim compensation for any kind of expenses incurred where the product is not defective or did not malfunction or its defect did not cause the injury or any other kind of damage (pecuniary or other). In short, therefore, a claimant can claim compensation for damages incurred due to a defective or malfunctioning product only if he is in a position to establish the causal link between the damage incurred and the defect of the product.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

The Greek courts do not award punitive damages in the sense that the term has gained in certain jurisdictions and especially in the United States. However, in the Greek jurisprudence and as explained above, it is common practice for claimants to claim (and, in successful claims, for the courts to award), moral damages.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, there is no maximum limit on the damages recoverable from one manufacturer.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The Greek Courts do award court fees and legal costs although these are significantly lower than the actual cost of legal fees of litigation. The defeated party is sentenced to pay the said costs. However, when the court considers that the defeated party had a reasonable doubt for the outcome of the case, it sets-off such expenses between the litigants.

7.2 Is public funding e.g. legal aid, available?

Until very recently legal aid or public funding was only available in criminal cases. However, Law 3226/2004, which came into effect in February 2004, introduced for the first time in Greece the institution of legal aid to low-income civilians for civil and commercial cases as well. More particularly, for the first time in Greece low-income civilians are given the opportunity to have recourse to justice without incurring the legal costs and court fees. To qualify for legal aid the interested party must file a petition to the judge of the court before which the case is pending or before which the
case will be introduced. In case the request for legal aid is rejected, the interested party has the right to appeal before the multi-member Athens Court of First Instance.

7.3 If so, are there any restrictions on the availability of public funding?

According to the above newly introduced law, which has not yet been applied in practice, legal aid consists in the exemption from the obligation to pay court fees and to the appointment of an attorney to represent and defend the beneficiary and to provide his legal services.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

In the event of legal aid, there is no such possibility. Law 3226/2004 states that the remuneration of the attorneys, who will be appointed to defend the beneficiaries of the legal-aid system, will be determined by a joint Ministerial Decision of the Minister of National Economy and the Minister of Justice, according to the minimum legal fees provided by the Greek Lawyer’s Code.

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In 1979 the law firm of Kyriacos and Constantine Kyriakides, established in 1933 by Kyriacos S. Kyriakides, merged with the law firm of Leonidas C. Georgopoulos. Ever since, the firm kept growing and in 1999 the firm took its present form which made it count among the first professional legal partnerships in Greece. The growth of the firm under the new renovated form was outstanding. The number of lawyers was doubled in 2000 and new offices were established, in Thessaloniki and Piraeus.

Today, approximately sixty lawyers, ten of whom are partners, offer, through the four offices of the firm, their legal services and expertise to high profile clients both in Greece and abroad, who acknowledge that the firm is one of the top law firms in the country and abroad. Kyriakides-Georgopoulos is considered one of the most highly rated Greek corporate firms and has the largest multidisciplinary work force, which comfortably sustains its leading position.
Chapter 25

Ireland

Matheson Ormsby Prentice

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

In Ireland, liability for defective products falls under four main headings:

- Statute.
- Tort.
- Contract.
- Criminal.

Statute

The principal product liability statute in Ireland is the Liability for Defective Products Act 1991 (“the 1991 Act”), which was enacted to implement EC Directive 85/374. This act supplements, rather than replaces, the pre-existing remedies in tort and contract (see below). S.2(1) of the Act provides for strict liability, making a producer “liable in damages in tort for damage caused wholly or partly by a defect in his product”.

It is worth noting that the 1991 Act covers only dangerous defective products. Products which are safe but shoddy do not fall within its scope.

Tort

Manufacturers, repairers, installers, suppliers and others may be sued in tort for reasonably foreseeable damage caused to those to whom they owe a duty of care. As opposed to liability under the Liability for Defective Products Act 1991, liability in tort is fault based.

For an action to lie in tort, there must be:

- a duty of care owed by the producer or manufacturer of the product;
- a breach of that duty of care; and
- a causal relationship between the breach and the damage caused to the user of the product.

Unlike under the 1991 Act, a plaintiff suing in tort may in certain circumstances succeed in an action for negligence for non-dangerous defects.

Contract

Contracts for the sale of goods are covered in Ireland by the Sale of Goods Act 1893 (“the 1893 Act”) and the Sale of Goods and Supply of Services Act 1980 (“the 1980 Act”). Section 10 of the 1980 Act operates to add an implied condition to contracts for the sale of goods that these goods are of “merchantable quality” where a seller sells them in the course of business. This means that the goods must be: “fit for the purpose or purposes for which goods of that kind are commonly bought and durable as it is reasonable to expect having regard to any description applied to them, the price (if relevant) and all other relevant circumstances”.

Contractual liability under the 1980 Act is strict. It must be borne in mind, however, that the principle of privity of contract applies, which often makes it difficult for an injured party to sue the manufacturer of a product in contract, since his contract is likely to be with the retailer of the product.

Criminal Liability

The principal legislation imposing criminal liability in the area of product liability is the European Communities (General Product Safety) Regulations 2004, (“the 2004 Regulations”) which implemented EC Directive 2001/95. These Regulations make it an offence to place unsafe products on the market and specify the duties of producers and distributors in this regard.

Under the 2004 Regulations, the Director of Consumer Affairs is given the authority to ensure that only safe products are placed on the market. There is also a duty on producers and distributors to inform the Director of Consumer Affairs where they know, or ought to know, that a product which has been placed on the market by them is incompatible with safety requirements. The Director of Consumer Affairs has also been given the power to order a product recall, as set out in question 1.4 below.

Criminal liability is fault based and must be proven beyond reasonable doubt.

1.2 Does the state operate any schemes of compensation for particular products?

This has been known to happen in Ireland in circumstances where some organ of the State may have a liability. The most notable instance was the Hepatitis C Compensation Tribunal, which was set up in 1997 to compensate women who had become infected with Hepatitis C having been
transfused with infected blood during pregnancy. A scheme was also set up to compensate haemophiliac victims of contaminated blood products. Such schemes are ad hoc, rather than statutorily required.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Statute
As stated above, s. 2(1) of the 1991 Act makes the “producer” of the defective product liable in damages caused wholly or partly by the defect in his product. In this regard, s.2(2) of the Act defines “producer” as:

- the manufacturer or producer of a finished product;
- the manufacturer or producer of any raw material or the manufacturer or producer of a component part of a product;
- in the case of products of the soil, of stock-farming and of fisheries and game, which have undergone initial processing, the person who carried out such processing;
- any person who, by putting his name, trade mark or other distinguishing feature on the product or using his name or any such mark or feature in relation to the product, has held himself out to be the producer of the product;
- any person who has imported the product into a Member State from a place outside the European Communities in order, in the course of any business of his, to supply it to another; or
- the supplier of the product where the manufacturer of the product cannot be identified through the plaintiff taking reasonable steps to establish his identity and where the supplier fails to identify the manufacturer of the product within a reasonable time of a request being made.

Tort
Under the law of tort, the test to be applied is whether a particular individual e.g. the manufacturer, retailer, supplier or importer owes a duty of care towards the injured party. If such a duty is owed and has been breached, that person is capable of having responsibility.

It is clear that the manufacturer of a product will owe a duty of care to all those who may foreseeably be injured or damaged by his product. The same will apply to retailers, suppliers and importers, though the scope of their duty will typically be narrower than that of manufacturers, extending to, for example, a duty to ensure that their stock is not out of date. In practice, a plaintiff will not be required to choose which of a number of possible defendants to sue and any or all potential tortfeasors are likely to be sued.

Contract
Under the 1893 Act and the 1980 Act, the seller will, subject to certain conditions and exemptions, have a contractual responsibility to the buyer in respect of faults or defects.

Criminal
In terms of the criminal law, the 2004 Regulations make a “producer” who places or attempts to place an unsafe product on the market guilty of an offence. The 2004 Regulations define a “producer” as:

- the manufacturer of a product and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product,
- the manufacturer’s representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product, or
- other professionals in the supply chain, in so far as their activities may affect the safety properties of a product placed on the market.

The 2004 Regulations also make distributors who supply or attempt to supply a dangerous product, which they know or it is reasonable to presume that they should know is dangerous, guilty of an offence. In this regard, a “distributor” is defined as any professional in the supply chain whose activity does not affect the safety properties of the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under s.9 of the 2004 Regulations, the Director of Consumer Affairs is given the power to “take all reasonable measures” to ensure that products placed on the market are safe, including issuing a direction ensuring “the immediate withdrawal of [a] product from the marketplace, its recall from consumers and its destruction in suitable conditions”. Under s.9 (2) of the 2004 Regulations, in taking this, or any other measure, under the Regulations, the Director of Consumer Affairs must act “in a manner proportional to the seriousness of the risk and taking due account of the precautionary principle”.

A person who fails to comply with a direction of the Direction of Consumer Affairs with respect to the recall of products is guilty of a criminal offence and is liable on summary conviction to a fine not exceeding €3,000, or to imprisonment for a term not exceeding 3 months, or to both. In addition, the common law duty of care imposed by the law of tort (see above) may extend to product recall depending on the circumstances of the particular case. Thus a failure to recall in particular circumstances may be a breach of such duty, giving rise to a civil action.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

As a general principle, it is for the injured party to prove the defect to the product and the damage caused. This is stated in s.4 of the 1991 Act and is a general rule of the laws of contract and tort.

In tort and contract, the standard of proof is “on the balance of probabilities”, while in criminal cases, the guilt of the accused must be proved “beyond reasonable doubt”.

In certain circumstances, particularly in tort, the doctrine of res ipso loquitur can be applied to, in effect, reverse the
burden of proof and place the onus on the defendant to disprove an allegation of negligence. Since the 1991 Act operates a system of strict liability and is thus unconcerned with the negligence or otherwise of the defendant, res ipsa loquitur will have no such application in the context of a claim relying solely on the provisions of the 1991 Act. In practice, however, for this reason, claims will seldom, if ever, be brought relying solely on the provisions of the 1991 Act.

In criminal cases, it is for the prosecution to prove the guilt of the accused. Under the 2004 Regulations, the prosecutor in such offences is the Director of Consumer Affairs.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have occurred without such exposure?

Section 4 of the 1991 Act provides that the injured person must prove the damage, the defect and the causal relationship between the two.

Wrongful exposure to an increased risk of injury will not, in itself, provide a claimant with a cause of action. The causal relationship to a concrete loss or injury must be proven. If a claimant cannot prove, on the balance of probabilities, that an injury would not have occurred without exposure to the product in question, he/she has not discharged the civil burden of proof on causation.

As stated above, where the claimant encounters problems in proving a causal relationship, the doctrine of res ipsa loquitur may be of assistance.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

As stated above, under s.2(3) of the 1991 Act, where the producer of a product cannot be identified through the plaintiff taking reasonable steps, the supplier of the product may be treated as its producer unless he informs the plaintiff of the identity of the producer, or of the person who supplied him with the product, “within a reasonable time” of such a request being made.

In terms of the law of tort, it would be usual, in circumstances where a plaintiff cannot, with absolute certainty, identify the producer of a defective product, that the plaintiff would institute proceedings against all parties whom he reasonably suspects could have been responsible for its manufacture. Notices of Indemnity and Contribution may be served by each of the defendants on their co-defendants and ultimate liability (or an apportionment thereof), if any, will be decided by a court at trial of the issue.

Market share liability has not, to date, been applied by the Irish courts in product liability cases.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

As in other Member States, Ireland’s membership of the European Union has necessitated the introduction of regulations in many industries stipulating specific information and warnings which must be provided to consumers as to the nature, ingredients/contents and safety of products. Failure to comply with these regulations can have consequences for product manufacturers and distributors. Such consequences vary depending on the provisions of the individual regulations.

Specific statutory requirements aside, however, the issue of whether warnings must be provided to consumers falls within the question of compliance with the standard of reasonable care under the Irish law of tort. It should be noted that an increased level of awareness in society of product safety and increased expectations on the provision of product information has made it more likely in recent times that the absence of an express warning in respect of a danger attaching to a product will be deemed to constitute negligence.

As further evidence of the pro-consumer approach within this jurisdiction, the relevance of intermediate examination has been consistently undermined by the law over the years. Formerly, it was not considered negligent to allow a potentially dangerous product into circulation if the danger could reasonably be discovered by way of intermediate examination by the consumer or a middleman in the chain of distribution. However, s.34(2)(f) of the Civil Liability Act 1961 provides that, while the possibility of intermediate examination may be taken into account as a factor in determining negligence, it is no longer conclusive. Whether the release of the product is seen as negligent will therefore depend on all the circumstances.

While the concept of a “learned intermediary” has not yet received specific judicial examination in Ireland, it is likely that the fact that an examining intermediary has some expertise in the composition and safety of the product could be pleaded to the benefit of the manufacturer in arguing that the release was not negligent in all the circumstances.

As regards criminal law, s.6 of the 2004 Regulations provides that a producer must provide consumers with “all relevant information” relating to a product which it has put on the market to “enable [the consumer] to assess the risks inherent in the product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings and to take
It is difficult to prove. In addition, powers are granted to the Director of Consumer Affairs under s.9 of the 2004 Regulations to issue a direction that a particular product be marked with a risk warning.

### 3 Defences and Estoppel

#### 3.1 What defences, if any, are available?

**Statute**

Under s.6 of the 1991 Act, a Producer is freed from liability under the Act if he proves:

- that he did not put the product into circulation;
- that it is probable that the defect causing the damage came into being after the product was put into circulation by him;
- that the product was not manufactured for a profit-making sale;
- that the product was neither manufactured nor distributed in the course of his business;
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities;
- that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered (“State of the Art” Defence); or
- in the case of a manufacturer of a component of the final product, that the defect is attributable to the design of the product or to the instructions given by the product manufacturer.

Furthermore, if the damage was caused, partly by a defect in the product, and partly by the fault of the injured person, or a person for whom the injured person was responsible, the provisions of the Civil Liability Act 1961 in relation to contributory negligence apply (see below).

**Tort**

**Contributory Negligence**

In Ireland, this defence is regulated by the Civil Liability Act, 1961 (“the 1961 Act”), which provides, with some exceptions, that where the plaintiff is partly at fault, damages will be reduced in proportion to that fault. It has been held that the fault necessary is to be equated with blameworthiness and not to the extent of the causative factors moving from each side. Equally, a plaintiff will be responsible for the acts of a person for whom he is vicariously liable (imputed contributory negligence). Finally, failure by a plaintiff to mitigate damage is also considered to be contributory negligence.

**Voluntary Assumption of Risk (Volenti Non Fit Injuria)**

This defence is regulated by Section 34(1)(b) of the 1961 Act. A defendant may escape liability in two cases:

- where he shows that by contract he is not liable (though the contract will be construed strictly against the party claiming the benefit of the exception); or
- where he shows that, before the act, the plaintiff agreed to waive his legal rights in respect of it.

In both cases, the burden of proof is on the defendant to prove that the defence applies. In practice, this defence is difficult to prove.

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**Contract**

To have a workable contract, the basic rules of contract formation must be complied with, i.e. there must be an offer, acceptance and consideration. The absence of these essential elements can act as a defence to an action in contract. Likewise, mistake, misrepresentation and duress will affect the validity of a contract. Furthermore, “illegal” contracts are invalid or in some cases may have the offending provision severed. Inadequate capacity to contract may also affect the validity of a contract.

**Criminal**

Under s.5 of the 2004 Regulations, a product shall be deemed safe if it conforms with any specific rules of the law of the State laying down the health and safety requirements which the product must satisfy in order to be marketed, or with voluntary Irish standards transposing European standards. However, notwithstanding this, the Director of Consumer Affairs may take “appropriate measures” to impose restrictions on a product being placed on the market, or to require its withdrawal or recall, where there is evidence that, despite such conformity, the product is dangerous.

#### 3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes, (see above) under the provisions of the 1991 Act. Where the defence is raised by a manufacturer, the burden of proof lies with the manufacturer to prove the state of scientific and technical knowledge at the relevant time and that the fault/defect was not discoverable.

#### 3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Yes, under s.6 of the 1991 Act, where this compliance can be shown to be the cause of the defect itself, this will be a defence to any cause of action based upon the 1991 Act. It may not necessarily, however, be a defence to a cause of action based upon breach of duty or breach of contract.

With respect to criminal law, please see question 3.1 above. While compliance with regulatory and statutory requirements will, prima facie, be taken to show that the product is safe, the Director of Consumer Affairs is given the power, under the 2004 Regulations, to take “appropriate measures” where there is evidence that the product is, nonetheless, dangerous.

#### 3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Provided they arise in separate proceedings brought by a different claimant, findings on issues of fact, as opposed to
issues of law, are of no precedent value and are not binding on a court. Issues of fault, defect and capability of a product to cause damage are issues of fact and unless the parties, of their own volition, or the court, by order, consolidates two or more claims into one set of proceedings, findings of fact will not be binding in respect of other claimants.

4 Procedure

4.1 Is the trial by a judge or a jury?

In civil cases for product liability, cases are heard by a judge, sitting without a jury.

As regards criminal liability, since the 2004 Regulations provide for summary prosecution only, it is not open to the accused to opt for a trial by jury. These cases will therefore also be heard by a judge sitting without a jury.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not appoint technical specialists to sit with the judge. It is up to the parties to an action to either adduce their own expert evidence or to agree on a single expert to provide evidence to the court. The judge alone must make the decision in any case.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

There is no mechanism under Irish procedural rules for a class action. Thus, litigation is conducted by individual named parties. There is a tendency in Irish multi-party litigation to take one or more test cases, whereby a small number of cases are selected from the group and progressed to trial. However, in the absence of agreement (see question 3.2 above), these cases are not binding on the parties in other cases.

Order 18 of the Rules of the Superior Courts provides that a plaintiff may apply to court to unite in the same action several causes of action if they can be conveniently disposed of together by the court and they meet certain limited criteria. Order 49 of the Rules of the Superior Courts provides that causes or matters pending in the High Court may be consolidated by order of the court on the application of any party.

The Law Reform Commission published a Consultation Paper in 2003 on Multiparty Litigation, which recommends that serious consideration be given to the implementation of a class action system. However, as yet, no final report has been published on these issues.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No. Representative and consumer associations will generally lack the necessary locus standi to bring such actions.

4.5 How long does it normally take to get to trial?

Following the enactment of the Personal Injuries Assessment Board Act 2003 any party wishing to bring personal injury proceedings (save for those involving medical negligence) must first submit their claim to the Personal Injuries Assessment Board (PIAB). PIAB is an independent body set up by the government to assess the level of compensation payable to those who have suffered personal injuries. If the respondent to a claim notifies PIAB that they intend to rely upon legal issues to defend their position PIAB will serve the claimant with a Release Certificate thereby enabling the claimant issue proceedings before the courts.

The length of time between service of proceedings and the actual hearing of the matter depends to a large extent on how quickly the procedural steps and delivery of pleadings are complied with by both parties. In a straightforward product liability personal injuries action, with no interlocutory applications, a hearing date might be obtained within one year. In reality, however, most matters are not heard for a period of 18 months to two years from service of proceedings. In more complex cases or cases where procedural time limits have not been complied with and/or a number of interlocutory applications (for example, for discovery, particulars or interrogatories) have been made, it is not unusual for a case not to be heard for three years or more.

The creation of a new Commercial Court, with effect from January 2004, which has procedures to streamline litigation, has, in certain instances, led to a much speedier conclusion of cases (although it does not apply to personal injury litigation).

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes. Orders 25 and 34 Rule 2 of the Rules of the Superior Courts provide for the preliminary trial of an issue of law where such is deemed expedient by the court for the saving of costs and/or time.

4.7 What appeal options are available?

First instance rulings in all civil cases may be appealed to a higher court. It should be noted, however, that appeals from the High Court to the Supreme Court (which is only an appellate court in civil matters) can be made only on a point of law.

Directions of the Director of Consumer Affairs under the 2004 Regulations, with respect to product recall or any other measures adopted, may be appealed to the Circuit Court within 21 days of receipt of the direction. An appeal to the High Court on foot of the decision of the Circuit Court on the direction may be appealed to the High Court on a question of law only.
4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The parties are free to appoint their own experts to put forward their opinion as evidence at trial. Such experts are never appointed by the court. Such experts are, however, entitled to be questioned on their evidence by the Judge, and, indeed, cross-examined by the opposing party.

General evidentiary principles apply to their evidence, so that e.g. it must be relevant to the issues at hand and within their field of expertise.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Experts are not required to present themselves for pre-trial deposition.

In High Court personal injury actions, there is an obligation on the parties under SI 391/1998 to exchange all written expert reports (but not statements of fact witnesses) in advance of the hearing of the action. In other cases, it is for the parties to decide between them whether to voluntarily exchange expert reports and/or witness statements.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

As a general rule, discovery of documentary evidence may only be sought by either party once pleadings have closed, i.e. once a defence has been delivered by the defendant. Discovery may be sought by a party to the proceedings against any other party to the proceedings, against third parties or against non-parties, subject to proof of relevance and necessity.

Discovery should be sought firstly on a voluntary basis and, if voluntary discovery is refused, it can then be sought by way of motion if necessary. Discovery relates to all documentation in the power, possession or procurement of a party to the proceedings (or non-party) which may enable the other party to advance their case.

Discovery prior to the institution of proceedings will only be granted in very exceptional circumstances (Norwich Pharmacal Orders).

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Statute

Under s. 7(1) of the 1991 Act, a limitation period of three years applies to proceedings for the recovery of damages under the Act. This period begins to run from the date on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.

Interestingly, s.7(2)(a) provides for a “long stop” provision, which extinguishes the rights conferred on the injured party pursuant to the Act on the expiry of ten years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.

Tort and Contract

In actions in tort or contract, the various time limits within which proceedings must be instituted are laid down in the Statute of Limitations 1957 and the Statute of Limitations (Amendment) Acts 1991 and 2000.

In an action for tort, these provisions set a general time limit of six years from the date on which the cause of action accrued- that is the date on which the negligent act occurred.

In an action claiming damages for negligence, nuisance or breach of duty where the plaintiff claims damages for personal injuries, the limitation period is shorter. This was formerly three years from the date of accrual of the action or the date on which he became aware of the accrual of the action, whichever is the later- (i.e. the date of discoverability is relevant). However, the Civil Liability and Courts Act 2004 has recently reduced the limitation period for personal injuries actions to two years for dates of accrual/knowledge on or after 31 March 2005.

In contract, there is a limitation period of six years from the date of the accrual of the action. This is the date on which the breach of contract occurred, not when the damage is suffered.

The courts have a discretion to strike out proceedings where there has been an inordinate and inexcusable delay or want of prosecution on the part of the plaintiff and the defendant has suffered prejudice as a result of this, so as to make it unfair to allow the case to proceed.

Criminal

As regards criminal sanctions, the 2004 Regulations do not provide for a period within which prosecutions must be brought. However, the period applicable to summary offences is six months.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

There are special limitation rules concerning persons who are under a disability:

- infants;
- persons of unsound mind;
- convicts subject to the operation of the Forfeiture Act, 1870, in whose cases no administrator or curator has been appointed under that Act; and
- victims of sexual abuse, committed while they were underage, suffering from consequent psychological injury that impaired them from bringing an action.

Furthermore in proceedings in which the Liability for Defective Product Act 1991 is pleaded the ‘Long Stop Date’ of ten years from the date the product is put into circulation by the producer would apply as per Section 7 (2) (a) of the 1991 Act.

Fraud on the part of the defendant may also prolong
limitation periods. No proceedings are maintainable in respect of any cause of action which has survived against the estate of a deceased person unless that the proceedings were commenced within the correct limitation period and were pending at the date of his death; or that the proceedings were commenced within the correct limitation period or within two years after his death, whichever period first expires. The court does not have a discretion to disapply time limits statutorily imposed.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In accordance with s.71 (1) of the Statute of Limitations 1957, where there has been concealment or fraud, the limitation period does not begin to run until the Plaintiff has discovered the fraud or, could, with reasonable diligence, have discovered it. Therefore, issues of concealment or fraud may prolong limitation periods.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Statute
S.1(1) of the 1991 Act defines “damage” as:
- personal injury; or
- loss of, damage to, or destruction of, any item of property other than the defective product itself;

Provided that the item of property:
- is of a type ordinarily intended for private use or consumption, and
- was used by the injured person mainly for his own private use or consumption.

It is interesting to note that this definition excludes damage to the product itself, preferring to leave such claims to the law of tort. It should also be noted that the final line of the definition above excludes damage to property used in the course of a trade, business or profession.

“Damage” under the 1991 Act will include damage for pain and suffering caused by the defective product.

Tort and Contract
The laws of tort and contract allow an injured party to claim damages for death or personal injury caused by the defective product, as well as for pain and suffering (both physical and mental), damage to property and, in contrast to the 1991 Act, for damage to the product itself.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

There is no precedent for the court to allow damages to be recovered in such circumstances. However, it is of significance that the Supreme Court has disallowed the recovery of damages in what have been referred to as asbestos “worried well” cases - i.e. cases where claimants sued for damages for mental distress in respect of an apprehension of injury or illness arising from having come in contact with asbestos in the past, where there was no evidence of actual injury or illness.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages may be awarded in exceptional circumstances. This would include e.g. circumstances where there has been a deliberate and conscious violation of rights. In Ireland, awards of punitive damages tend to be in fractions of the general damage award, rather than in multiples.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No. The ordinary jurisdictional rules of the Courts apply. There is no upper limit on the amount of damages which can be awarded by the High Court against a single manufacturer. However, s.3 of the 1991 Act does provide for a minimum threshold of damages, stating that the provisions of the Act will apply only where damage exceeding €444.41 in value has been suffered by the injured party. This provision was clearly motivated by a fear that the strict liability provisions of the Act might release a rush of trivial claims.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Yes. The general rule is that “costs follow the event”. The judge has full discretion in this matter, however. Costs will include lawyer costs, court fees and incidental expenses, necessarily incurred in the prosecution or defence of the action.

In criminal prosecutions under the 2004 Regulations, the Director of Consumer Affairs will recover the costs of a successful prosecution from the convicted party, including the costs of investigations and detention of products, unless, under s.21 of the 2004 Regulations, the court is satisfied that there are “special and substantial reasons” for not ordering the recovery of these costs.

7.2 Is public funding e.g. legal aid, available?

There exists a civil legal aid scheme in Ireland, but limited funding would only very rarely be made available for personal injuries actions.

7.3 If so, are there any restrictions on the availability of public funding?

Yes. The applicant must satisfy financial criteria i.e. means...
test, must have as a matter of law reasonable grounds for proceeding with the litigation and must be reasonably likely to succeed in the litigation. In practice, nearly all personal injury actions are run without the benefit of legal aid.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The practice of charging contingency fees is illegal in Ireland, as it is considered to be champerty, i.e. aiding a claimant to litigate without good cause and taking a share of the profits. An exception relates to recovery of a debt or a liquidated demand.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

In Italy product liability was traditionally based upon the general torts clause provided by section 2043 of the Italian Civil Code (hereinafter CC), providing that any person who by willful or negligent conduct causes unfair detriment to another must compensate the victim for any damages suffered as a result. This rule is considered the expression of the general principle that a person should not harm another (the so-called neminem laedere principle). This approach still coexists with the strict liability system introduced in Italy by Presidential Decree (DPR) no. 224 of 24 May 1988 (hereinafter DPR 224/88) implementing the Product Liability Directive 85/374EC. Other available product liability systems include, to a limited extent, contractual liability (section 1490 CC) and liability for dangerous activities (section 2050 CC).

Traditional approach (fault based tort liability)
Under the traditional, fault-based tort liability approach reflected in section 2043 CC, which has been applied to product liability issues since the 1960s, consumers have been able to sue manufacturers for damage caused by defective products even in the absence of a direct contractual relationship, based on the neminem laedere principle. Originally, negligence was considered a necessary element in establishing liability. Subsequently, case law further developed the theory, establishing that the defective nature of a product per se proves defaults in the manufacturing process, and therefore a manufacturer’s fault can be proved by the very existence of the defect generating the injury.

Courts have also established that if several entities are involved in the production process, each shall be held liable for its own negligence, although this does not exclude the liability of the final assembler of the product, who has a duty to check the product diligently before placing it on the market.

DPR 224/88 (strict liability)
DPR 224/88 introduced a strict product liability regime which provides detailed definitions of “product”, “defective product”, “manufacturer” and “supplier”, and defines the scope of liability of manufacturers and suppliers. Section 8 of DPR 224/88 explicitly states that the injured party must prove the damage, the defect in the product and causation, but is not required to prove fault on the part of the manufacturer. In recent years recourse by plaintiffs to this cause of action has become increasingly frequent. Because section 15 of DPR 224/88 allows consumers to seek (alternatively or cumulatively) other forms of protection provided by the law, most often a product liability case will be brought based on claims under both DPR 224/88 and section 2043 CC.

Liability in contract
The law of contract plays a limited role in product liability litigation. Under the rules governing the sale of goods, liability is limited to any contractual duties of the seller in cases where the manufacturer or distributor has a direct contractual relationship with the ultimate consumer (which very seldom occurs in relation to mass produced goods). In any such case, the purchaser may invoke the seller’s liability whenever a latent defect manifests itself following the sale (section 1490 CC).

Dangerous activities (presumption of fault)
Under section 2050 CC, whoever injures another in carrying out an activity which is dangerous per se is (strictly) liable for damages unless he or she proves having adopted all possible measures to avoid the damage. Some court decisions have applied this provision to issues involving liability for damage caused by hazardous products. So, for example, the marketing and distribution of toxic chemical substances and blood derivatives are both considered dangerous activities. Courts have held manufacturers liable under section 2050 for not having taken the necessary measures to avoid injury after circulating blood contaminated with hepatitis-B, notwithstanding full compliance with applicable laws. Recently section 2050 has been applied to tobacco products in a case where the manufacture of cigarettes was found to be a hazardous activity.

In theory, section 2050 has limited scope in relation to product liability. For one thing, it can only apply to products that are either classified by express provisions of law as “hazardous” or considered to be inherently dangerous and likely to cause damage to the user even if appropriately handled. Moreover, it is debatable whether section 2050 can apply to product liability cases which fall within the scope of the Product Liability Directive as implemented in Italy by
DPR 224/88. According to the European Court of Justice in González Sánchez v. Medicinas Asturianas SA (Case C-183/00 [2002]), Member States may not, in such cases, apply national strict liability systems which provide consumers with a higher level of protection than does the Product Liability Directive itself.

1.2 Does the state operate any schemes of compensation for particular products?

Yes. A number of ad hoc laws providing for public funding and state compensation schemes have been enacted in specific fields for particular products.

Act no. 210 of 1992, as amended by Act no. 238 of 1997, promotes state-operated indemnity schemes in connection with contaminated blood transfusions and blood derivatives, and in favour of victims suffering injuries or illnesses causing a permanent impairment of psycho-physical integrity as a result of undergoing a mandatory vaccination. The indemnity also covers people who suffer damages as a result of interacting with vaccinated persons, who are subject to vaccination for work reasons or for travel in a foreign country, and healthcare personnel who are considered “at risk” and are therefore subject to vaccines which are not generally considered mandatory. The indemnity does not constitute complete compensation but offers limited restoration and does not prevent victims from separately seeking damages under DPR 224/88 or sections 2043 or 2050 CC.

Other provisions may be found in disparate areas of the law. For instance, ad hoc state funding may be available where product liability issues arise in the context of natural catastrophes; a limited state indemnity is granted in connection with operating nuclear plants and state compensation may be available in circumstances where damages are caused to individuals by space objects.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under section 3 of DPR 224/88 a “manufacturer” is any manufacturer of a chattel that has entered the stream of commerce, including any individual or entity taking part in the production process thereof. Each manufacturer is liable for the damages caused by the defects in its product, even if it is a component of a final product. Under section 3 subparagraph 3 of DPR 224/88 anybody who appears to consumers to be the manufacturer of the product, by placing his own trademark or trade name or other distinctive sign on the product, is considered a manufacturer.

Regarding the issue of “apparent” manufacturers, a distinction could be drawn between a trademark (which identifies the manufacturer of the marketed goods) and a brand or merchandise mark (which identifies the advertiser of the goods or the person or entity who markets the goods). However, since consumers may not be aware of this distinction, liability is not limited to the manufacturer of the defective product, but is extended to the person or entity who markets the product. Obviously, if the name of the manufacturer is known to consumers, the former shall be liable to the latter. Finally, the last subparagraph of section 3 of DPR 224/88 extends product liability to importers of products coming from outside the European Union. The importer will be entitled to sue the manufacturer by filing an action for contribution.

Under section 4 of DPR 224/88, if the manufacturer of the defective product is not identified, a supplier having distributed the product in the exercise of its business is equally liable and is de facto considered a manufacturer under the provisions of DPR 224/88 if he fails to provide the consumer with the name and address of the manufacturer (or of the supplier who sold the products to him) within three months from receipt of any such request by the consumer. This way, the supplier only has a subsidiary liability, which he may avoid by simply informing the consumer of the identity of the person or entity which manufactured the product or sold the product to him. Anybody dealing with the sale, lease, hire or any other form of marketing of the product is considered a “manufacturer” as long as he has dealt with transferring the product from the manufacturer to the consumer. This includes persons in charge of delivering the product for mere advertising purposes.

Traditionally, for product liability suits brought under section 2043 CC (general tort liability clause), the manufacturer, the importer, the distributor and the retail supplier could be held jointly or severally liable for the fault/defect, if the wrongful conduct was ascribable to any or to each of them. For instance, both the manufacturer and the distributor could be held liable in tort for a product proven to be defective both for construction or design failures and for subsequent deterioration due to unfit storage or delayed distribution (as in the case of fresh foods). In all such cases, the victim may choose to sue any or all of the above persons, and each defendant may in turn join any third party deemed liable: hence, in the example above, if the consumer sued the manufacturer only, the latter could join the distributor in the proceeding.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Traditionally, Italian law prescribed no specific duty for a manufacturer to recall a defective product. On 17 March 1995 Italy enacted Legislative Decree no. 115 of 1995 (hereinafter LD 115/95) encomprising general rules on accident prevention, thereby partially implementing the General Product Safety Directive 92/59/EEC. LD 115/95 applies in the absence of ad hoc legislation covering safety requirements for specific products (as is the case for beverages which are covered by Legislative Decree no. 123 of 1993). Under section 3(4) of LD 115/95, a manufacturer was required to take all necessary measures to ensure that products it placed on the market were safe including, if necessary, recalling that product from the market if it turned out to be unsafe. A manufacturer’s recall obligations included requirements to notify the authorities.

In May 2004 Legislative Decree no. 172 of 21 May 2004 (hereinafter LD 172/04) was enacted to implement the revised General Product Safety Directive 2001/95/EC. Under section 3.7 of LD 172/04 the duty of a manufacturer or a distributor to inform the competent authorities is triggered whenever a manufacturer or distributor is aware (or should be aware based on the information available in its position as a business entrepreneur) that a product placed on the market or otherwise supplied to consumers presents risks which are incompatible with the manufacturer’s /
2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under DPR 224/88, in product liability claims the injured party must:

(i) provide evidence of the defect (based upon the DPR 224/88 definition of defective product);
(ii) provide evidence of the damage incurred (based upon the general tort rules on damages); and
(iii) provide evidence of the causal relationship between defect and damage (based upon the general principles of causation in tort law, proof of causation often being achieved through presumptions); but
(iv) need not prove fault (the injurer’s fault is presumed as a consequence of the existence of the defect).

Therefore, under DPR 224/88 the burden of proving fault does not lie on the plaintiff, and it is up to the defendant to provide any evidence of reasons why he or she should not be held liable (for instance, by proving an inappropriate use of the product by the plaintiff). This is why when dealing with DPR 224/88 product liability issues, authors often speak of a shifting of the burden of proof to the manufacturer, distributor, supplier, etc.

In tort, under section 2043 CC, the plaintiff:

(i) must prove the defect;
(ii) must prove the damage suffered;
(iii) must prove the existence of a causal nexus between the defect and the damage; and
(iv) must prove negligence or willfulness on the part of the defendant.

It can be particularly difficult for a consumer to provide evidence of fault in connection with products whose manufacturing processes are particularly complex. Case law has developed a theory establishing that if a product is defective, this in itself proves failure by the manufacturer (or by those who placed the product in the stream of commerce) in the manufacturing or distribution process: hence, the existence of the defect per se is evidence of fault or negligence by the manufacturer or the distributor or the retailer.

In issues connected to damages arising from performing a dangerous activity, under section 2050 CC, the injured party:

(i) must prove that the injurer performed a dangerous activity (according to the definition thereof provided by case law);
(ii) must prove the damage suffered; and
(iii) must prove the existence of a causal nexus between the dangerous activity and the damages; but
(iv) need not prove fault or negligence on part of the person who performed the dangerous activity (fault is presumed from the very fact of carrying out a hazardous activity).

Therefore, under 2050 CC it is up to the person who carried out the dangerous activity to prove that he having adopted all possible measures to avoid the damage. Once again, authors speak of a shifting of the burden of proof to the defendant.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The claimant must prove the defect, the injury and the causal nexus between the former and the latter. Causation must be proved by the claimant, and based on standards applied by case law in respect of both product liability claims and tort claims. These standards are that the injury shall be, under probabilistic criteria, the direct and immediate consequence of the defendant's act or omission. Although in principle it is for the claimant to prove that the injury would not have occurred but for the defendant's act or omission, in practice courts tend to require that positive proof be given by the defendant that the injury was not, in actual fact, the consequence of the defendant's conduct.

In addition, if the defendant is able to prove that an additional cause pertaining either to the claimant (contributory negligence or a pre-existing impairment of the claimant) or to an external factor is the exclusive or concurrent cause of the injuries, liability of the defendant can be excluded or reduced proportionally.

Finally, as regards assessment of causation, this often implies technical/medical knowledge or skill, so that, in practice, the court refers to court-appointed experts to determine causation (please see answer to questions 4.8 and 4.9).

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

According to section 9 of DPR 224/88, when more than one individual or entity is responsible for damage, they shall be held jointly and severally liable to the injured party. Each of them shall have a right of recourse against the other(s) based upon the degree of fault and liability ascribed to each. In case of uncertainty in respect of the percentage of liability that each must bear, the obligation to compensate damages is divided equally amongst them.

The same principles generally apply in tort. Under section 2055 CC, if a tort is ascribable to two or more persons, all are jointly liable to the injured party for damage redress. Any liable person having fully compensated the damage has a right of recourse against the other persons held liable,
according to their respective degrees of fault and to the consequences related thereto. In the event of doubt as to the establishment of the degree of fault of each, all are presumed equally at fault.

Generally speaking, market-share liability is not a principle applied by Italian courts in product liability issues.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The assessment of the defectiveness of a product will include an examination of, among other things, its presentation to the public and its instructions and warnings, including any descriptions, manuals, stickers, writing on the package and advertisements. This implies that the manufacturer has a duty to inform consumers of the features (and possible dangers) of the product. The nature of the information required to be provided will depend on the type and projected use of the product and on the anticipated user's level of awareness.

A consumer will be entitled to recover damages if the instructions or warnings were wrong, incomplete, contradictory or too short.

For products destined for children, courts have held that the manufacturer's level of attention to instructions and warnings should go so far as foreseeing abnormal behaviour by children in using the product (but not so far as covering uses of the product which are clearly in contradiction with the scope of the product).

With respect to the injured party, the only information that can be taken into account is that which is directly provided to it or publicly available, but not that which is directed to different people. The answer is different if the product can only be obtained through an intermediary who in his function assumes the legal liability of e.g. prescribing a medicine (a doctor) or installing a medical device (a surgeon); the pharmacist who recommends a medicine does not assume any liability as the recommendation is a mere suggestion with no legal value and the consumer takes the medicine with free will and full liability, as long as the product is not defective. However, the principle is valid only where medical professionals have to assess the suitability of a non-defective product: if the product is acknowledged to be defective (and not simply non-suitable for a specific patient or illness), the only liable party remains the producer.

Under Italian law there is no principle of “learned intermediary” in relation to defective products.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under section 6 of DPR 224/88 a manufacturer may avoid liability if:

a. “the manufacturer did not place the product on the market”. In this respect, section 7 provides that the product must be considered as released on the market “when it is delivered to the purchaser, user or an assistant to this, also just for viewing or testing same”;

b. “the defect that caused the damage did not exist when the manufacturer released the product onto the market”: obviously, this is intended to protect the manufacturer in cases of tampering with the product by third parties. In this case, the burden on the manufacturer to prove the exemption is in part mitigated by the provision contained in the second part of the second paragraph of section 8, according to which “for the purpose of the envisaged exclusion of liability...it is sufficient to prove that, taking into account the circumstances, it is likely that the defect did not exist at the time when the product was released on the market”;

c. “the manufacturer did not manufacture the product for sale or any other form of distribution against payment of a consideration, and did not manufacture or distribute the product in the exercise of his professional activity”;

d. the defect depends on the “compliance of the product with a mandatory legal rule or a binding measure”;

e. the manufacturer or supplier of a component part of the product fully complied with the instructions given by the manufacturer who used the component or the defect is fully due to the concept of the product in which the part was incorporated; and

f. the state of scientific and technical knowledge at the time when the product was released on the market did not allow the existence of the defect to be discovered”.

In relation to the “state of the art” defence, Italian legal authors have taken a rather strict position, excluding the possibility that a defect may be considered unpredictable only because the scientific theses that confirm its existence are not yet fully consolidated or because they are not directly and immediately accessible. Case law is also orientated towards considering a defect predictable in such cases.

Under section 5 of DPR 224/88, a manufacturer may be held liable for damages only if the product is defective in relation to its ordinary, typical use.

Under section 10 subparagraph 1 of DPR 224/88, if the injured party contributed to causing the injury, damages shall be assessed according to section 1227 CC, i.e. based on the seriousness and degree of the victim’s contributory negligence and the level of consequences due to the victim’s own negligence. No damages shall be awarded if the victim could have avoided the injury by acting with ordinary reasonableness and diligence (section 1227, subsection 2 CC). Furthermore, there will be no damage award if the consumer was aware of the defect and of the risks connected thereto, but nevertheless accepted being exposed to the danger by continuing to use the product. The principle of the “undertaking of the risk” was introduced in the Italian
system by the second paragraph of section 10 of DPR 224/88, which provides that “no indemnification is due when the injured party is aware of the defect of the product and of the hazard deriving therefrom and, nevertheless, willfully exposed himself/herself thereto”.

Traditional defences in tort to exclude a manufacturer’s liability include a variety of arguments, and may include proving that the manufacturer did not place the product on the market, or that it was not intended for marketing purposes, or that it was not defective when it was placed on the market, or that the state of the art did not allow identification of the defect at the time when the product was manufactured. Defences by distributors and manufacturers of parts of the product may include proof of having complied with instructions provided by the assembler or by the manufacturer of the main product.

3.2 Is there a state of the art/development risk defence?
Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

As noted above in the answer to question 3.1, under section 6(e) of DPR 224/88 the manufacturer’s liability is excluded if the level of technical and scientific knowledge at the time the product was placed on the market did not allow the defect to be discovered. Under section 7 of DPR 224/88, the time when the product is placed on the market is either the time when it is delivered to the purchaser, or to the user, or to an agent thereof, including when it is delivered for trial purposes or for inspection.

Under section 8.2 of DPR 224/88, any element that may exonerate the manufacturer from liability must be proved by the manufacturer himself. Accordingly, the burden of proving that the defect was not known or knowable at the time the product was placed on the market lies with the manufacturer (as also confirmed by case law).

A manufacturer shall be liable if it continues to market a product after technical and scientific knowledge has actually found the product to be defective and no ad hoc measures are adopted to avoid the defect or to cure it by providing an updated version of the product, or upon failure by the manufacturer to inform consumers of the risks connected to the product.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under section 6(d) of DPR 224/88 the manufacturer is exonerated from liability if the defect is due to conformity of the product with a mandatory rule or a binding provision, the reason being the impossibility of sanctioning conduct that is mandatory. However, the legal provisions regulating product safety and the manufacturing process of goods are limited to a few sectors such as the processing of food and beverages (Legislative Decree no. 123 of 1993), medicines, pharmaceuticals, household electric appliances, and cosmetics (Legislative Decree no. 50/05 of 15 February 2005).

The rule established by section 6(d) of DPR 224/88 does not exonerate manufacturers from liability for damages caused by defective products placed on the market simply because the manufacturer abided by all existing safety standards or production guidelines. Compliance with such rules may support the manufacturer’s position, but if the product is defective the manufacturer shall be liable regardless of compliance with existing rules.

The same rule applies to torts, even though the general definition of faulty conduct includes any form of “negligence, imprudence, lack of skill or failure to abide to existing laws, regulations, orders and guidelines” (as per the definition of ‘fault’ provided by section 43 of the Criminal Code, unanimously applied by analogy to civil tort matters). In practice, compliance with existing rules does not exclude tort liability if the agent is found to have acted with negligence, imprudence or lack of skill as per the definitions of these concepts given by case law.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Different claimants can litigate issues of fault, defect or damage that had been previously litigated by another claimant in another case in relation to the same product. Indeed, procedurally speaking, the two cases are considered different because they involve diverse parties to the dispute, even if they regard the same product and even if the very same issues arise and are litigated in the case. However, it is most likely that de facto the decision in the subsequent case will be affected by the outcome of the previous case.

4 Procedure

4.1 Is the trial by a judge or a jury?

Italy belongs to the civil law tradition which does not contemplate trial by jury. Hence, all civil proceedings are governed by a single judge or a panel of judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes. A judge can appoint technical experts (Consulente Tecnico di Ufficio - CTU) to assist him in specific or technical activities (e.g. medical assessment of certain health damages, calculation of economical damages, technical surveys, translations from foreign languages, etc.). The results achieved can be evaluated only by the judge and they do not represent a piece of evidence. See also the answers to questions 4.8 and 4.9 below.
4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

The existing Consumer Protection Act (law no. 281 enacted 30 July 1998) does allow certain consumers’ associations listed in a special register to bring proceedings for injunctive relief in the interest of consumers (see answer to question 4.4 below). However, no specific group or class action procedure for multiple claims for damages brought by consumers currently exists. Multi-party proceedings may thus only be the result of application of procedural instruments such as third party joinder or consolidation of actions brought by different plaintiffs against the same defendant for identical or connected claims.

The traditional Italian approach may soon be abandoned after the presentation of a bill in Parliament in 2004 for the introduction of class actions in Italy, giving standing to consumer and user associations and their national representatives to sue in the event of torts affecting a large number of consumers or users. The bill was approved by the House on 21 July 2004 and is now being examined by the Senate. The bill amends the existing Consumer Protection Act by introducing new provisions (section 3) entitling consumers, consumer associations, investors associations, professional societies and chambers of commerce to file direct claims for damages on behalf of a number of individual consumers who have incurred losses as a result of tortious liability arising from legal relationships regarding business-to-consumer agreements finalised with pre-printed standard forms (so-called contracts en masse).

Procedurally speaking, under the new bill an association will be entitled to sue manufacturers and seek to obtain a favourable court decision on liability. Following publication of the court ruling, individual consumers shall then be entitled to bring suit against the tortfeasor asking the court to verify that they possess the requisites identified in the aforesaid ruling and to assess the exact amount of the damages or indemnity owing to them as a result of the court ruling, individual consumers shall then be entitled to bring suit against the tortfeasor asking the court to verify that they possess the requisites identified in the aforesaid ruling and to assess the exact amount of the damages or indemnity owing to them as a result of the ruling. The final decision is then enforceable against the tortfeasor.

In practice, according to the current version of the bill, the proceedings are carried out in three stages: in the first stage, the judge ascertains whether the alleged unlawful conduct has actually been committed and determines liability; the second consists of a mediation phase aimed at settling the dispute, and in the third stage, individual consumers can have resort upon their own initiative to the competent court and, upon declaration that they fall within the “class”, seek assessment and payment of damages.

Several large consumer associations (including CODACONS, Italy’s largest) have voiced their dissatisfaction as to the current text of the bill. They claim that a three-phase mechanism such as the one contemplated in the bill would force consumers to wait several years before obtaining damages in small amounts. Beyond this, many are worried that class actions are likely to further overburden Italian courts, aside from the fact that the approval of the bill would certainly require substantial amendments of a number of provisions of Italy’s overall legal framework.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Under Italian law, as a general principle each individual claimant must take part in a civil proceeding directly to represent his own interests and in this respect it is usually not possible to bring a claim on behalf of third parties.

As noted above in the answer to question 4.3, under the Consumer Protection Act consumers’ associations listed in a special register have standing to bring proceedings in the interest of consumers. However, they can only request the court to order that conduct likely to prejudice an indefinite number of consumers be prohibited (no direct compensation for damages can be obtained).

Prior to the enactment of the Consumer Protection Act in 1998, in Italy the primary issue involving interests shared by large classes of people has always been whether and to what extent associations, societies or public bodies representing said persons should be entitled to sue for damages and whether or not they could be classified as victims of a tort. Indeed, often in tort cases involving a number of victims damages are exorbitant taken as a whole, but each victim suffers relatively small losses and is often discouraged from suing, especially considering the legal costs associated with filing an action, whereas associations representing classes of victims may very well be encouraged to sue for larger amounts. This issue has most often arisen in connection with civil actions arising out of a criminal proceeding. In several cases, the Criminal Division of the Supreme Court has held that not all persons who have incurred damages arising out of the perpetration of a crime are entitled to file a civil action in a criminal proceeding, but that only those persons having suffered a loss directly and immediately deriving from the crime have standing to sue.

In the past, Italian courts have widely accepted and admitted civil actions brought in criminal proceedings by town authorities and other public bodies, as well as entities deriving from the crime have standing to sue. On the contrary, private associations have rarely accomplished this aim, and when they have there has been much debate over their acceptance.

The scope for representative bodies to bring claims on behalf of consumers is likely to broaden in the near future with the final adoption of the class action bill (see answer to question 4.3).

4.5 How long does it normally take to get to trial?

The common law concept of “trial” is unknown to the Italian civil procedure system: Italian proceedings consist of an introductory stage when the statement of claim and statement of defence and the subsequent briefs with specification of the claims and defences are filed, an evidentiary stage when fact witnesses are heard and court-appointed experts carry out their assessments, and a final stage when conclusive briefs are submitted by the parties and the case is reserved for decision by the court. The duration of the proceedings depends on the complexity of the case, on the number of fact witnesses heard and on the time devoted to court-appointed experts. Generally, up to 3 years may be required to reach a first instance decision.
4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

In principle, the court can try preliminary issues (e.g. lack of jurisdiction, lack of territorial venue, lack of locus standi or statute of limitation) prior to examining the merits of the case. In practice, however, courts tend to determine the preliminary issue at the end of the case, along with the merits. Some preliminary issues (such as lack of territorial venue or statute of limitation) must be raised by the defendant in the statement of defence, otherwise they cannot be raised at all. Others (such as lack of jurisdiction or lack of locus standi) can be raised ex officio by the court without input from the parties and at any stage of proceedings (including the appeal stage).

4.7 What appeal options are available?

Any party to a claim has a right of appeal to the Court of Appeal (second instance) and, on issues of law only, to the Supreme Court of Cassation. Two other “exceptional” appeal options are available: revocation and third party opposition. No leave to appeal is required.

Appeal

As a rule, the losing party to a partial or final judgment can challenge the decision before the Court of Appeal, formed by a panel of three judges. The appeal must be filed within thirty days from the service of the judgment of first instance (service is usually requested by the winner upon the loser); failing service, the term to appeal is one year from the date when the judgment is lodged with the court clerk. All claims raised in the first instance can be referred to the Court of Appeal and any error the appellant asserts has been committed by the first instance court can be grounds for appeal (in this sense an appeal is an unlimited challenge). At the appeal stage, no new objections can be raised and the parties may not produce new evidence. The appellate court issues a new judgment which replaces that of the first instance court.

Cassation

The second instance judgment can be challenged before the Supreme Court of Cassation. The appeal must be filed within sixty days from service of the judgment; failing service, the term to appeal is one year from the date when the judgment is lodged. The appeal before the Supreme Court does not entail a new examination on the merits; the court only evaluates whether legal principles have been complied with in the previous instances. When the court ascertains errors, it sets aside the judgment appealed from and remits the case for judgment on the merits to a lower court, which must re-examine the facts in the light of the legal principle fixed by the Supreme Court. In cases where the judgment appealed from is set aside due to a violation or incorrect application of rules of law and there is no need for re-examination of the facts, the court itself issues a new judgment based upon the correct principle of law.

Revocation and third party opposition

Revocation is a proceeding before the court that issued the challenged judgment and can be filed only in few cases expressly listed by law (e.g. manifest mistake in the evaluation of facts or documents, wilful misconduct of one of the parties or of the judge during the proceedings, judgment issued on the basis of false evidence, etc). Third party opposition may be raised by someone who was not a party to the original proceedings, complaining that the judgment was rendered in his absence and that this has infringed his rights, or has ruled thereon, or has created a right inconsistent with his own rights.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As noted in the answer to question 4.2, during the course of proceedings the judge can appoint a technical expert (CTU) to assist in activities that the judge cannot directly perform. When the court appoints a CTU the parties can also appoint their own experts (Consulente Tecnico di Parte - CTP). CTPs will participate in the technical investigations and draft a report in the interest of the party who appointed them. In product liability claims a technical assessment of the allegedly defective product is often needed and expert investigations can be the core of the action.

In addition, before the commencement of a case, if there is an urgent need to verify the state of a place or an object before they are modified in a way that could hinder their use as evidence in proceedings (e.g. the scene of an accident or a product that, by its nature, deteriorates, like a food or beverage), a party can request from the President of the Court a pre-trial technical investigation (Accertamento Tecnico Preventivo - ATP).

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Factual witnesses

Procedurally speaking, Italian civil law does not distinguish between pre-trial and trial as is often the case in common law jurisdictions in connection with witness depositions. A party wishing to depose a factual witness in a civil proceeding will file the relevant request in the introductory brief or in the statement of defence and in the subsequent briefs on evidence, listing the questions on the factual circumstances of the case that they wish the judge to ask the witness. The counterpart has the right to counter-depose the witness. The judge has the power to admit or dismiss any such witnesses and to allow or strike off the suggested questions. Witnesses must appear personally at a prescribed hearing scheduled by the judge, and the latter is the only person entitled to ask questions. Depositions constitute full evidence.

Expert witnesses may not be deposed under Italian civil procedure law. Evidence in the form of sworn affidavit is not admissible, although experts may prepare reports in writing that parties are entitled to file with the court as documentary evidence.
Court-appointed experts

As noted above in the answer to question 4.8, the judge may seek the aid of an expert for any issues requiring technical skills, by ordering a technical assessment. The judge will designate a court-appointed expert, who will appear before him to be sworn in, and the parties are entitled to name their own experts to attend the assessment. The outcome of the assessment is the filing of reports by the court-appointed expert and by the party experts. Technically speaking, court-appointed experts are assistants of the judge and not witnesses and their findings are not pieces of evidence. Their report serves the purpose of clarifying highly technical aspects to the judge, but the judge is not bound to follow any conclusions reached by the expert on specific issues. Court-appointed experts are never deposed as witnesses.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

In the Italian procedural system there are no disclosure obligations. The basic principle is that the claimant must prove its claims by submitting to the judge all relevant evidence it possesses (documents, witnesses, etc). The same applies to the defendant in proving statements made in its defence. Normally the evidentiary phase of a trial is limited to such document production and the hearing of witnesses (if any). If a party fails to submit documentary evidence on its own behalf, it suffers no adverse consequence in the proceedings save that (obviously) its claims may not be proved to the judge’s satisfaction.

Sections 118 and 210 of the Italian Code of Civil Procedure provide that the judge may, if he deems it necessary in order to ascertain the facts on which the claim is based or if he has received a request for disclosure from one of the parties, order the inspection of all items in the possession of another party to the proceedings or of a third party. (“Items” like documents are, of course, usually produced in the trial by one of the parties as evidence of its claim, rather than “inspected”). If the request originates from one of the parties to the proceedings, this must specifically indicate the particular document to be disclosed, and cannot be a “fishing expedition” for generic classes of documents. The judge may refuse a request for disclosure where the filing might cause serious damage to the party or third person concerned. In addition to the above mentioned sections of the Italian Code of Civil Procedure, section 2711 CC stipulates that a judge can order a company which is a party to proceedings to disclose specific documents (in the nature of accounting books and internal documents of a company) concerning the claim. Company accounts and registers are in any event public.

If the party against whom the order has been made refuses, without good grounds, to consent to the inspection or produce the document, the judge may infer that the document is adverse to that party. If the refusal comes from a third party the judge can only impose a fine. It must be stressed that a disclosure order cannot be specifically enforced by the judge nor by the party for the benefit of whom the disclosure is ordered. A party may refuse to comply with such an order on the grounds that a document is protected under “professional or official secrecy”. The Italian procedural system treats documents as falling within this protection in limited cases only, namely where they are communications with:

a. lawyers (in relation to facts learnt in the management of a file and correspondence exchanged with the lawyer of a counterparty marked as “privileged and confidential”);

b. court-appointed experts;

c. accountants (save in relation to the activity of balance sheet certification);

d. public notaries and certain public authorities (e.g. the Bank of Italy); or

e. health professionals, priests and any other professional expressly indicated under the law.

Thus if one party is in possession of documents not covered by any of these categories, the other party cannot prevent their production by the first party for its own benefit.

All of a party’s private or internal documents and correspondence must be considered confidential. Art. 15 of the Italian Constitution affords secrecy to correspondence and communications in general, the scope of which can be limited only by means of a reasoned order of the judicial authorities, issued in any case in respect of the guarantees provided by the law.

The production at trial of correspondence internal to another company (whether or not it is party to the proceedings) appears not only to be forbidden, but also in violation of the criminal law (art. 616 of the Italian Criminal Code punishes the person who “violates” -i.e. reads or steals correspondence not directed to him).

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes. The statute of limitation depends on whether the plaintiff is suing in tort or contract or under DPR 224/88.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Claims brought in tort are subject to the 5-year general tort liability statute of limitations, running from the time when the claimant could exercise his/her rights. The time limit is extended if the tort is connected to the perpetration of a crime.

The general 10-year statute of limitations covers most other areas of the law, including the enforcement of contractual remedies.

Under section 13 of DPR 224/88, consumers are time-barred from filing an action against manufacturers after a three-year period, running from the time when victims (should reasonably have) become aware of the damage, of the defect in the product and of the identity of the manufacturer. In any case, the statute of limitations runs out after 10 years from the time when the manufacturer (or the importer in the European Union) placed the product on the market (section 14 of DPR 224/88).
Statute of limitations rules are binding and mandatory in Italy. Courts have no discretion to disapply time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The existence of concealment or fraud -if acknowledged- does not affect the running of time limits for the commencement of civil proceedings.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under section 11 of DPR 224/88, the following types of damage are recoverable: injury to life or limb, and destruction or deterioration of property other than the defective product itself, if normally intended for private use or consumption and employed accordingly by the injured party. Redress may only be sought if recoverable property damages exceed € 387.34.

If the victim is suing under contract law, recoverable damages resulting from breach of contract include actual damage and lost profit. Damages may be sought for failure to perform a contractual duty as long as the damages are a direct and immediate consequence of the nonperformance.

If the victim is suing under tort law, recoverable damages include material damages and moral damages. Until recent (2003) case law, moral damages were awarded only if the tort was also a crime under Italian criminal law. Under the new doctrine, moral damages are broadly awarded for any violation of individual rights which is not appreciable in monetary terms whenever the tortious conduct breaches section 2043 CC. The extension of this doctrine to DPR 224/88 is a disputed issue, although recent case law has held that section 2043 CC and DPR 224/88 share equal principles, thus extending the broad award of moral damages to cases brought under DPR 224/88.

Recoverable damages in tort and within the context of a product liability claim may also include so-called “biological” damages, i.e. injuries affecting the victim’s personality and capacity to lead a peaceful existence. Injured parties may claim no more than the damages actually incurred, the purpose of the tort rules being to restore the victim’s position prior to the occurrence of the tort. Damage assessment is generally based upon factual evidence, although damages may at times be awarded by the judge based upon statistical criteria and presumptions, or otherwise according to equitable criteria (section 1226 CC).

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury but may do so in future?

In principle, under Italian law a victim may only recover the damages actually incurred. No specific case law has dealt with damage recovery in respect of the cost of medical monitoring in circumstances where a product has not yet malfunctioned and caused injury but may do so in the future. However, courts have dealt with similar issues allowing recovery of future damages that the victim is likely to suffer as a consequence of damages already incurred as long as signs of the onset of the damages are clearly traceable (as is the case for increasingly deteriorating illnesses after exposure to noxious substances such as asbestos, whereby the symptoms of cancer may very well be detected beforehand although the illness may critically develop at a later stage). In all such cases, courts may seek an estimate and award costs for future medical treatment whenever there is medical certainty or statistical evidence of a high likelihood of having to incur such costs in the future.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

A basic principle of Italian tort law is that a victim may recover nothing other that the damage actually suffered. Hence, punitive damages are not provided for in the Italian legal system.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no limit on the amount of damages awarded (with the sole exception of liability for nuclear activity, see answer to question 1.2 above).

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

During the proceedings each party must pay its own costs. The cost of the acts considered necessary by the judge must be paid by the party who will take advantage of them (e.g. appointment of an interpreter or translator).

At the end of the proceedings, the general rule in the Italian system is that costs follow the event: however, the judge can decide to “set off” the costs in which case each party shall bear its own costs.

The judge may also impose compensation for the damages suffered by a winning defendant in case of abuse of process by the plaintiff (section 96 of the Italian Code of Civil Proceedings).

7.2 Is public funding e.g. legal aid, available?

Yes. The legal aid system in Italy is called “gratuito patrocinio”.

7.3 If so, are there any restrictions on the availability of public funding?

Italy has a very limited legal aid system. In order to benefit a plaintiff must show both that he has a well-founded case and that he falls below certain economic thresholds (an annual income less than € 9,296.22); legal aid is therefore seldom granted in practice.
7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency or conditional fees are not permitted under the Italian bar rules.

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The Italian office of Lovells is one of the premier Italian full-service law firms with over 70 lawyers based in Milan and Rome, working in close co-ordination with Lovells’ other international offices.

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Lovells is an international law firm, with more than 1,600 lawyers operating worldwide, from 26 offices in 19 countries.

Lovells, through its European Product Liability Network, has the largest specialist product liability practice in Europe. The practice comprises over 50 lawyers who are able to advise on all aspects of litigation, regulation and risk management.

Our lawyers have been closely involved in most of the major product liability controversies over the last decade and have experience of advising on a wide range of products including: pharmaceuticals; food; medical devices; cars; tobacco; vaccines; mobile phones; cosmetics; blood products; aircraft; and trains.

Lovells has particular expertise of co-ordinating multi-party product liability litigation and currently acts in respect of litigation in over 17 countries.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

There are two general legal regimes available for establishing liability and seeking damages for injuries which result from defective products. One regime is the Product Liability Law (Law No. 85, 1994) (seizobutsu sekinin ho) (the “PLL”) and the other regime is the Civil Code of Japan (minpo) (the “Civil Code”).

As a preliminary matter, it should be noted that with respect to product liability claims, the PLL is considered to be a “special” law and the Civil Code is considered to be a “general” law. This means that if a cause of action does not fall within the ambit of the PLL, it must be brought under the Civil Code.

Article 3 of the PLL provides that “the manufacturer shall be liable for damages caused by the injury, when he injured someone’s life, body or property by the defect in his delivered product which he manufactured, processed, imported or put the representation of name. . .” “Defect” is defined in Article 3 (2) of the PLL to mean a “lack of safety that the product ordinarily should provide, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time when the manufacturer delivered the product, and other circumstances concerning the product.” There are three types of defects: (i) manufacturing defects, (ii) design defects and (iii) information defects.

Article 6 of the PLL expressly provides that, unless otherwise provided in the PLL, “the liability of the manufacturer for damages caused by a defect in the product shall be subject to the provisions of the Civil Code.” Damages and causation are governed by Article 416 of the Civil Code (see answer to question 2.2).

Article 709 of the Civil Code provides that “A person who violates intentionally or negligently the right of another is bound to make compensation for damages arising therefrom.” Courts in Japan have determined that negligence arises in the product liability context where: (i) the causal connection between a defective product and the subsequent injury is reasonably foreseeable; and (ii) the defendant failed to take adequate, reasonable precautions against the manufacture of the defective product.

In addition to negligence-based liability, the Civil Code also establishes liability for injury that arises from a breach of an obligation. Article 415 of the Civil Code provides that “if an obligor fails to effect performance in accordance with the tenor and purport of the obligation, the obligee may demand compensation for damages”. This provision has also been used to establish liability for product-related injuries which stem from the breach of contractual provisions.

1.2 Does the state operate any schemes of compensation for particular products?

The Government of Japan does not generally operate schemes of compensation, such as funds, for any damages which result from any particular product.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under Item 3 of Article 2 of the PLL, a person may, in principle, be held liable for the damages arising from a defective product if: (i) he manufactures, processes or imports the product; or (ii) he affixes his name, trade or other indication to a product indicating that he is either the manufacturer or the “substantial” manufacturer of the product. Under the PLL, a distributor may not be held liable for defective goods, unless it affixes its name to the product and is deemed to be a manufacturer.

Under the Civil Code, the negligent party under Article 709 of the Civil Code or the party with a legal obligation under Article 415 of the Civil Code bears responsibility for the fault or defect.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Courts do not have the power to cause a manufacturer to recall defective products. Outside of the judicial process, administrative agencies which oversee the operation of certain industries, such as the pharmaceutical industry and the automotive industry, have the power to order a manufacturer to recall defective products which are deemed to pose a threat to society.

For example, Article 69-3 of the Drugs, Cosmetics and
Medical Instruments Act, the Minister of Health and Labor has the power to issue an emergency order (kinkyu meirei) to decree the cessation of any activities related to pharmaceutical products, cosmetic products and machinery which may cause a danger to human health. Additionally, Article 63-2 of the Roads and Transportation Vehicle Law (rodo unsoshia ryoho) specifically provides that the Minister of Transportation may recommend that necessary corrective measures be taken with respect to vehicles which are deemed to be not in compliance with certain standards. The Minister of Economy and Industry also has power to take necessary steps under Article 39-18 of the Gas Enterprises Act (gasu jigyo ho) to protect consumers against harmful gas products.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

While technically Article 3 of the PLL establishes the concept of “strict” liability, the plaintiff has the burden of proving defect and damage. In Japan some judges have stated that the application of the test for defect may practically function to require the plaintiff to establish a degree of fault on the part of the defendant because the plaintiff, as a practical matter, is required to first demonstrate the “normal” standard for a product and then show that the allegedly defective product in fact deviated from that standard.

Under Article 709 of Civil Code, the plaintiff is required to prove the existence of (i) an injury; (ii) a negligent or intentional act on the part of the defendant; and (iii) a causal connection between the injury and the negligent or intentional act.

Under Article 415 of the Civil Code, the plaintiff must demonstrate (i) the existence of an obligation; (ii) the breach of the obligation; and (iii) the fact that the breach of the obligation led to the plaintiff’s injury.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The PLL itself does not set forth any specific test for the proof of causation. In order to determine causation, courts have applied the test set forth in Article 416 of the Civil Code, which requires a demonstration of a “reasonable linkage” between the cause and the injury and a demonstration of the fact that, from the perspective of the injury, there is a “common sense” linkage between the events alleged to have caused the harm and the harm. In applying this test, courts have often looked at “subjective” factors, such as the knowledge and the intent of the defendant, which are set forth in Article 416 (2) of the Civil Code (tokubetsu jijo).

The same test for causation is typically applied for product-related negligence and breach of obligation theories of liability brought under the Civil Code.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Japanese law recognises a quasi-form of enterprise liability known as kyodo-fuhokai (Article 719 of the Civil Code), which literally means “collective wrongful action.” This theory of liability is typically used where the plaintiff has proven defect, damage and a set of responsible parties, but it is not possible with available scientific evidence to determine precisely which defendant caused the injury or to apportion liability between all defendants. In order to prevail on this theory, a plaintiff is not required to prove that there was a conspiracy to harm among the defendants, the plaintiff must minimally show some level of negligence between the defendants as a group. If a plaintiff can make this showing, it can recover the full sum of damages from any of the defendants.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g., a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

As noted above in the response to question 1.1, one of the types of defects under the PLL is an “information defect”, which is tantamount to a failure to warn. There is no one specific test to determine what, and through what channels, specific information must be provided to product users. Often the nature of the burden regarding the steps that must be taken to make the consumer aware of specific product risks depends on how dangerous the product is. For certain products, such as pharmaceutical products, the burden on manufacturers may be high.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Article 4 of the PLL provides that if Article 3 applies, the manufacturer shall not be liable if it proves “that the state of scientific or technical knowledge at the time when the manufacturer delivered the product was not such as to enable the existence of the defect of the product to be discovered.” Article 4 (2) provides that “in the case where the product is used as a component or raw material of another product, if the defect is substantially attributable to compliance with the instruction concerning the specifications given by the manufacturer of the other product, the manufacturer is not
negligent regarding occurrence of the defect.” If the plaintiff’s cause of action is brought under Article 709 of the Civil Code, the defendant may, as with many types of causes of action including causes of action based on Article 415 of the Civil Code, discussed below, raise defences based on what are referred to as “objective” factors and “subjective factors.” Regarding objective factors, the defendant will not be liable if the plaintiff does not establish that the product was defective or that there was a causal link between the defendant’s actions and the plaintiff’s damages. Concerning subjective factors, the defendant will not be liable if he can demonstrate that the injury was not reasonably foreseeable or that it was “unavoidable.” The test of unavoidability is that, based upon a balancing of risks and benefits of a course of action, the benefits outweighed the risk.

In the event that a plaintiff’s cause of action is brought under Article 415, a defendant first has contract-based defences. The defendant could argue that there was no breach or the non-existence of the claimed obligation due to an express disclaimer in the contract; however, the effectiveness of a disclaimer is limited. A defendant could also argue that he was not responsible for the non-performance of the obligation on the grounds of impossibility or impracticality. Apart from these contract-based defences, the defendant can also escape liability if it can demonstrate, as under Civil Code Article 709, the injury was not foreseeable or that it was unavoidable.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or its it for the manufacturer to provide that it was not?

See answer to question 3.1. Once a plaintiff establishes that a product was defective, the burden is on the defendant to establish compliance with existing scientific and technical knowledge.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

See answer to question 3.1.

4 Procedure

4.1 Is the trial by a judge or a jury?

While all trials in Japan are conducted by a judge, it should be noted that Japan is planning to introduce a quasi-jury system (saibanin) in connection with criminal trials in the near future. As currently planned, the jury verdict would be taken into consideration by, but not necessarily binding on, the presiding judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court may appoint certain specialists pursuant to Article 212 of the Civil Procedure Law (minijiosohohō), known as kanteinin, to assist the court with respect to technical matters. Kanteinin typically are requested to prepare reports or appraisals which the court considers with additional evidence proffered at trial. It is noted, however, that the court is not bound to follow any opinions or recommendations of the kanteinin.

In cases regarding intellectual property, the court may appoint intellectual property specialists (chosakan). Instead of merely providing reports, the chosakan provides advice to the court throughout the entire trial.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

While there is no mechanism for a class action law suit in Japan, it is noteworthy that in certain types of cases involving perceived danger to the public at large, such as with pharmaceutical products or pollution, the courts may practically make strong efforts to make sure that plaintiffs in different proceedings are treated similarly. There are proposals in Japan to institute a quasi-class action law suit mechanism in certain areas within a limited scope.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

While traditionally claims could not be brought by a representative body such as a consumer association, lawyer advocate groups have brought cases for groups of litigants in some circumstances. It has recently been announced, however, that starting next year this system will be strengthened and a new system of consumer group advocacy (shohisha dantai) will commence. The shohisha dantai will have the power to file a claim on behalf of claimants (shohi dantai sosho). This system may be viewed as a necessary complement to the current system of consumer claims, including product liability claims, given the rapidly increasing incidence of claims regarding products and the fact that these groups can take action prior to the execution of a contract and prior to the occurrence of actual harm.

4.5 How long does it normally take to get to trial?

As there is no post-complaint filing division between the pre-trial phase and the trial phase in Japan, the “trial” may be understood to commence upon the filing of the complaint. The time it takes to complete the trial can vary significantly based on the nature of the case and the court’s docket. Product liability cases, which are often complex and highly fact intensive, generally take around two or three years to litigate, and can take longer depending upon the situation.
4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

According to the system of “intermediary judgment”, a litigant has the right, pursuant to Article 145 of the Civil Code, to request that the court try certain threshold issues before trying other issues raised in the complaint (chukan kakanin no uttae). In response, the court can issue a decision on these threshold issues, known as a chukan hanketsu.

4.7 What appeal options are available?

District Court (chihosai bansho) judgments may be appealed as a matter of right to the Court of Appeals (kotosai bansho). If a litigant does not prevail at the Court of Appeals, he may petition the Supreme Court to hear an appeal based upon limited reasons. The Supreme Court can only hear appeals in cases involving the Constitution of Japan or violation of laws which clearly affect the judgment.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

While not compelled to do so, a trial court has wide latitude in permitting the admission of expert testimony and reports. In a case where an expert opinion is sought, the court will ordinarily provide other litigants in the proceedings with the opportunity to provide their own expert reports.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Technically speaking, Japan does not recognise a “pre-trial” discovery period. Once the complaint is filed before the relevant court the case may properly be considered to be in the “trial” phase. In the event that expert opinions or reports are provided the parties would ordinarily have the opportunity to review the expert’s report and question the expert before the tribunal.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

There is typically no obligation to disclose documentary evidence prior to the commencement of proceedings. It is noted, however, that the court has the power prior to the commencement of formal proceedings to take steps to cause certain sensitive information to be secured (shokohozen) (Article 234 of the Civil Procedure Law).

Once legal proceedings are commenced, litigants have a general obligation under Article 220 (1) of the Civil Procedure Law to disclose relevant documents. However, there are, compared to common law jurisdictions such as the United States, relatively broad exemptions in the Civil Procedure Law for the production of certain types of information, such as confidential business information.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The time limit for actions brought under the PLL is: (i) ten years from the date of delivery of the defective product or (ii) three years from the date that the victim or its legal representative identifies the damages or injuries and the responsible parties.

Under Article 724 of the Civil Code, the time limit for actions brought under Article 709 of the Civil Code is three years after the injured party became aware of the identity of the party causing the injury or twenty years after the unlawful act in question was committed.

The time limit for an action brought under Article 415 is generally ten years (Article 167, Provision 1 of the Civil Code), and five years after the date of breach by the obligor if the obligation arose out of a commercial transaction (Article 522 of the Commercial Code).

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

As noted above, issues of concealment or fraud affect the running of time limits because, under causes of action in connection with both the PLL and the Civil Code, the statute of limitations begins to run once the plaintiff is aware of the injury.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The damages that may be recovered under the PLL are those caused to the victim’s life, body or property due to the injury; damages for the defective product itself cannot be recovered under the PLL (Article 3).

Under Article 415 of the Civil Code, damages can include not only the cost of the replacement of the goods in question, but also consequential damages to the extent that such damages were or could have been foreseen within the scope of Article 416 of the Civil Code (see answer to question 2.2). Lost profits may also be recovered if those profits are deemed to be within the reasonable scope of the damages.
6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

It is possible for a plaintiff to recover damages for the cost of medical monitoring even if the plaintiff has not established as a matter of law the existence of an injury arising from a defect. In these circumstances, however, the plaintiff is required to demonstrate a causal relationship between the defendant’s product and the feared harm and the likelihood that the plaintiff would suffer such injury based upon Article 416 of the Civil Code.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are deemed to be a violation of “public order and morals” (kojoryozoku ihan) under Article 90 of the Civil Code and are not recoverable. Similarly, while Japanese courts may enforce judgments against a Japanese party obtained abroad if the requirements under Article 118 of the Civil Procedure Law are fulfilled, any portion of the judgment containing a punitive damages component will not be enforceable.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There are no caps on the amount of potentially recoverable damages under the PLL or the Civil Code. However, for a number of different reasons (such as the prohibition against punitive damages and the absence of jury trials), damages awards to plaintiffs in Japan have typically been said to be smaller than damages awards to plaintiffs in the United States.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As a general rule, each litigation party must pay its own costs. In some cases, however, such as those involving malicious torts, courts have awarded legal fees to the winning party. The award for fees and expenses in these cases may be around 5% to 20% of the overall damages award but may differ depending upon the amount of damages awarded.

7.2 Is public funding e.g. legal aid, available?

Public funding for plaintiffs is available in certain circumstances. Under one such system (minji horitsu fujo jigyo), plaintiffs may receive financial and legal assistance from a legal aid association (horitsu fujo kyokai) if: (i) their monthly income is at or below a certain amount, determined by the size of their family; (ii) the plaintiff has some chance of prevailing; and (iii) the purpose of the assistance is deemed to be proper and suitable.

It is also noted that the courts may waive filing fee requirements for plaintiffs who establish that they are indigent.

7.3 If so, are there any restrictions on the availability of public funding?

To obtain funding from a horitsu fujo kyokai, applicants for the funding must comply with the requirements established by the horitsu fujo kyokai from which funding is sought.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Attorneys in Japan may take cases on a contingency fee arrangement. In these types of fee arrangements clients will typically pay an initial retainer fee (chakushukin) and then pay additional compensation if the outcome of the litigation is successful (seikohoshu), but these arrangements can differ depending on agreements between lawyers and their clients.
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Chapter 28

Korea

Kim & Chang

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Product liability claims may be based on theories of strict liability, tort, or breach of contract. Under the Product Liability Act (“PLA”), a manufacturer is held strictly liable for damages that are caused by defective products. Thus, in cases where a defect is found in a product, fault or negligence will be presumed. Liability in tort is based on the Korean Civil Code, which provides that any person who wilfully or negligently causes loss to, or inflicts injury on, another person by an unlawful act shall be liable for compensation for damages sustained as a result of such unlawful act. In order to bring a product liability action based on contract, the plaintiff must be in privity of contract with the manufacturer or seller. The threshold question in imposing liability in contract is whether a contractual relationship exists between the plaintiff and the defendant.

1.2 Does the state operate any schemes of compensation for particular products?

Under the Consumer Protection Act, a party may file a report of a product defect to the relevant central administrative agency. When an administrative agency receives a report of a product defect, the head of the relevant central administrative agency will request an appropriate inspection agency to inspect or test the product for defects. If the result of the inspection confirms that the defect of a product or a service might potentially injure the consumer or cause damage to property, the head of the central administrative agency could order based on the seriousness of the defect the manufacturer to recall the product.

We note that there are two types of recalls in Korea: (i) voluntary recalls, and (ii) mandatory recalls. Although there are no sanctions against a manufacturer who does not initiate a voluntary recall, the manufacturer has the responsibility to report any defect and will be assessed an administrative fine if it fails to do so, and in the event actual accidents occur, it is likely that the manufacturer would be ordered to institute a mandatory recall. A manufacturer could also be required to compensate for damages claimed by consumers.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The PLA imposes liability to any or all parties along the chain of manufacture of any product, for damage caused by the defective product, so as to provide a financial guarantee for compensation. This means that the manufacturer of component parts, an assembling manufacturer, and an importer of a product could be liable to the consumer. In certain cases, the distributor or the wholesaler and the retail store owner may also be subject to liability in the event that it is difficult to identify the manufacturer of a product, and if they know or should have known the source of the product, they have not, within a reasonable period, disclosed to the injured persons or their legal representative the identity of the manufacturer or the supplier of the relevant product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under the Consumer Protection Act, when an administrative agency receives a report of a product defect, the head of the relevant central administrative agency will request an appropriate inspection agency to inspect or test the product for defects. If the result of the inspection confirms that the defect of a product or a service might potentially injure the consumer or cause damage to property, the head of the central administrative agency could order based on the seriousness of the defect the manufacturer to recall the product. We note that there are two types of recalls in Korea: (i) voluntary recalls, and (ii) mandatory recalls. Although there are no sanctions against a manufacturer who does not initiate a voluntary recall, the manufacturer has the responsibility to report any defect and will be assessed an administrative fine if it fails to do so, and in the event actual accidents occur, it is likely that the manufacturer would be ordered to institute a mandatory recall. A manufacturer could also be required to compensate for damages claimed by consumers.
2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In principle, the party who files the complaint bears the responsibility of meeting the burden of proof of existence of fault/defect and damage. In practice, however, courts hearing particular cases tend to mitigate the plaintiff’s burden of proving the existence of a ‘defect’ considering the inherent difficulty in proving the technical and complex nature of a ‘defect’.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The recent trend by Korean courts is to alleviate the burden of proof with respect to the issue of causation in specific cases. However, the PLA does not specifically discuss the standard for causation, and there is no consistent or otherwise reliable judicial precedents establishing the standard or test applicable to the proof of causation.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Under Article 5 of the PLA, if two or more persons are deemed to be liable to compensate a party for the same damages, they shall jointly and severally compensate for such damages. With regard to tort liability, where it is uncertain which tortfeasor caused the damage, the tortfeasors are jointly and severally liable, and each tortfeasor has the responsibility to pay the full amount of damages to the victim. A joint tortfeasor who has paid the full amount of damages to the victim may claim from the other tortfeasors their respective portions of the damage payment. However, there is no case precedent where the court clearly addresses the market-share rule in allocation of damage liability on the part of co-tortfeasors.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The Consumer Protection Act requires that the responsible party for a potentially defective product, which may cause damage to persons or property, to inform the at-risk persons of such danger. Under the PLA, a defective product is defined as a product that lacks the level of safety that would be ordinarily expected by a consumer. The three types of defects recognised under the PLA are: (i) manufacturing defect; (ii) design defect; and (iii) indication defect. An indication defect would be found if the indications (i.e. instructions) provided were not reasonable or adequate to warn of the dangers of using the product or of foreseeable misuses of the product. Thus, manufacturers may need to take some proactive measures to ensure the safety of their products even after delivery into the market, which includes providing the consumer with reasonable warning or notice of a malfunction upon discovering the existence of such malfunction.

However, there is no single case where the court clearly addressed the standard or test applicable to the issue of the content or appropriateness of warnings to the consumers. The ‘learned-intermediary’ rule, typically applicable to pharmaceutical products, has not yet been made a part of judicial precedents although the rule has been widely discussed in academic treatises and journals.

3 Defences and Estoppel

3.1 What defences, if any, are available?

With regard to defences that may be asserted by manufacturers in product liability cases, Article 4, Section 1 of the PLA provides four exemptions from liability. Proof of any of the circumstances expressly set forth in Article 4 would be an affirmative defence to liability arising from injuries caused by a defective product. Article 4 provides exemptions from liability if: (i) the manufacturer did not supply the product; (ii) the manufacturer proves that it was not possible to discover the defect given the state of scientific or technical knowledge at the time the relevant products were delivered (the “state of the art” defence); (iii) the defect in the product existed due to compliance with standards designated by applicable law at the time the products were delivered; or (iv) the product was used as a part or base material in another product, and the alleged
defect was necessary to comply with the specifications relating to the design and manufacture of such other product.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific or technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

A state of the art defence does exist for Product Liability claims. Article 4 of the PLA provides an exemption from liability if the manufacturer proves that it was not possible to discover the defect given the state of scientific or technical knowledge at the time the relevant products were delivered. Notwithstanding this defence, Article 4, Section 2 of the PLA expressly precludes the application of such defence if the manufacturer knew or could have known of the existence of the defect in the relevant product after delivery of the product, and nevertheless did not take appropriate measures to prevent the injury that was caused by such defect.

The burden rests with the manufacturer to establish and prove the state-of-the-art defence. The manufacturer is required to prove, among other things, that the defect was not discoverable at the time of supply even with due care. Further, the manufacturer is required to prove that he or she has taken all necessary proactive measures to vigilantly guard and ensure the safety of the product even after the delivery into the marketplace.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Article 4, Section 1 of the PLA also stipulates that an exemption from liability may exist if it is proven that the defect in the product existed due to compliance with standards designated by applicable law at the time the products were delivered. However, a mere showing of manufacturer’s compliance with regulatory and/or statutory requirements does not provide a defence.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Claimants can re-litigate issues of fault, defect or capability of a product even if the issues have been contested and finally resolved in different cases. Unlike estoppel or res judicata, issue estoppel normally does not preclude claimants from initiating new cases. Courts, however, tend to give deference to the decisions rendered by another court in similar cases.

4 Procedure

4.1 Is the trial by a judge or a jury?

There is no jury system in Korea, and the judges are always the triers of facts as well as legal issues. However, there is currently growing demand to introduce the jury system into Korean jurisprudence. However, unlike criminal litigation, there is a very slight possibility that the jury system will be introduced into civil litigation in the near future.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Currently, there is no such system operating in general Korean judicial practice. A single exception is in patent court litigation where an intellectual property technical specialist sits with the judge and presents an advisory opinion on the merits of a case. However, this exception is unrelated to product liability issues.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Currently, there is no general class action legislation in Korea. Although there have been several attempts to pass the class action bill, no legislation has been enacted allowing for a general class action before the courts. Although there is a limited type of class action bill called the Securities-related Class Action, this is unrelated to product liability.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Although there is no general class action legislation in Korea, the Government has proactively sought legislation whereby consumer groups can seek damages for victims. On May 31, 2004, the Ministry of Finance and Economy issued a media release discussing a proposal for an amendment to the Consumer Protection Act, whereby a consumer group may file a suit on behalf of consumers. However, it is uncertain whether this proposal will be adopted into legislation.

4.5 How long does it normally take to get to trial?

Upon receipt of a complaint, the presiding judge will require the defendant to submit a response. Subsequent to the defendant’s response, several exchanges of briefs usually take place prior to the designation of the first hearing. It takes approximately 3 to 6 months from the filing of the complaint to the designation of the first hearing.
4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court can try preliminary issues without further proceeding with the merits of the disputes. Typically, those issues relate to matters of law. Examples are: lack of jurisdiction, standing to sue, case and controversy, validity/extent of not-to-sue agreement, case estoppel, and statute of limitations.

4.7 What appeal options are available?

A party who is dissatisfied with the judgment of the District Court or any question of fact or law may appeal to the High Court. Appeals against the rulings or judgments of the High Court must be filed with the Supreme Court, where only questions of law may be heard. Although the High Court may give weight to the District Court’s decision and findings of fact, it is not required to give deference to the District Court's conclusions on issues of either fact or law and the parties to litigation may introduce new evidence and arguments even if such evidence or arguments were never entertained on the District Court level. In contrast, grounds of appeal to the highest court against the decision of the intermediary appellate court are strictly limited to questions of law. Certiorari applies in the selection of cases that the highest court is willing to hear.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint experts in considering technical issues and the parties may also present expert evidence. Written witness statements, declarations, or affidavits from experts are permissible. An expert opinion may also be used as evidence, and can be provided with or without the court's order for its submission. Once an expert opinion is submitted, the court, on its own initiative or at the request of a party, may order the expert to make an oral testimony in order to clarify or supplement the expert's written opinion. There is no particular restriction on the nature or extent of expert evidence given that judges exercise the discretion to decide on the admissibility of evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Factual or expert witnesses are not required to present themselves for pre-trial proceedings, and depositions are not yet part of Korean civil litigation procedure. Further, the party willing to present witness statements or expert reports to the court is not required to exchange them with the opposing party prior to trial. Once the trial is initiated, those documents are presented to the court as a part of documentary evidence and then served on the other party.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Currently, there is no system under Korean law providing for extensive discovery. The Korean Code of Civil Procedure (“CCP”), however, governs the requirements for document production. With regard to the procedure for requesting that documents be produced, parties to an action may file any application requesting that the court order a holder of documentary evidence to produce the document to the court. A party may file an application for an order for document production in the following circumstances: (i) when the other party possesses the document that it cited to during the lawsuit; (ii) when the applicant party is legally entitled to request the holder of the document to deliver it or make it available for inspection; or (iii) when the document has been prepared for the benefit of the applicant, or prepared as a result of the legal relationship between the applicant and the holder of such document.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

With regard to the statute of limitations for product liability cases, the PLA provides for a three-year, short-term statute of limitations and a ten-year, long-term statute of limitations.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The statute of limitations will bar a claim under the PLA if such claim is not filed within three years of the awareness of the occurrence of the damage and of the identity of the person responsible for the damage, or within ten years from the date that the defective product was delivered, whichever occurs earlier. The age or condition of the parties does not affect the statute of limitations, and the court does not have the discretion to disapply time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Issues of concealment or fraud do not affect the running of the statute of limitations.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The PLA does not limit the maximum amount that a plaintiff may be awarded in regard to a product liability claim. Although there is no risk that punitive damages (no such concept in the Korean judicial system) will be part of product liability damage awards, there are risks of...
significant damage awards for claims involving serious bodily harm or death since damage awards are not capped under the PLA.

Under the PLA, “damages” include damage to human life, human body and/or property. Damage to the product itself is not included. In addition, the scope of damage to be recovered under the PLA is not defined in the PLA itself. Instead, the PLA provides that the provisions of the Korean Civil Code shall apply with respect to matters that are not specifically covered by the PLA. In this regard, the scope of damages for a tortious act, as set forth in the Civil Code, is categorised into two (2) basic types: “ordinary damages” and “extraordinary damages.” Ordinary damages are damages that would normally be expected to result from a particular breach. Extraordinary damages, which are all other damages that may arise, are available only to the extent the parties could have reasonably foreseen such damages under the particular circumstances.

Damages for mental distress have been recognised by Korean courts. However, the courts will review the totality of circumstances so as to decide whether to award the compensation for such damages and the amount of compensation. As a very general rule, it is more likely that the courts will recognise damages for mental distress in case of bodily damages (i.e., injuries and deaths) than in case of damages to properties.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

In principle, in cases where the tortious act has not yet caused damage, the claim for damage compensation is not granted. However, if all the elements constituting tort liability are established and proved except for the past/present damage and it is highly likely to cause damage in the near future particularly from the proximate causation viewpoint, the damage claim is granted. In that case, future damage, i.e., medical monitoring expenses, is calculated on the basis of computation of present value.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive or treble damages are not allowed under Korean law.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The PLA does not limit the maximum amount that a plaintiff may be awarded with respect to a product liability claim.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As for the costs involved in litigation, there is a filing fee which is commonly referred to as the “stamp tax.” The amount of the stamp tax is calculated by a formula based on the total claim amount. In addition, there is a nominal fee for service of process and witness fees. The stamp tax, service of process and witness fees are all recoverable in full by the winning party. In principle, legal expenses are to be borne by the losing side and a claim for reimbursement of legal costs can be filed with the court after its final decision has been rendered. However, attorney’s fees are not fully recoverable pursuant to Supreme Court regulation and is calculated based on a tariff schedule (based on the claim amount).

7.2 Is public funding e.g. legal aid, available?

Legal aid is granted if the court determines that (i) the applicant is insolvent based on evidence presented by the applicant, and (ii) it is not highly likely based on the facts that the applicant will lose the case. The granting of legal aid relieves a party from paying court fees and costs in whole or in part, and can be challenged by the opposing party.

7.3 If so, are there any restrictions on the availability of public funding?

As noted above, a plaintiff in a case may file an application for legal aid to the competent court, and the court must review whether to grant such legal aid. Once a legal aid application is granted, the stamp tax and related legal expenses necessary to file and maintain a lawsuit will either be waived or delayed. Under Korean legal procedures, a court is prohibited from granting such legal aid when it is apparent that the applicant’s case is without merit. Thus, if a court has granted, even in part, such legal aid, this usually means that the court believes prima facie that a plaintiff’s complaint is not totally without merit.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Government funding or legal aid does not operate on the basis of conditional or contingency fees. With regard to contingency fee arrangements provided by plaintiffs’ lawyers, such fee arrangements are allowed in Korea, and are frequently used in practice.

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Chapter 29

Latvia

Lejins, Torgans & Vonsovics

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Under the Latvian law, liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty can be claimed on the basis of tort or contract.

Tort law based claims can be brought on the basis of the Law on Liability for Defects in Products or Services (adopted on June 20, 2000) (“Product Liability Law”) providing for strict liability, or on the basis of Civil Law (adopted on January 28, 1937) providing for fault based liability. The scope of liability that can be claimed on the basis of the Product Liability Law is limited to damages to the life or health of an individual (e.g., disease or injury) and damages to the property (subject to certain limitations).

The contractual liability can be claimed on the basis of Civil Law and the Consumer Rights Protection Law (adopted on March 18, 1999) if the person suffering damage from the defective product has purchased or otherwise acquired it against consideration. According to Article 1593 of Civil Law, any transferor of title to the good is liable against the acquirer of title for defects and/or for absence of any of the good qualities which have been expressly promised or impliedly are deemed to be present.

1.2 Does the state operate any schemes of compensation for particular products?

The state operates a compulsory insurance scheme under the Land Transportation Means Owners’ Civil Liability Compulsory Insurance Law (adopted on April 7, 2004) for certain traffic-related injuries and damage. Compulsory insurance is also provided for civil liability of various professionals, e.g., doctors, notaries, court bailiffs, persons engaged in construction, etc. (representing compensation schemes for particular services). These schemes apply as parallel sources of remedies along with product liability under the Product Liability Law.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the Product Liability Law, primarily the responsibility for the fault/defect rests with the manufacturer or the importer. If it is not possible to identify the manufacturer or importer of the product the Product Liability Law permits the claim to be brought against the distributor of the product or against any other person who has sold or otherwise distributed the product. The latter shall be released from liability if it provides information on the manufacturer or importer of the product or on other person who has supplied the product to it.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

According to the Products and Services Safety Law (adopted on April 7, 2004), the manufacturer is obliged to take any measures as may be necessary to evaluate and eliminate the risks related to the use of the products, including, withdrawal of the products from the market, warning of the consumers, and recall of the products. The recall of the products may take place voluntarily or at the request of the supervisory authorities. The law does not identify any particular circumstances or criteria for the recall of the products leaving it to the discretion of the authorities to evaluate the necessity of such measures on a case per case basis. Breach of the duty to recall generally will be dealt with by the competent authorities under administrative enforcement procedures.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under the Product Liability Law based claim the claimant will have to prove the defect, damage (loss) and the causation between the defect and damage (loss). In all other claims, whether tort or contract law based, the claimant will have to prove the fault also.
2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The Latvian laws do not contain specific provisions to determine the standard for proof of causation in product liability related claims and there is no relevant court practice either. Therefore, such issue would be a highly disputable. The more likely probability in view of the general court practice is that it would not be considered sufficient to establish a causal link if the claimant cannot prove that the injury would not have arisen without such exposure.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability is not recognised in Latvia. There is no relevant court practice in such cases, therefore it is unclear what position a court would take if a plaintiff could not prove the link between the defective product and the particular manufacturer. It is likely that the burden of proof will be deemed to rest with the plaintiff to prove that the particular defendant is responsible for the particular product.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

According to the Latvian product safety and consumer protection laws, the manufacturer is obliged to provide to the consumer true and full information on the product (including warnings) to enable the customer to evaluate the risks relating to the use of the product during the normal or predictable period of use and to take precautionary measures, unless such risks are evident without special warnings. If the information provided by the manufacturer would be deemed insufficient or incorrect the product may qualify as unsafe.

Under Product Liability Law based claims only information provided directly to the injured party will be taken into account, and the manufacturer cannot escape liability in cases where information has been provided to the intermediary in the chain of supply but the information was not channelled further to the consumer. In such cases the manufacturer may have a recourse against the intermediary. Under fault-based claims the manufacturer has a defence of proving that the information was provided to the intermediary.

There is no concept of “learned intermediary” under the Latvian law and there are no special provisions regulating cases when the product can be obtained only through the intermediary who owes a separate obligation to assess the suitability of the product for the particular customer. The cases of damage being caused to the consumer by a doctor prescribing a medicine, by a surgeon using a medical device, etc. under Latvian law will fall under “service liability” rather than under “product liability”, i.e., the respective professional will be directly liable to the consumer for defective service on the basis of Product Liability Law in its capacity as the service provider but it may have a recourse against the manufacturer of medicine, medical device, etc.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under Product Liability Law based claims the manufacturer can release itself from liability if it proves that one or several of the following circumstances took place:

- the manufacturer has not released the product for circulation;
- at the time when the product was released for circulation it did not have the defect which caused loss, respectively, such defect occurred later;
- the product was not intended for offering, sale or for other commercial distribution;
- at the time when the product was released for circulation the level of the scientific and technological development had not reached the level to allow to discover the deficiency or defect;
- the defect was caused due to compliance of the manufacturer with the requirements set forth by the state or self-government.

The liability of the manufacturer can also be limited or excluded in case of reciprocal fault, i.e., if the manufacturer proves circumstances indicating to malicious intent or negligence of the plaintiff.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There are such defences available (see question 3.1 above). There is no relevant court practice therefore it is difficult to predict how the burden of proof shall be deemed to apply where the defendant refers to the level of scientific / technical knowledge. It is likely, however, that the burden of proof shall be deemed to rest with the defendant, i.e., the manufacturer will have to prove that the defect was not discoverable.
3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Again, there is no relevant court practice. It is likely that compliance with regulatory requirements or the fact that the product has been appropriately tested or licensed per se will not be considered sufficient defence, unless it can be shown that the defect was caused by or inevitably resulted from compliance with mandatory requirements.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

According to the Civil Procedure Law, a case where a final and valid court judgement has been rendered can be re-litigated in very limited circumstances only. Thus, the case can be re-litigated if "newly discovered circumstances" are found, which include material circumstances that existed during the proceedings of which the applicant for re-initiation of the case was not aware and could not have been aware, cancellation of the judgement or the decision of an authority which served as the basis for the particular court judgement, etc. As a general rule, a final judgment on issues of fault, defect or the capability of a product to cause a certain type of damage is an absolute bar to the same issues being raised in subsequent proceedings between the same parties.

4 Procedure

4.1 Is the trial by a judge or a jury?

There are no juries in Latvian courts. The trial is by a single judge in District Courts (lower level courts) and the Regional Courts (the second level courts). The appeals are heard in the Regional Courts by the panel of three judges. At the Supreme Court level all cases are tried by a panel of three judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, the Latvian law does not provide for 'expert assessors' or the like.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Class action is not available in Latvia. It is permitted to bring common claims only where the claims concern essentially the same legal relationship. Thus, multi-party product liability claims can be brought e.g. if the damages stem from the same act.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

The Latvian laws do not provide for the right of some representative body (public organisation, association, etc.) to bring the product liability related claim on behalf of a number of claimants. The Consumer Rights Protection Centre (the state public authority supervising compliance with the consumer rights protection laws) is entitled to bring claims with the court in order to protect rights and legal interests of the consumers, however, according to the current practice it extends only to the claims relating to the condition of the product, its replacement, compensation of value of the product and the like, but it does not extend to any claims for compensation of damages.

4.5 How long does it normally take to get to trial?

It depends on the particular court and the complexity of the case. Due to very tight schedules of judges and a significant backlog of cases (in particular with the Regional Courts) it may take even a year or more after the submission of the claim to get to the trial. Hearings with the District Court are usually scheduled to be held within three months from the date of submission of the claim.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court cannot try preliminary issues the result of which determine whether the remainder of the trial should proceed. The issues like jurisdiction, venue, defects/discrepancies in the claim or counter-claim, or the supporting documents submitted by either of the parties, application of provisional remedies, etc. shall be resolved without trial by the judge acting at its sole discretion. In few cases a court hearing will be summoned to decide on a particular issue, for example, obtaining witness testimony before the trial (see also question 4.9 below).

4.7 What appeal options are available?

There are two levels of appeal under the Latvian court system. The first level appeal (appeal de novo) is available on an issue of law or fact. The court that will hear such an appeal is dependant upon the first instance court in which the case was originally tried (for example, if the case was tried by the District Court the appeal has to be brought with the Regional Court). The second level appeal ( cassation) is available only on an issue of law. Such appeals are always heard by the Senate of the Supreme Court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Yes, the court is entitled on its own initiative or at the request of either of the parties to the proceedings to appoint an
expert to provide an opinion on the technical issues or any other issues requiring expert knowledge. There is no approved list of experts. The court may ask the parties for suggestions as to the names of potential candidates for the expert and the parties will also be requested to submit a list of questions to be answered by the expert. If the parties cannot agree on a particular expert, or the court rejects their suggestions, it will generally draw on the Latvian State Examination Scientific Research Laboratory, a state institution owned by the Ministry of Justice. The court appointed expert must submit a written opinion which will usually be shared with the parties.

The parties are also entitled to retain their own experts although it is within the court’s discretion whether to admit the retained expert’s opinion as evidence (there are no particular restrictions on the nature or extent of such evidence). The parties will normally be given an opportunity to cross examine both the court appointed experts and the privately retained experts allowed by the court.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The issues of concealment or fraud may affect the running of the 3-year time limit for bringing a Product Liability Law based claim to the extent the plaintiff’s awareness of the defect, the loss and the potential respondent is affected by the respondent’s concealment or fraud. It does not, however, affect the general statute of limitation - 10 years.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under Product Liability Law based claims the types of recoverable damage include damage to the life or health of an individual (e.g., disease or injury), and damage to the property of an individual or legal entity. The damage to property will be recoverable provided certain criteria are met: the damage is caused to the property other than the defective product, the damaged or lost property is the property which is used for personal needs or consumption, and at the time when damage was caused the amount of the loss exceeded equivalent of EUR 500 in Latvian lats. Under fault based claims (Civil Law and Consumer Rights Protection Law) the scope of recoverable damage is not limited by type of damage.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Under the Latvian law there are no express provisions regarding recovery of such costs and thus far there is no court practice either. Theoretically, recovery of such damages would be permissible, however, it is likely that such claim would have to be fault based rather than strict liability based.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable under Latvian law.
6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The court fees (i.e., state duty for submission of claim, chancellery duties, etc.) on the basis of the court ruling shall be covered by the losing party. If the claim has been granted only partially, the plaintiff is entitled to recover court costs in proportion to the scope of claim granted by the court and the defendant is entitled to recover in proportion to the scope of the claim that has been denied.

The party’s own legal costs of bringing the proceedings (i.e., legal fees, costs for traveling to the court hearings, etc.) may also be recovered from the losing party but is subject to certain limitations. For example, the legal fees recoverable may not exceed 5% of the sum of the claim granted, the defendant may recover its legal costs only if the plaintiff’s claim is rejected entirely, etc.

7.2 Is public funding e.g. legal aid, available?

The Law on Latvian Bar Association provides for that each person must be provided access to legal aid in case of necessity. Individuals in poor financial condition who cannot afford an attorney to protect their interests in civil proceedings are entitled to apply to the Chairman of the court or the Latvian Bar Association to appoint an attorney to represent their interests. If the request is considered motivated the attorney shall be appointed and his/her services shall be paid for from the state treasury at officially established rates.

7.3 If so, are there any restrictions on the availability of public funding?

There are no fixed financial or other criteria for eligibility for legal aid.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The payments for the services of attorney shall be made at the officially established rates. The state funding is not allowed through conditional or contingency fees.

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There are two principal systems of civil liability for defective products in Lithuania: (a) strict liability under the Law on Product Safety of 1 June 1999 (the “Law on Product Safety”) and Civil Code of the Republic of Lithuania of 18 July 2000 (the “Civil Code”), and (b) fault-based liability (contractual and non-contractual) under the Civil Code, the Law on Protection of Consumer Rights of 10 November 1994 and other legal acts.

The EC Directive No. 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (the “Defective Products Directive”) was implemented into Lithuanian law on 1 July 2001, when the new Civil Code came into force. Of note, by virtue of provisions of the Civil Code, the requirements of the Defective Products Directive are transposed into Lithuanian national law as well as protection of consumers is expanded by applying the provisions on compensation for damage caused by defective products to the same extent as for the damage caused by defective products. Therefore, the Civil Code provides for liability of both the producers of products and providers of services. With the certain below-indicated exceptions, the liability of the producer of defective products or the provider of defective services is regarded as strict in all cases under Lithuanian law if the damage occurs to a consumer. Following the provisions of the Civil Code, damage caused by a defective product is compensated only if the injured person proves (a) the occurrence of damage; (b) existence of defects in the product; and (c) the causal relationship between the defects and the damage. Defective products liability is a specific regime in the Lithuanian law, as the fault of the producer of the defective product is not held as a necessary precondition of his civil liability. However, specific strict liability regime is applicable only in respect of certain type of non-contractual damages, caused by defective product (see question 6.1) and is not applicable to any of the form of contractual liability and contractual remedies (i.e., warranty claims to replace or change the defective product, non-conforming to the contract; claims on repayment of price, paid for the defective product, non-conforming to the contract, etc.). Moreover, the claims for the damage caused by a defective product to a legal or natural person, who has purchased the product for his professional matters, also for the damage caused by immovable property or certain activities, like, inter alia, the health-care services, legal services, education services, heating, gas and water supply, waste water disposal and transport services, do not fall within the specific product liability framework and can be grounded only on the traditional civil liability.

Before the new Civil Code came into force, i.e. until 1 July 2001, the damage caused by a defective product was subject to compensation only following the provisions of the traditional civil liability, therefore, it was required to ascertain not only the occurrence of damage, existence of defects in the product and causal relationship between the defects and the damage, but also the fault of the producer of the defective product. Pursuant to the provisions of the Civil Code, it is not required that the injured person and the producer of a defective product are in a contractual relationship, but the injured person is entitled to claim compensation for damage caused by the defective product or service irrespective of whether he/she is or is not a party to an agreement with the producer or service provider. However, if the injured person and the person providing the product are in a contractual relationship, in addition to the product liability claims, contractual claims may be based on the law of contract or the contract itself, as the delivery of a defective product can be considered to be a non-fulfilment or improper fulfilment of contractual obligations.

The state operates compulsory insurance schemes under the Law on Damage Compensation in Accident at Work or Occupational Disease Cases for work-related injuries and occupational diseases. In addition, compulsory civil liability insurance of health-care institutions covers insurance of liability vis-à-vis the patients for defective pharmaceutical products. These laws and schemes apply in parallel to the remedies along with the product liability under the Law on Product Safety and the Civil Code.
1.3 Who bears responsibility for the fault/defect? The producer, the importer, the distributor, the “retail” supplier or all of these?

In determining persons responsible for defective products or services, Lithuanian law simply enacts the provisions of the Defective Products Directive and adds the same responsibilities to providers of services.

Under the strict liability regime enshrined by virtue of the Civil Code for cases of defective products, responsibility for defective products and services rest on both the producer of the product or provider of the services and the distributor (marketer). In the Law on Product Safety, the producer is defined to be (a) a producer of a finished product or, the producer of any raw material or, the producer of a component party; (b) a provider of a service or any other person who, by putting its/his/her name, trade mark or other distinguishing feature on the product (or service) presents himself as the producer of such product (or provider of such a service); or (c) a representative of the producer, in case the producer has no establishment in EU. Any person who imports a defective product intended for sale, lease or any other form of distribution in the European Union in the course of his/her business activities, shall be held responsible as the producer.

The liability of the aforementioned persons is joint and several.

Where the producer of the product cannot be identified, the supplier of the product is deemed to be the producer of such product unless the supplier informs the injured person, within a reasonable time of the identity of the producer or the person who delivered the product to the supplier. The same applies to an imported product if such product does not indicate the identity of the importer, even if the product bears the name of the producer.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Notably, producer’s obligations do not end with placement of the product on the market. The producer is under an obligation to monitor his products and to take appropriate measures when he has received information on risks associated with a product, which is already on the market. Pursuant to the Law on Product Safety, a producer, distributor or provider of services is bound to place on the market only safe products or services and to provide consumers with relevant information on the product or service and the risk that may emerge while using it. When a producer, distributor or provider of services learns about any damage or injury that a particular product or service causes, he must immediately inform thereof and withdraw the product from the market or suspend the provision of the service in the manner prescribed by the Government.

Law on Product Safety establishes an obligation of the producer to report to the competent authority on the intended product recall. As a matter of practice, producer upon finding out that the product is not safe or is considered as dangerous, shall immediately: (a) inform the consumers (by informing the distributors and sellers; providing the necessary instructions on product recall and withdrawal of the products from the sale; describing, in particular, the actions taken to prevent risk to the consumer, etc., placing appropriate notice in the national press (daily paper, internet portal, etc.)); (b) inform the State Inspection of Non-Food Products Inspection under the Ministry of Economy; (c) inform the Council of Consumer Rights Protection under the Ministry of Justice; and (d) take all the steps necessary to withdraw those products from the market and, if necessary and as a last resort, to recall them.

Claims for compensation of damages caused to consumers by defective products or services may be submitted under the procedures prescribed by the provisions mentioned above. It is also possible to bring a preventative action in which the court can order that the producer prevent a possible occurrence of anticipated damage by e.g. recalling the defective or dangerous product. Breach of the duty to recall products does not in itself establish grounds for a civil claim under Lithuanian law, but could be treated as a negligent conduct on the part of producer.

The state regulatory authorities have the right to withdraw defective products and/or services from the market, in case the producer, distributor or provider of services does not obey the order to do so. If the state regulatory authority withdraws a defective product from the market, the expenses incurred thereby are recovered from the producer, distributor or provider of services by way other than litigation.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Pursuant to the provisions of the Civil Code, providing the strict liability regime to be applicable to product liability cases, an injured party is required to prove damage, defect and causal relationship between the defect and the damage.

It is not necessary to ascertain the fault of the producer of the defective product since the fault is not held as a precondition for the producer’s civil liability to arise. Thus, the question of the fault is somewhat irrelevant in the product liability cases heard under the strict-liability rule.

Where the provisions of the traditional civil liability are applied instead of the strict liability regime, the claimant must prove the damage, unlawful actions and causal relationship, presumption of fault being established by virtue of the Civil Code. However, legal assumption of fault does not in itself eliminate the fault as a necessary precondition for the liability on the part of defendant to occur; rather, such legal assumption only redistributes the onus probandi, thus shifting the burden of proof on the defendant.

In lines with the general law of contract, the claimant must prove the non-fulfilment or improper fulfilment of contractual obligations, the damage and the causal link between the two.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The Civil Code provides for a flexible causation doctrine.
Pursuant to the provisions of the Civil Code, the defendant’s actions are not required to be the sole cause of emergence of damage. Therefore, in order to set causation it is enough to prove that the actions are a sufficient, though not the sole, cause of the damage. The said flexible causation doctrine covers two types of causation: direct and indirect. It is noteworthy that in any case the damage shouldn’t be a distant consequence of the defendant’s behaviour.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If several persons are liable for the same damage, their liability is joint and several. Following the provisions of the Civil Code, the claimant has the right to demand performance both from all or several defendants jointly, or from a single defendant alone, either for the whole or part of the compensation. After one of the defendants fully performs the joint obligation, other defendants are released from the claimant’s claims. A defendant, who has fully performed the joint obligation on behalf of all defendants, has the right of recourse from the other defendants in order to recover compensation from them subject to each defendants’ fault in the damage.

There is no concept of market share liability in Lithuania.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the producer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the producer to the ultimate consumer to make available appropriate product information?

Pursuant to the Law on Product Safety, a producer, distributor or provider of services is bound to provide consumers with relevant information on the product and/or service and the risk that might emerge while using it. Before a product (or service) is delivered (or provided), the producer (or provider of services) must inform consumers about the possible risks that might emerge while using it. A distributor has an obligation to provide the consumers with all important information regarding the product, including all information that the distributor has received from the producer. Since the distributor must give to the consumer all relevant information about the product, the producer must provide the distributor with full and true information, advice and warnings regarding the product.

Where the product is a medicinal preparation, the holder of the registration certificate is responsible for package markings and provision of other information. Information on a medicinal preparation must be always provided to consumers even if such product can only be obtained through an intermediary (e.g. a doctor, pharmacist, etc.) who owes a separate obligation to assess the suitability of the product for a particular consumer.

In case a producer, distributor or provider of services fails to perform the duties mentioned above, they may become subject to economic sanctions set forth in the Law on Product Safety, and may become subject to administrative liability under the provisions of administrative law. If a consumer suffers damage as a result of not being provided with the required information, he/she may present claims under the procedures set in the Civil Code.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the strict liability regime, the producer, importer, etc. (the defendant) may invoke, inter alia, the following defences: (a) the dangerous product has not been placed on the market; (b) the product became dangerous as a result of actions of a third person during an improper (unsafe) transportation or keeping (storage) or because of any other reasons; (c) at the time when the dangerous product was placed on the market, the level of science and technology was not adequate for establishing a potential risk (the state of the art defence); (d) the consumer used the product in breach of the instructions, precautions and safety measures, which resulted in the damage; (e) at the time when the product was placed on the market, it was of a proper quality or that the quality of the product has deteriorated later; or (f) the dangerous properties of the product resulted as a consequence of force majeure situation.

Under the law of non-contractual liability, the defendant may prove that there was no fault on his part.

Under the law of contract, the defendant may prove that the non-fulfilment or improper fulfilment of the contract was due to reasons that were not attributable to him. In any case, the defendant may prove that the injured person has contributed to a certain extent to the emergence or increase of the damage.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the producer to prove that it was not?

The Law on Product Safety establishes that a producer has the duty to duly mark the products and provide consumers with all relevant information so that the consumers can assess the risks related to the product during its term of use, provided that the risk without the said notification is not obvious. However, such notification does not release the producer from the obligation to comply with other requirements provided for by relevant legislation regulating product safety.

The general principle is that the producer (seller) has the duty to guarantee that the product does not have any hidden
defects at the time of supply (at the moment of entering into a sale-purchase contract) because of which the product would not be suitable for use for the intended purpose or because of which the utility of the product would lessen so as to hold the consumer, if aware of such defects, from buying the product at all or paying certain price. However, the producer (seller) does not have to guarantee that the product has no hidden defects the consumer is aware whereof or which are so obvious that any reasonably careful consumer would notice without any special examination. The producer (seller) is responsible for the defects of the products provided he proves that they had occurred before the transfer of products or because of the reasons that had occurred before the transfer of products. In addition, the producer (seller) that failed to provide the consumer with necessary information regarding the product is responsible for the defects, which occurred after the transfer of products to the consumer if the consumer proves that the defects occurred because of the fact that he did not have relevant information.

In practice, a state of the art defence is available under the strict product liability regime. It is for the producer to prove that the dangerous properties of the product could not have been discovered, taking into account the state of scientific and technical knowledge at the time the product was put on the market.

3.3 Is it a defence for the producer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Yes, it is. See answer to the question 3.1.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

According to Lithuanian law, any judgment has the effect of res judicata as between the parties to the proceedings with regard to the subject matter and the underlying facts. Therefore, although the court refuses to accept the claim if the court decision in the dispute between the same parties in respect of the same matter and on the same ground is in force, this does not prevent a different claimant bringing an action regarding a certain product. In addition, the court having established that there are several proceedings instituted by several claimants against the same defendant (producer) may join these cases into one case in order to examine them together provided that in such case the settlement of disputes is streamlined, as well as in case the claims are mutually related and therefore cannot be heard separately. In any case, the court decision in one case may have a prejudicial effect as to the matters of fact and law in other proceedings.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is by a judge. During the civil litigation by the district courts, which are the courts of first instance, cases are heard by one judge. Cases, adjudicated in courts of appellate instance are heard by three judges. Lithuanian law does not stipulate for a jury trial for any kind of court proceedings.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

According to the provisions of the Code of Civil Procedure of the Republic of Lithuania of 28 February 2002 (the “Code of Civil Procedure”), with the purpose to ascertain issues arising during the proceedings that require special knowledge of science, medicine, art, technique or craft and having considered the opinion of the parties of the case the court may appoint an expert or commit a competent expertise institution to perform expert examination or to appoint some experts or commission of experts, as case may be. The findings of the expert are laid down in the expert report; however, the court may additionally ask the expert to explain its finding verbally or answer additional questions.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

According to the Code of Civil Procedure in situations that involve defence of the public interest a group (joint) actions are possible. However, there are no legislative instruments implementing the mechanism of group (joint) actions. Moreover, Lithuanian laws do not establish legal basis for class actions. Mainly because of the above-mentioned reason and also of the novelty of the said procedural institution, there has so far been none, or only very few group action cases in Lithuania. Although there is no statistical information available on this issue, there have not been any cases involving group actions, related to product liability reported by the Supreme Court.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes. In certain cases provided for in relevant legislation of the Republic of Lithuania state or municipality institutions, namely consumer protection institutions (e.g., National Consumer Rights Protection Board) or public consumer organisations, are allowed to bring actions in defence of public interests. Moreover, actions brought by a prosecutor in defence of public interests are also possible. In case the said actions in defence of public interest are related to the rights of consumers, the latter may be involved in the proceedings as third persons or the claimants.
4.5 How long does it normally take to get to trial?

The duration of the period from the submission of the claim till the first hearing depends on many factors, in particular the workload of the court, the imperfections of the submitted documents, etc. However, the approximate length of the said period is one month, though it may last up to two months in some cases.

Civil litigation in the courts begins with a preparatory stage followed by the main proceedings. In the preparatory stage, the parties exchange written pleadings (application for summons, response, and possibly subsequent written submissions). The preparatory stage usually takes 3-6 months, but may extend over a year in more complex cases.

4.6 Can the court try preliminary issues, the results of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court is required to try defence pleas made in connection with the defendant’s first response, concerning matters of procedure. However, a preliminary decision could be adopted by the court only if extraordinary documentary proceedings are instituted. In such a case the preliminary decision, relating both to matters of law and issues of fact, comes into effect unless the defendant opposes the latter. After opposition by the defendant, preliminary decision of the court is either overturned, or approved by the final decision of the court, which may be subject to further appeals, etc.

4.7 What appeal options are available?

Lithuanian law provides for a three instances court system. The decision of the court of the first instance can be appealed within 30 days (in case the place of residence or the registered office of the appellant is in a foreign state - 40 days) from the day of the decision of the court of first instance. However, the right of appeal is subject to certain restrictions. For instance, appeal is not possible in minor disputes if the sum at issue does not amount to LTL (Lithuanian Litas) 250 with some exceptions (e.g., in disputes related to employment relationships the said restriction is not applicable).

Appellate courts decisions are subject to cassation (to the Supreme Court of Lithuania) pursuant to certain restrictions. The cassation is not possible:

1) in respect of the decisions of the courts of first instance that have not been appealed; and

2) in property disputes provided the sum at issue does not amount to LTL 5,000 (this restriction is not applicable in respect of disputes related to employment relationships, health injury, etc.).

The decisions of the Supreme Court are final and subject to no further appeal. However, even after the final decision of the Supreme Court the civil process could still be renewed upon existence of exceptional circumstances.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Yes, the court does, see answer to the question 4.2.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Lithuanian law does not provide for the discovery of evidence prior to court proceedings, therefore witness statements/ expert reports are not exchanged prior to the submission of the claim. The court will review what witnesses the parties intend to hear during an oral hearing conducted before the main hearing, or during the main hearing. See also answer to the question 4.10.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

As indicated above, Lithuanian law does not provide for the discovery of evidence before the proceedings are instituted. It is not customary to disclose any evidence to the opposite party before proceedings are initiated and it is not regulated in any way by the Code of Civil Procedure or other Lithuanian laws.

Under the provisions of the Code of Civil Procedure, during the preparation for the hearing of the case the parties and third persons should present to the court all available evidence and explanations that are important in the particular case as well as to indicate evidence they are not able to present, as well as indicating reasons which hinder them from doing this. During later procedural stages the court is entitled to refuse to accept evidence that could have been presented earlier if in its opinion the later submission thereof would protract the passing of a decision in the case. However, the Code of Civil Procedure provides for a possibility to secure the evidences before the preliminary proceedings take place. In relation to that purpose the parties may address the court with the request to order the appropriate interim measures.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The time limits on bringing proceedings for compensation for damages caused by the consumption of defective products or services are specified in separate special provisions of the Civil Code. The time limits and the singularities of their application are described in detail in the answer to question 5.2.
5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have discretion to disapply time limits?

The time limit on bringing proceedings for compensation for damages caused by the consumption of defective products or services constitutes three years from the day on which the injured person became or should have become aware of the following three circumstances:

1. of the damage caused to the injured person;
2. of the non-conformance that caused the damage; and
3. of the identity of the producer or the provider of services.

All the above circumstances must have taken place to start the course of the time limit. For instance, if the injured person is aware of the damage caused and of the defect of a product that caused the damage, but is still unaware of the identity of the producer, the time limit is deemed not to have started. Only once the injured person becomes aware (or once it becomes obvious that he should have become aware) of all three of the above-mentioned circumstances, the progression of the time limit is started.

The liability of the producer of defective products or the provider of defective services is regarded as strict in all cases under Lithuanian law if the damage occurs to a consumer. Therefore, the question on the varying time limit depending on whether the liability is fault based or strict is irrelevant.

The age and condition of the claimant affect the calculation of any time limits in the following manner: if the claimant does not bring action in the aforementioned time limit of three years, the court may restore the exceeded time limit after its expiration. The restoration of the time limit is possible only if the time limit was exceeded due to substantial reasons. One of the few substantial reasons for the restoration of time limits recognised by Lithuanian courts is a serious illness of the claimant.

Notwithstanding the fact that the 3-year prescription term for product liability has not yet lapsed, the injured person shall be prevented from instituting the proceedings against the responsible producer, if the 10-year “long stop” period is over. In considering the claim for compensation of damages caused by a defective product the court shall not have a discretion to suspend or refuse to apply the “long stop” period of 10 years, established in the Civil Code.

According to Article 6.300 of the Civil Code, the injured person shall have a right to present a claim on the compensation of damage, caused by a defective product only until the expiry of a period of 10 years from the date on which the producer put into circulation the actual product, which caused the damage. The Civil Code does not provide for a definition of “putting into circulation”. However, according to the Law on Product Safety, “placing on the market” of a product intended for transfer to consumers shall mean storage, sale, lease (rent) or any other transfer for consumption.

It must be noted that in Lithuanian civil law the time limit on bringing proceedings is regarded to be interrupted by actions of a debtor whereby the debtor acknowledges his obligation to the creditor. An interrupted time-limit is resumed anew from the moment of interruption. For instance, if the producer repays part of the damages claimed, he is deemed to have acknowledged his obligation vis-à-vis the injured consumer and the consumer enjoys a new three-year time limit to bring an action for the rest of damages. The producer may acknowledge his obligation to the injured consumer not only by the partial repayment of damages but in different other ways as well, for example, by a written acknowledgment in his written answer to any claims put directly to the producer by the consumer.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

As the time limit on bringing proceedings for compensation of damages caused by the consumption of defective products or services, as explained in the answer to question 5.1, is deemed to have started from the day on which the injured consumer became or should have become aware of the damage caused, the non-conformance that caused the damage and of the identity of the producer or the provider of services, concealment or fraud do not affect the running of the time limit. The rights of the consumer are protected by the described method designed to determine the inception of the time limit.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The following types of damage are recoverable under Lithuanian legislation:

1. damage caused by death or by personal injuries, including non-material damage; and
2. damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of the amount in LTL equal to EUR 500 under the official ratio of LTL to the Euro, published by the central bank of the Republic of Lithuania. The item of property must be intended for private use or consumption, and must have been used by the injured person mainly for his own private use or consumption. Any amounts of damages under the prescribed threshold are recovered under the general civil liability provisions of the Civil Code. Notably, the aforementioned lower threshold is not applicable in case of the damage caused by defective services, i.e. any amount of damage caused by defective services is recovered under the special provisions described in this questionnaire and not under the general provisions of the Civil Code.

The Republic of Lithuania has not used the discretion, granted by virtue of Article 16 of the Defective Products Directive for any EU member state to stipulate in their respective national legislation that a producer’s total liability for damage resulting from a death or personal injury and caused by identical items with the same defect is limited to an amount which may not be less than EUR 70 million. Therefore, the liability is governed by the principle of restitutio in integrum, i.e. all damage (including non-pecuniary damage) resulting from a death or personal injury caused by defective products or services are to be recovered without any limitations.
6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The general provisions on civil liability in the Civil Code establish that the court may evaluate future damage upon assessment of its real probability. In such cases the court may award a fixed amount of damages or instalment payments. The court may also obligate the debtor to secure the recovery of damage (e.g. by a bank guarantee). The described provisions are generally applied in the cases when damage has already occurred but exact amounts of damage are difficult to calculate and there is an acute need in funds for an urgent surgery of the claimant, health-care treatment, medication, etc. However, the said provisions can also be applied with regard to the cost of medical investigations or tests in circumstances where the product has not yet malfunctioned and caused any injury, but may do so in the future.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not known in the Lithuanian legal system. According to the provisions of the Civil Code, in case both damages and penalty are awarded (e.g. LTL 100,000 of damages and LTL 50,000 of penalty), the whole amount of the award will equal to LTL 100,000, as penalty is included in damages but not added to the latter.

6.4 Is there a maximum limit on the damages recoverable from one producer e.g. for a series of claims arising from one incident or accident?

Under the Lithuanian legislation, each occurrence of damage is regarded separately and there are no limits on the amounts recoverable from a producer for a series of claims arising from one incident or accident, i.e. every plaintiff capable of proving the occurrence of damage to him is entitled to file his respective claim.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Under the national provisions of the civil procedure, the successful party can recover all court fees and all the necessary incidental expenses that it is able to prove to have incurred.

However, attorney fees can be recovered only in amounts not exceeding the fees as established by the Government and/or the Ministry of Justice.

As to the moment no such mandatory fees are approved, although as a matter of practise courts observe the fees, as recommended by the Ministry of Justice.

7.2 Is public funding e.g. legal aid, available?

Lithuanian legislation provides for a system of legal aid guaranteed by the state. The outline of the system is given in the answer to question 7.3.

7.3 If so, are there any restrictions on the availability of public funding?

Primary and secondary legal aid guaranteed by the state are available under the Lithuanian legislation. The primary legal aid implies legal consultations and general pre-litigation advice. The secondary legal aid constitutes representation of claimants in court and the exemption from, or assistance with, the cost of proceedings. Claimants must meet requirements established by the law to be eligible for the secondary legal aid. The requirements are summarised as the first level of assets and income, and the second level of assets and income. The claimants whose low income make them eligible for the secondary legal aid of the first level are refunded 100 per cent of the secondary legal aid costs. The claimants eligible for the secondary legal aid of the second level are refunded 50 per cent of the secondary legal aid costs. The costs of the primary legal aid are refunded in full to all recipients.

The citizens of the member states of the European Union and the third-country nationals residing lawfully in any of the member states are provided with primary and secondary legal aid in the Republic of Lithuania only in cross-border disputes as they are defined in the Council Directive 2002/8/EC of 27 January 2003 to improve access to justice in cross-border disputes by establishing minimum common rules relating to legal aid for such disputes.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

After recent (mid-2004) amendments of the Law on the Bar of the Republic of Lithuania, contingency fees are allowed in civil cases as well as for civil actions brought in criminal cases. However, contingency fee is a new phenomenon in the Lithuanian legal environment as for around the last 15 years contingency fee was at first forbidden by the law in all cases, then until recently due to the later amendments of legislation contingency fees were allowed only for claims for the recovery of bodily injury (up to 30 per cent of the award).
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The law firm Norcous & Partners has a substantial domestic and international practice, with a strategic focus on mergers and acquisitions, corporate advisory and disputes, banking and finance, technology and communications. Yet our broad spectrum of specialist expertise gives us a comprehensive basis for providing advice on special areas of business law such as pharmaceutical, employment, intellectual property, marketing, real estate, arbitration, insolvency, insurance, tax and competition. The firm has also acted on behalf of foreign companies before the courts of Lithuania and other dispute resolution institutions.

The firm and its lawyers are active in international matters and have well established connections with the law firms in virtually all jurisdictions having trade relations with Lithuania. In particular, we maintain very close co-operation relationships with all the leading pan-Baltic law firms through RoschierRaidla - a new four-party cooperation among Roschier Holmberg in Finland, Raidla & Partners in Estonia and Lejins, Torgans & Vonsovics in Latvia.
Chapter 31

Malaysia

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

In recent years, increasing prominence has been given to the protection of consumer rights in Malaysia. A significant development in this regard was the enactment of the Consumer Protection Act 1999 (“the CPA”), which provides greater rights and remedies for the benefit of consumers affected by defective products than those traditionally available at common law. Present day product liability in Malaysia therefore falls under three distinct heads, namely the CPA, tort and contract.

The CPA

The CPA came into force on 15th November 1999 and is designed to protect ‘consumers’, namely persons who acquire or use goods of a kind ordinarily acquired for personal, domestic or household purposes, use or consumption, and do not acquire or use the goods primarily for purposes of trade. The ‘goods’ covered by the CPA are accordingly limited to those that are primarily purchased, used or consumed for personal, domestic or household purposes. It should also be noted that the CPA generally does not apply to contracts made before 15th November 1999, securities, futures contracts, land or interests in land and trade transactions effected by electronic means.

The provisions of the CPA regarding product liability envisage strict liability on the part of the parties specified therein, to the extent that the consumer does not have to establish fault. However, the consumer will still have to prove that the product was in fact defective and that the defect caused him injury or loss. The CPA also overcomes issues of privity that would normally arise in contract. In practical terms, it is the manufacturer and supplier of a defective product who face increased potential liability under the CPA.

The legislature’s intent in ensuring that consumers’ rights and remedies under the CPA are preserved is evidenced by the fact that any choice of law clause in the contract of sale which applies the law of another country will be ousted, where the clause appears to have been imposed wholly or mainly for the purpose of enabling the party imposing it to evade the operation of the CPA. In addition, parties are not only prohibited from contracting out of the CPA, but it is in fact an offence for the manufacturer or supplier of the product to do so.

A consumer can elect to bring his claim before either the civil courts or the Tribunal for Consumer Claims. Most claims of significance will be brought in the civil courts, given that the Tribunal’s jurisdiction to award compensation is limited to RM25,000 unless the parties otherwise agree.

Tort

Although the CPA has been in force for more than 5 years, its provisions are seldom relied upon by consumers, who instead tend to bring product liability claims solely based on the common law tort of negligence. This fact is likely to change as consumers and their lawyers become increasingly familiar with the provisions and scope of the CPA.

With regard to negligence, the plaintiff will normally sue the manufacturer and/or supplier of the defective product, and will have to establish fault on the part of the defendant. In such a situation, the question of privity of contract does not arise. The plaintiff can establish liability on the part of the defendant if he can prove that the defendant owed him a duty to take reasonable care in all the circumstances of the case, that the defendant breached that duty, and that the damage or injury suffered by the plaintiff was reasonably foreseeable.

There is little doubt that in the case of a defective product, the manufacturer owes a duty to the purchaser of the product to take reasonable care in manufacturing and designing the product, or any components used in the assembly of the product.

Contract

The purchaser of a defective product can sue the party from whom he purchased the product for breach of contract, and recover any loss or damage suffered, upon establishing that the party concerned has breached the contract of sale. In most situations the party to the contract will be the supplier. Given that the doctrine of privity of contract dictates that the suit can only be brought against the actual party to the contract, manufacturers are seldom sued as there is usually no contractual relationship between the manufacturer and the purchaser. However, the manufacturer may on occasion independently undertake liability to the purchaser (e.g. through a warranty), in which case he may be liable.

In addition to the normal contractual terms, conditions may be implied in certain circumstances by the Sale of Goods Act
1957 to the effect that the product shall be reasonably fit for the purpose for which it is required, and that the product shall be of merchantable quality. These terms are however frequently excluded by the terms of the contract of sale.

More importantly, where the CPA applies Parts V to VII imply inter alia guarantees on the part of the supplier and manufacturer of a product that the product is of acceptable quality, and a guarantee on the part of the supplier that the product is reasonably fit for the purpose for which it is acquired. Quite apart from the fact that liability under Parts V to VII cannot be excluded, it should be noted that a ‘manufacturer’ is broadly defined as a person who carries on a business of assembling, producing or processing goods, and includes:

- any person who holds himself out to the public as a manufacturer of the goods;
- any person who affixes his brand or mark, or causes or permits his brand or mark to be affixed, to the goods; and
- where the goods are manufactured outside Malaysia and the foreign manufacturer of the goods does not have an ordinary place of business in Malaysia, a person who imports or distributes those goods.

Where the CPA does not apply, the extent of the supplier’s contractual liability will inevitably depend on the terms and conditions of the contract, and the supplier can choose to exclude or limit his liability if he so wishes.

1.2 Does the state operate any schemes of compensation for particular products?

There is no state-operated compensation scheme.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The CPA

Part III provides that the supplier shall adopt and observe a reasonable standard of safety to be expected by a reasonable consumer, due regard being had to the nature of the product, and that no person shall import, supply or offer to or advertise for supply, goods which do not meet such a standard of safety. These obligations do not however apply to healthcare goods and food. In addition, no person shall advertise for supply, goods which do not meet such a standard of safety. These terms are however frequently excluded by the terms of the contract of sale.

In determining what a person is generally entitled to expect in relation to a product, all relevant circumstances shall be taken into account including:

- the manner in which, and the purposes for which, the product has been marketed;
- the get-up of the product;
- the use of any mark in relation to the product;
- instructions for or warnings with respect to doing or refraining from doing anything with or in relation to the product;
- what may reasonably be expected to be done with, or in relation to, the product; and
- the time when the product was supplied by its producer to another person.

In the event that the defect wholly or partly causes death, personal injury, or loss of or damage to any property, the following persons are automatically liable for the same, unless they can establish the defences referred to in the answer to question 3.1 below:

- The producer of the product, namely -
  - the person who manufactured it;
- in the case of a substance which is not manufactured but is won or abstracted, the person who won or abstracted it; and
- in the case of a product which is not manufactured, won or abstracted but the essential characteristics of which are attributable to an industrial or other process having been carried out, the person who carried out that process.

- The person who, by putting his name on the product or using a trade mark or other distinguishing mark in relation to the product, has held himself out to be the producer of the product.

- The person who has, in the course of his business, imported the product to Malaysia in order to supply it to another person.

Interestingly, if the consumer is unaware of the identity of one or more of the aforesaid persons, he may within a reasonable period after the damage occurs request the supplier to identify any or all of the aforesaid persons, whether or not he is or they are still in existence, and in the
event that the supplier fails to comply with the said request within a reasonable time having regard to all the circumstances, he shall be held liable for the loss or damage. In this regard, it is immaterial whether the supplier supplied the defective product to the person who suffered the damage, the producer of a product in which the defective product is comprised therein, or any other person.

Once again, the liability of a person under Part X cannot be contractually limited or excluded. The effect of the provisions of Parts III and X is to potentially hold all parties in the distribution chain of a product liable for its defects.

Tort
There is in principle no restriction on the parties in the chain of distribution who can be held liable in the tort of negligence, subject to the satisfaction of the criteria referred to in the answer to question 1.1 above. However, in practice it is often the manufacturer who is found to be at fault, being the creator of the defect, and the other parties in the chain of distribution may not necessarily have the means or responsibility of discovering the defect.

Contract
As stated in the answer to question 1.1 above, liability is governed by the terms of the contract, and the doctrine of privity will apply. As such, in most cases the supplier of the product bears liability.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The CPA
Under Part III, the Minister of Domestic Trade and Consumer Affairs may, by order published in the Government Gazette, declare any goods or any class of goods to be prohibited goods, where the goods or goods of that class have caused or are likely to cause injury to any person or property or are otherwise unsafe. Such an order may require the supplier, in such manner and within such period as may be specified in the order, and at the supplier’s own expense, to:

- recall the prohibited goods;
- stop the supply and advertisement of the prohibited goods;
- disclose to the public any information relating to the characteristics of the prohibited goods which render them unsafe, the circumstances in which use of the prohibited goods are unsafe, and any other matter relating to the prohibited goods or the use of the prohibited goods as may be specified;

- repair or replace the prohibited goods; and

- refund to any person to whom the prohibited goods were supplied the price paid or the value of the consideration given for the prohibited goods or any lesser amount as may be reasonable having regard to the use that that person has had of the prohibited goods.

Failure by the supplier to comply with the order will result in the penalties referred to in the answer to question 1.1 above. In addition, where such an order is in effect:

- no person shall supply, or offer to or advertise for supply, any prohibited goods; and
- no supplier shall -
  - where the notice identifies a defect in, or a dangerous characteristic of, the prohibited goods, supply goods of a kind to which the order relates which contain the defect or have the characteristic; or
  - in any other case, supply goods of a kind to which the order relates.

Tort
The failure to recall a defective product once the defect is discovered may in itself amount to negligence in the circumstances of the case, particularly if the risk to the purchaser is serious. In addition, such a failure could, in certain circumstances, lead to a claim for aggravated or exemplary damages.

Contract
The failure to recall a defective product once the defect is discovered will generally be of no consequence in a contractual claim.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The CPA
The consumer bears the burden of proving that the product is defective and that he has suffered injury, loss or damage in consequence of the defect. Once this burden is discharged, the defendant will be liable unless he can establish any of the statutory defences.

Tort
The onus is on the plaintiff to prove the defect, fault and damage. The plaintiff may in exceptional circumstances rely on the doctrine of res ipsa loquitur (the thing speaks for itself), in which event the onus of disproving negligence will fall on the defendant. However, this doctrine can only be relied upon where an event which, in the ordinary course of things, was more likely than not to have been caused by negligence is by itself evidence of negligence, and depends on the absence of explanation for the event.

Contract
The onus is on the plaintiff to prove the breach of the contract and the damage suffered.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The CPA
While the CPA does not expressly set out the test for...
2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account when establishing the identity of the manufacturer of the defective product?


2.3 What is the legal position if it cannot be established what happened in the case? What do you have to prove concerning the circumstances of the case and warning of the dangers of the product?


2.2 When a product is released into the market, a prudent manufacturer should attempt to warn the consumer of the dangers of his product whenever possible. The content of the warning will vary with the product, and the information furnished may be basic or detailed, depending on the person to whom the warning is directed.

In certain circumstances, warnings to a professional intermediary, instead of the consumer, may suffice e.g. if the product is complex and the consumer is unlikely to be adequately qualified to understand the warning.

The mere fact that the product can only be obtained through an intermediary who himself owes an independent obligation to assess the suitability of the product for the particular consumer, does not of itself absolve the manufacturer of the necessity to warn the intermediary and/or the consumer of the dangers of the product. However, in such a situation it may be argued that, in the circumstances of the case, the information furnished by the manufacturer to the intermediary constitutes an adequate warning of the dangers of the product.

While there is no general principle of ‘learned intermediary’ in Malaysia, information disclosed to such an intermediary may be deemed adequate depending on the circumstances of the case.

It should be borne in mind that even if the manufacturer has failed to adequately warn the consumer or intermediary of the dangers of the product and/or disclose information pertaining to such dangers, the plaintiff still has to prove that the absence of the warning and/or information did in fact cause his injury.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The CPA

In civil proceedings under Part X, the defendant may avail himself of any of the following defences, namely:

- that the defect is attributable to compliance with any requirement imposed under any written law;
- that he did not at any time supply the defective product to another person;
- that the defect did not exist in the product at the relevant time;
- that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question may reasonably be expected to discover the defect if it had existed in his product while it was under his control; and
- that the defect -
  - is a defect in a product in which the product in question is comprised therein ("the subsequent product"); and
  - is wholly attributable to the design of the subsequent product or compliance by the producer of the product in question with instructions given by the producer of the subsequent product.
In the case of a failure to comply with safety standards under Part III, the defendant may show that the alleged failure is attributable to compliance with a requirement imposed under any written law, or that the alleged failure is a failure to do more than is required by Part III.

**Tort**
Apart from asserting that he took reasonable care in all the circumstances of the case, the defendant may assert the defence of volenti non fit injuria (i.e. that the plaintiff had voluntarily assumed the risk in question), although the defence is not easy to establish. In addition, the defendant may plead novus actus interveniens (new intervening act) in the event that the act of a third party has broken the chain of causation. The defendant may also plead contributory negligence on the part of the plaintiff, if established, will result in a partial reduction of the damages payable by the defendant. Where there is also a contractual nexus between the plaintiff and the defendant, it is possible for the defendant to exclude his liability for negligence, provided that clear words are used to this effect.

**Contract**
Apart from asserting that he did not breach the contract, the defendant may rely on any exclusion or limitation clause in the contract.

### 3.2 Is there a state of the art/development risk defence?

- **Is there a state of the art/development risk defence?**
- **Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply?**

If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

**The CPA**
Please see the answer to question 3.1 above. The defendant will bear the onus of proving that the defect was not discoverable.

**Tort**
Although the defence is not available, the fact that the defect was not discoverable in the light of the state of scientific and technical knowledge at the time may be strong evidence that the defendant was not negligent. Once again, it is for the defendant to prove this fact.

**Contract**
The defence is inapplicable.

### 3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

**The CPA**
Please see the answer to question 3.1 above.

**Tort**
No such defence is available. However, non-compliance with regulatory or statutory requirements is often relied upon by the plaintiff as evidence of the defendant’s negligence.

**Contract**
The defence is inapplicable.

### 3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

So long as the claimants and proceedings are different, issues of fault, defect and the capability of the product to cause damage may be re-litigated.

#### 4 Procedure

**4.1 Is the trial by a judge or a jury?**
The trial is by a judge.

**4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?**
The court does not have the power to appoint expert assessors.

**4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?**

Under Order 15 Rule 12 of the Rules of the High Court 1980 (“the RHC”), where numerous persons have the same interest in any proceedings, the proceedings may be begun by any one or more of them as representing all, or as representing all except one or more of them. However, the plaintiff must establish the following, namely:
- that he and those represented by him are members of a class and that these members have a common interest;
- that he and those represented by him have a common grievance; and
- that the relief sought is in its nature beneficial to them all.

Although representative proceedings are rare in Malaysia, it is nevertheless possible that representative proceedings will be commenced if there is widespread liability to a number of persons resulting from a particular type or category of defective product.

**4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?**

Claims cannot be brought by a representative body as it would not have the necessary locus standi.
4.5 How long does it normally take to get to trial?

A High Court suit will normally be tried two to four years after proceedings are commenced.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

With regard to pure questions of law, Order 14A of the RHC states that the court may upon the application of a party or of its own motion determine any question of law or construction of any document arising in any cause or matter at any stage of the proceedings where it appears to the court that such question is suitable for determination without the full trial of the action, and that such determination will finally determine the entire cause or matter or any claim or issue therein.

Where questions of fact are involved, Order 33 Rule 2 of the RHC provides that the court may order any question or issue arising in a cause or matter, whether of fact or law or partly of fact and partly of law, to be tried before, at or after the trial of the cause or matter.

4.7 What appeal options are available?

Sections 67 and 68 of the Courts of Judicature Act 1964 (“the CJA”) provide for a right of appeal to the Court of Appeal against a decision of a Judge of the High Court. However, where the amount or value of the subject-matter of the claim (exclusive of interest) is less than RM250,000, leave of the Court of Appeal must first be obtained.

Pursuant to Section 96 of the CJA, a decision of the Court of Appeal in respect of any civil cause or matter decided by the High Court in the exercise of its original jurisdiction is only appealable to the apex court, namely the Federal Court, with the leave of the Federal Court, if it involves:

- a question of general principle decided for the first time; or
- a question of importance upon which further argument and a decision of the Federal Court would be to public advantage.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Under Order 40 of the RHC, the court may, on the application of any party, appoint an independent expert to inquire and report upon any question of fact or opinion not involving questions of law or of construction. In practice however, it is very rare for a court expert to be appointed. What is far more common is for the parties to present expert evidence, although the court may limit the number of expert witnesses. Expert evidence will normally be allowed in product liability cases when the court has to form an opinion upon a scientific issue, and the evidence of the expert (who must be specially skilled in that science) is relevant. The basis for allowing the expert’s evidence in such a case is necessity, in that the court is not in a position to form a correct judgment without the expert’s assistance.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

While pre-trial depositions are not taken, evidence is commonly adduced via witness statements. Some judges require the witness statements to be exchanged prior to the commencement of the trial, although the RHC does not require this. However, in most cases a witness statement is only produced in court when the witness commences his testimony.

Under Order 34 of the RHC, the parties are required to attend pre-trial case management conferences with the judge. During such conferences, the court may order the parties to inter alia furnish their respective expert reports within a specific time. In the event that a party fails to comply with such an order, the judge may make such order against the defaulting party as meets the ends of justice.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

There is no general obligation to disclose documents prior to the commencement of proceedings. Once proceedings are commenced, during the pre-trial case management conferences the court will normally order parties to disclose and exchange all relevant documents. In this regard, a document is relevant if it contains information which may damage a party’s case or enable an opponent to advance his own case, or which fairly leads an opponent to a train of inquiry which may have either of these consequences.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The Limitation Act 1953 imposes time limits in certain situations for a plaintiff to commence proceedings. However, these time limits are only relevant if pleaded as a defence.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Actions under the CPA, in tort and in contract cannot be brought after the expiration of six years from the date on which the cause of action accrued. No distinction is made between fault-based liability and strict liability, and the court does not have a general discretion to disapply time limits.

In cases of disability (i.e. while a person is an infant or of unsound mind) however, the limitation period may be extended to six years from the date when such person ceased to be under the disability or died (whichever event first
occurred), notwithstanding that the period of limitation had expired.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In cases of fraud, or concealment of a right of action by fraud, the period of limitation will not begin to run until the plaintiff has discovered the fraud, or could with reasonable diligence have discovered it.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The CPA
Under Part X, “damage” is defined as death or personal injury, or any loss of or damage to property (including land). However, the consumer cannot recover loss of or damage to:
- the defective product;
- the whole or any part of the product which comprises the defective product; or
- any property which at the time it is lost or damaged is:
  - of a description of property ordinarily intended for private use, occupation or consumption; and
  - intended by the person suffering the loss or damage mainly for his own private use, occupation or consumption.

In the case of a contravention of Part III, the court may award the consumer inter alia the refund of the money paid and the amount of loss or damage incurred. Curiously, this provision appears to be wider than the aforesaid provisions of Part X, in that similar restrictions are not imposed on the scope of the compensation that may be awarded.

Tort
Damages in negligence are intended to put the injured party in the position as if the negligent act had not occurred. Damages can accordingly be awarded for death, personal injury, mental damage and property damage. A recent decision of the Court of Appeal in Arab-Malaysian Finance Berhad v Steven Phoa Cheng Loo & Ors and other appeals [2003] 1 MLJ 567 suggests that damages can be recovered in certain circumstances for pure economic loss (i.e. financial loss that is not consequent upon injury to person or damage to property). Although this decision is pending appeal to the Federal Court, the current position in Malaysia is therefore that pure economic loss is recoverable in principle. As such, damage to the product itself will be recoverable. This is to be contrasted with the definition of ‘damage’ under the CPA, which excludes recovery for damage to the product itself.

Contract
Damages in contract are intended to put the parties in the position as if the contract had been performed. The plaintiff will be entitled to recover compensation for any loss or damage caused to him by the defendant’s breach which naturally arose in the usual course of things from the breach, or which the parties knew, when they made the contract, to be likely to result from the breach of it, although compensation will not be awarded for any remote and indirect loss or damage sustained by reason of the breach. As such, compensation for damage to the product itself, for bodily injury, mental damage and property damage can be recovered as long as such damage or injury naturally arose as a consequence of the breach, or was within the contemplation of the parties when they made the contract.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The CPA
The cost of medical monitoring does not fall within the definition of ‘damage’ under Part X and would not be recoverable. However, such cost may be recoverable in the context of an action for contravention of Part III.

Tort
The cost of medical monitoring in circumstances where the product has not yet malfunctioned would constitute pure economic loss, and hence is currently recoverable in negligence.

Contract
The cost is recoverable if it naturally arose as a consequence of the breach, or was within the contemplation of the parties when they made the contract.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

The CPA
The CPA does not expressly prevent the court from awarding exemplary (or punitive) damages. As such, exemplary damages may be awarded in proceedings brought under the CPA if the defendant’s conduct was calculated by him to make a profit for himself which may exceed the compensation payable to the plaintiff.

Tort
Exemplary damages may be awarded in tort.

Contract
Exemplary damages are generally not awarded in contract.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No. The manufacturer, if liable, will be obliged to compensate each plaintiff for his loss.
7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party will normally tax his costs, and the taxing process is conducted by an officer of the court. Costs are generally taxed on a party and party basis, and on that basis all costs as were necessary or proper for the attainment of justice or for enforcing or defending the rights of the party concerned will be recoverable. This will include all court fees and ‘out-of-pocket’ expenses. However, the successful party will normally only recover part of his legal costs in bringing or defending the proceedings, as the awards made by the taxing officers do not generally tally with the actual fees charged by lawyers in Malaysia.

7.2 Is public funding e.g. legal aid, available?

Under the Legal Aid Act 1971 (“the LAA”), legal aid may be granted in respect of consumer claims. Although ‘consumer claims’ are not defined by the LAA, it is likely that product liability claims brought by individuals will be classified as consumer claims.

7.3 If so, are there any restrictions on the availability of public funding?

The applicant for legal aid will have to satisfy the means test under the LAA and may in certain situations be required to contribute to the expenses incurred on his behalf.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Conditional or contingency fees are prohibited in Malaysia by Section 112 of the Legal Profession Act 1976.
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Shearn Delamore & Co. is one of the oldest and largest law firms in Malaysia, and provides a comprehensive range of services to a broad spectrum of clients ranging from private individuals to the largest multinationals. We have 38 partners and almost 90 fee earners in our principal office at Kuala Lumpur and our branch office at Penang. All our lawyers are Advocates and Solicitors of the High Court of Malaya, with many being additionally qualified in other jurisdictions including England and Wales, Singapore, Australia, New Zealand and Brunei.

We have the following Practice Groups, which in turn are divided into specialized Practice Areas:

- Corporate & Commercial
- Dispute Resolution
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- Financial Services
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- Property & Probate
1 Liability Systems

1.1 What systems of product liability are available (i.e., liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

In Mexican law, liability arising out of illicit action is regulated by a variety of laws that work together and must be interpreted and applied in a harmonious manner. Examples of the most important of these are: The Federal Civil Code (or the state code for each state), the Federal Consumer Protection Law, the General Health Law, the Federal Labor Law, the Ecological Balance and Environmental Protection Law, among many others.

The Mexican legal system has contained provisions that, in a general sense, have regulated the liability arising out of illicit action and provided a right to damages to an injured party. The concept of “product liability” per se, however, did not exist as such in Mexican legislation until the most recent amendments to the Federal Consumer Protection Law (May 4, 2004) when the concept of product liability was expressly incorporated. Nevertheless, one must note that this reference is still vague and/or imprecise.

It is precisely in the above stated general laws that regulate the liability arising out of illegal action; particularly the Civil Code in Articles 1910 in fine.

It must be noted that according to Articles 1910 and 1913 of the Civil Code, someone causing loss or damage to another is obliged to respond by paying damages, unless it is proven that the damage was a product of the inexcusable fault or negligence of the victim.

Hence, to be liable for payment of damages, it is necessary that the loss or damage (including lost profits) be a direct and immediate consequence of the illicit action, or the breach of an obligation.

It should be understood that liability for loss or damage suffered by someone as a result of the use of a product or service, depends on the following:

i) Existence of an obligation (whether by agreement by the parties or imposed by law).

ii) Breach of an obligation or acting in an illicit manner.

iii) Causation between the breach and/or illicit act and the loss or damage.

iv) Detriment to the victim’s property suffered as a result of the action in question.

v) Deprivation of earnings that would have been obtained by fulfillment of the obligation or if the illicit conduct had not taken place.

vi) Damages not produced as a consequence of the inexcusable fault or negligence of the victim.

From a simple reading and analysis of the articles cited above, it can be noted that the Civil Code does not deal with the concept of product liability. That is why, the most recent amendments to the Federal Consumer Protection Law, mentioned previously, were of great importance because they established a legal concept, that of product liability, not previously specifically contemplated under Mexican legislation.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The Federal Consumer Protection Law, in Article 79, establishes that, with respect to the protection it provides for consumers and the fulfillment of warranties offered “…The enforcement of warranties is claimable, without distinction, from the manufacturer, the importer-exporter, or from the distributor unless one of them, or a third party, expressly accepts the obligations in writing…”

Article 93 of the Federal Consumer Protection Law, determines that consumers may “…choose to present [a claim], without distinction, to the seller, manufacturer, or importer-exporter…”

While it is true that the consumer may choose to file a claim or complaint for the enforcement of a warranty “…without distinction, [against] from the seller, manufacturer, or importer-exporter…,” nevertheless, in the event of damage caused by a product, and in accordance with the Civil Code, the manufacturer or services provider is to be held directly responsible for the damage. This does not affect the need to determine, in each case, the liability of those involved and that they may be different from the manufacturer, e.g. a
doctor prescribes medication contrary to what is appropriate for the ailment.

The previous statement is sustained by the fact that liability will fall on the person who actually caused the damage because our legal system applies the theory of causation. This means that loss or damage must be a direct and immediate consequence of the illicit action or the breach of an obligation. Liability will therefore fall on the person that caused the damage.

On the other hand, in the event that it is not possible to determine with exactness who is responsible for the loss or damage suffered by the consumer caused by a product or service, the consumer must present his claim against the manufacturer, the importer-exporter, or the distributor. This avoids a compulsory joinder of defendants - i.e. that the court is unable to admit and try the case without including in the claim all and each one of the involved parties.

In addition to what is above stated, please consider the answers to the subsequent questions 2.2, 2.3, and 2.4.

### 2 Causation

#### 2.1 Who has the burden of proving fault/defect and damage?

Under Mexican legislation, the burden of proof of fault/defect and damage falls on the plaintiff. The plaintiff has to prove the illicit actions and/or breach of an obligation of the defendant. The plaintiff must prove, as well, the existence of the loss or damage that was inflicted and that this was a direct consequence of the breach of the obligation and/or illicit action (or in the case of objective liability, the use of a mechanism, instrument, equipment, or dangerous substance).

The above stated is corroborated by the provisions contained in the majority of the state civil procedure codes, in that it is repeatedly established that “the parties have the burden of proof of the facts constituting their claims”, through the appropriate means of proof that are approved by law.

The defendant, for its part, has the obligation to prove that the damage was not caused by its product or service, or that the damage originated from the recklessness, negligence, or lack of ability of the plaintiff.

#### 2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

According to Mexican law, loss or damage must be the direct and immediate consequence of an illicit action (action contrary to law or public policy), or a breach of an obligation entered into by the parties.

In addition, please consider the response to question 1.1.

#### 2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In principle, pursuant to Articles 79 and 93 of the Federal Consumer Protection Law, all of them will be jointly and severally liable vis-à-vis the consumer, if the damage has been proven. Total or partial discharge from liability will only apply with respect to any of the parties if that party can prove that the damage was not caused by it.

Liability for product defects is strict, in that the Mexican legal system always requires proof of the cause-effect relationship. Thus, it is highly improbable that a given producer would be made answerable in the absence of proof that the damage was caused directly and immediately by its product. Although the Civil Procedure Code allows for the burden of proof to be reversed, such reversion is inadmissible in the case of an impossible proof. It should also be noted that, in Mexican law, joint and several liability cannot be presumed, but will apply only if it expressly arises from the law or from contract. It is therefore not possible, for example, to infer joint and several liability among producers based simply on market-share or similar criteria.

#### 2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account? only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Yes. If the producer fails to establish and specify the warnings that apply and must be followed with respect to its product, and this product is acquired by consumers who suffer damage from using the product, the producer will be liable under the following circumstances:

- a) When the law, rules, and/or official Mexican standards applicable to the product in question, state the
obligation to establish specific warnings for the appropriate use of the product.

b) Even when the law, rules, and/or official Mexican standards applicable to the product in question do not state the obligation to establish specific warnings for the appropriate use of the product, if the manufacturer is aware of the need to warn of the possible risk of using the product.

In light of the ideas stated above, one must consider that liability varies in accordance with the damage caused for lack of information about the product. That is, liability will be different if the damages are caused from lack of information about the product. If, on the other hand, the information is not appropriately provided by an intermediary when recommending or prescribing the use or consumption of the product - by not considering the individual consumer’s circumstances, the intermediary will be liable.

We also refer to our answer in the previous question 2.2: liability for loss or damage suffered by the consumer is the responsibility of the party that acting illicitly or failing to fulfill an obligation caused the same.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Liability for the loss or damage that a person suffers from the use of a product or service depends on the following:

i) The existence of an obligation (be it by agreement by the parties or imposed by law).

ii) A failure to fulfill an obligation or by acting in an illicit manner.

iii) A cause and effect relation between this lack of fulfillment and/or acting illicitly and the loss or damage.

iv) A detriment to the plaintiff’s property as a result of the damage.

v) The loss of profits that would have been obtained with the fulfillment of the obligation or if the illicit conduct had not taken place.

vi) That the damages were not produced as a consequence of the inexcusable fault or negligence of the victim.

Under Mexican law, the person who causes damage to another is obliged to compensate for it and pay damage unless it is proven that the damage was inflicted as a consequence of the inexcusable fault or negligence of the victim.

Regardless of the aforementioned exemption, Article 35 of the Federal District Civil Procedure Code provides procedural defences that the defendant may make use of to answer a claim and which are additional to any available substantive defences.

Mexican law does not restrict the defences that may be raised by the defendant in an action brought claiming compensation for loss or damage caused by a product or service. If limitations were to be in effect, they would be in violation of the individual guarantees that are intrinsic to the nature of a trial, as they would limit the parties’ constitutional right to due process of law, as provided by Article 14 of the Federal Constitution by not providing the opportunity to the defendant to defend itself and to establish and prove all the defences available to counter the plaintiff’s claim.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

No. There is no regulation providing for a state of the art/development risk defence. However, such defence could be asserted, and if it is backed by enough evidence, it could help reduce the damages to be borne by a manufacturer, since it may prove a cautious and prudent attitude. However, it does not release the manufacturer from liability.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

A supplier may raise, as a defence to a claim, that the product or service did in fact comply with the official legal standards in effect at the time, such as the appropriate techniques and safety standards. Of course it will ultimately be up to a judge to determine if this defence is sufficient to free the supplier of liability for the loss or damage that may have been caused to the consumer.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

It is possible to use as proof to support a claim; the court actions, proceedings, and rulings in a claim brought by a third party, if they assist in proving the manufacturer’s liability of a determined product. Nevertheless according to Mexican legislation it is not possible to initiate a new trial (or file the same action) for a cause that has already been subject matter of a previous trial and that constitutes, res judicata - case closed by a final and conclusive judgment. This is supported by the Constitutional Principle non bis in idem, provided for in article 23 of the Constitution of the United States of Mexico, which holds that nobody can be tried twice for the same offence.

As a matter of fact, in terms of the Mexican legislation, the rendition of a final judgment has the same effects of res judicata. In accordance to article 426 of the Civil Procedures Code of the Federal District, “there is res judicata when the judgement becomes final and conclusive”.

Notwithstanding the above stated, it must be noted that one of the most recent reforms to the Civil Procedures Code for the Federal District, was the addition of the legal concept of “action for annulment of a concluded trial”. As the name indicates, said action has the purpose to declare nil a trial that was concluded by a final and conclusive judgment, by means of a judicial decree. This action is admissible when any of the following hypotheses provided for in the Civil Procedures Code for the Federal District take place.
It is most important to note that the action for annulment of a concluded trial is solely provided for in the Civil Procedure Code of the Federal District. Considering the recent date of the incorporation of said judicial term, there are no court precedents that sustain this action’s constitutional standing; many legal scholars consider that the action for annulment of a concluded trial is unconstitutional because it is deemed as a violation of the non bis in idem Constitutional Principle above stated.

4 Procedure

4.1 Is the trial by a judge or a jury?

Trials are heard by a judge. The Mexican legal system does not provide for trials to be heard by a jury.

The conciliatory proceeding in which the consumer may present a claim to the Consumer Protection Agency against a supplier for the acquired goods, products, or services is heard by the authority in charge of these proceedings. Since this is not a judicial proceeding, there is no stipulation for a jury or judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The Mexican legal system does not allow for courts to appoint technical specialists to sit with the judge. The legal principle is that only the judge or justices are to assess/weigh the evidence presented by the parties.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

In the Mexican legal system and practice, group or class actions are not common. Still, Article 26 of the Federal Consumer Protection Law authorises the Federal Consumer Protection Agency to file a group action with the courts as a consumer representative. In such an action, a court may issue:

a) A judgment that declares that one or several people have engaged in conduct that has caused loss or damage to consumers and as a consequence, order an assessment of damages.

b) An order to impede, suspend, or modify the conduct that caused or may cause loss or damage to consumers.

c) After assessment, an order may be issued requiring payment of compensation of the loss or damage suffered by consumers, based on the judgment mentioned above.

Finally, it must be noted that in accordance with Article 60 of the General Health Law, a member of the public may submit a complaint to the health authorities concerning facts, events, acts, or omissions that pose a health risk or cause damage to public health.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

As indicated in the answer of the previous question 4.3, Article 26 of the Federal Consumer Protection Law gives the Consumer Protection Agency authority to file an action, as representative of a group of consumers, with the courts.

4.5 How long does it normally take to get to trial?

An action is initiated formally when the plaintiff files with a court the claim for damages. The claim is entered immediately, unless the judge considers that the plaintiff must clarify certain issues. The same procedure is followed with an administrative proceeding with the Consumer Protection Agency or the Department of Health.

A claim for damages filed with a court usually takes from 12 to 18 months to conclude, depending on the complexity of the subject matter. This time period does not include any possible appeals.

The conciliatory administrative proceeding heard by the Consumer Protection Agency will take up to six months, but, as was stated previously, this proceeding is optional and not the ideal means to obtain a judgment that determines the liability of the defendant and provide damages. This conciliatory administrative proceeding is not a prerequisite for a consumer filing a court claim for damages. Nevertheless, in practice, this conciliatory administrative proceeding has been more popular with the general consumer population.

4.6 Can the court try preliminary issues, the result of which determines whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Under the Mexican legal system, it is not possible for a court to determine or try preliminary issues as matters of fact or issues of fact.

There are some matters which may be dealt with prior to trial, as provided for by Article 193 of the Federal District Civil Procedure Code. Some of these include requesting that witnesses be examined due to old age, threat of imminent death or the proximity of a prolonged absence that makes it difficult to communicate. This may take place if the evidence is essential to the trial and the necessary requirements are satisfied.

4.7 What appeal options are available?

If any of the parties at trial is dissatisfied with a procedural decision or ruling of a court during the trial or upon judgment, the party may file an appeal that is heard by an appellate court, composed of three judges. This appeal usually lasts from three to six months, approximately.

If any of the parties to the appeal is dissatisfied with the final judgment issued by the appellate court, the party may file an action for constitutional relief by way of a petition for a writ of amparo (‘...a constitutional action alleging the violation for rights committed by the government or by a court of law;
with no exact equivalent under U.S. law ...” Javier F. Becerra. (1999) Diccionario de Terminología Jurídica Mexicana (Español - Inglés). Dictionary of Mexican Legal Terminology (Spanish - English). George E. Humphrey (assistant). Escuela Libre de Derecho: México), if the party considers that its constitutional rights and freedoms are violated by the judgment. The action for constitutional relief under a writ of amparo is not a remedy or a third instance (further appeal), it constitutes a constitutional proceeding that is independent from the original claim and it usually takes from three to six months to finalise. In some infrequent cases, a further appeal may be made to the Federal Supreme Court of Justice.

In respect to the decisions of the Consumer Protection Agency and/or the Department of Health, be it the conciliatory administrative proceeding or an administrative proceeding for infringement of the law, the decision may be challenged be a motion to review that is provided for in the Federal Law for Administrative Procedure.

It is important to note that the motion to review is an optional remedy to challenge the decisions of the Consumer Protection Agency and/or the Department of Health. The motion is filed with the authority that issued the decision and is resolved by the immediate superior of the person who issued the original decision.

If a fine is imposed by the Consumer Protection Agency and/or the Department of Health on the supplier; the supplier may challenge the fine through an annulment action filed with the Federal Tax and Administrative Justice Tribunal. If no fine is imposed, the supplier may challenge the decision by an action for constitutional relief by way of filing a petition for a writ of amparo.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

In accordance with Mexican legislation, in order to determine the truth of issues in controversy, the court may make use of any person (whether a party to the action or a third party, such as an expert) and of any object or document (whether belonging to a party or a third party). The only limit to this authority is that the evidence must be legally admissible.

In addition, a court may order the introduction of evidence at the trial or evidence to illustrate or explain existing evidence, as long as it is relevant and pertinent to the determination of the truth of the issues in question.

Furthermore, the parties are authorised to present any and all evidence as long as it is allowed by law (interrogatories, proceedings, expert evidence or expert testimony, witnesses, on-site court inspection, documentary evidence, and evidentiary presumptions) and relevant to the issues.

The parties are authorised to offer technical opinions by expert witnesses with respect to a specialised knowledge in a science, art, technique, trade or industry. In addition, the court may be requested, through a written motion, to ask for the technical opinion of an expert.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Our legal system does not provide for pre-trial proceedings, hence, in an action for damages, evidence is submitted only during the appropriate stage of the proceedings. At this stage, once the judge has accepted all the submitted evidence, including testimony and/or expert evidence, the parties will be entitled to cross-examine the witnesses and experts (with regards to their report or technical opinion).

Notwithstanding the above, Article 193 for the Federal District Civil Procedure Code provides for the allowance of testimony prior to trial in certain circumstances. To this effect, Mexican legislation allows for several proceedings for preparation for trial. As an example, some of these preliminary procedures include a request to examine a witness due to old age, threat of death or the proximity of a prolonged absence that makes it difficult to communicate. In order for this to be approved by a judge, it must be shown that the evidence is necessary to decide the outcome of the action.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

See questions 4.8 and 4.9 above. As it has been stated previously, our legal system does not provide for pre-trial proceedings. In an action for damages, the proposed evidence must be mentioned, and documentary evidence must be submitted at the time the complaint is filed, not subsequently. A similar rule applies to evidence that will be offered by the defendant, which must be mentioned and/or filed together with the defence.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Mexican legislation establishes specific time limits to file a claim for damages and bring other proceedings.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to dispose time limits?

The limitation periods are as follows:

a) Administrative proceedings heard by the Federal Consumer Protection Agency (PROFECO) and brought by consumers against a supplier for product liability have a limitation period of one year.

b) In judicial proceedings initiated by filing an action for damage the limitation periods go in two different directions: (i) If the damage was caused by conduct contrary to law or public policy, the Civil Code in its article 1934 states a time limit is of two years, calculated from the date in which the damage was caused; and, (ii) if the damage was caused by a breach of a contractual obligation, the Civil Code provides in its article 1159 for a limitation period of...
ten years, calculated from the date on which the obligation was to be performed otherwise, from the date when the offended party had a right to demand the performance of that obligation.

The age and specific condition of the plaintiff, in principle, may not be taken into consideration by a judicial or administrative authority to waive or extend the limitation periods.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

See question 5.2 above.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damage is the “loss or detriment inflicted in the property for lack of fulfillment of an obligation” and lost profits are “the detriment of any licit earnings that may have been obtained with the fulfillment of the obligation”, as defined by articles 2108 and 2109 of the Civil Code.

Recoverable damages include:

a) The restitution of the parties to the situation prevailing immediately prior to the damage, if possible.
b) The payment of damages, compensating for the damage suffered, including any loss of profits.
c) When the damage inflicted causes death, or injury resulting in disability, damages will be calculated in accordance with the provisions of the Federal Labor Law, based on a formula requiring payment of four times the highest minimum salary in effect for the part of Mexico where victim is located, multiplied by the number of days stated in the Federal Labor Law for each specific disability - e.g. a person that dislocated his shoulder, would be awarded damage for approximately $40,986.80 Mexican pesos according to this formula.
d) Non-pecuniary damage, pain and suffering or mental distress. The amount of the indemnity will be determined by the judge by taking into consideration the nature of the damage, the degree of liability, the financial standing of the liable party and the victim, and any special circumstances of the case. Moreover, when the moral damage affected the victim in his or her dignity, honour, reputation or consideration, the judge will order, by petition of the victim, for the liable party to pay for the publication, on the media the judge deems convenient, of an excerpt of the judgment that accurately reflects its nature and scope. If the damages derive from an act that was broadcasted in the information media, the judge will issue an order that will call for the same media to publish the excerpt of the judgment with the same importance that was allotted to the initial broadcasting.

d) Non-pecuniary damage, pain and suffering or mental distress. The amount of the indemnity will be determined by the judge by taking into consideration the nature of the damage, the degree of liability, the financial standing of the liable party and the victim, and any special circumstances of the case. Moreover, when the moral damage affected the victim in his or her dignity, honour, reputation or consideration, the judge will order, by petition of the victim, for the liable party to pay for the publication, on the media the judge deems convenient, of an excerpt of the judgment that accurately reflects its nature and scope. If the damages derive from an act that was broadcasted in the information media, the judge will issue an order that will call for the same media to publish the excerpt of the judgment with the same importance that was allotted to the initial broadcasting.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No. Damage must be the direct and immediate consequence of an illicit action (action contrary to law or public policy), or a breach of an obligation entered into by the parties. The possibility of a product or service causing damage or injury in the future is not grounds for an action for damages to be admissible in court; therefore, no damages in respect of the cost of medical monitoring may be recovered.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

No. There is no provision in our legal system for awarding punitive damages.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There are limits on the damages recoverable from one manufacturer, as stated in question 6.1, there is a limit to the liability of a manufacturer for pecuniary damages. For example, in a situation of injury, the limit is set out in the Federal Labor Law. There is no such limit for non-pecuniary damages although the court must take into consideration: i) infringed rights; ii) the degree of liability; iii) the financial standing of the liable party and the victim; and iv) any special circumstances of the case.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In ordinary civil actions, or ordinary civil procedures in which a claim for indemnity of damages and lost profits has been brought, the successful party may recover legal costs and court fees or other incidental fees. The Civil Procedures Code establishes several cases for the recovery of these fees, costs, or expenses.

These costs, fees, and expenses do not include the attorney’s fees, except for minor amounts. For example, legal costs in the first instance will be from 6% to 10%, depending on the amount subject matter in trial.

7.2 Is public funding e.g. legal aid, available?

The Federal Consumer Protection Agency is a government agency created to protect the interests of the general consumer population through administrative proceedings arising from infringements of the law by or representing groups of consumers. There is no charge for its services. In addition, the state provides free legal assistance to those parties who have no means or are unable to hire the services of an attorney for their legal counsel. There is a wide network of law firms in Mexico that provide free legal counsel to those unable to afford a lawyer. These
law firms are mostly sponsored by universities, associations, or non-governmental organisations.

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7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

See question 7.2 above.

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Chapter 33

Netherlands

Lovells

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?


The Directive has not superseded or replaced systems of liability that existed prior to implementation. Product liability cases may still be based on the contractual relationship between the consumer and the producer/supplier or on an unlawful act (tort) on the part of the producer/supplier.

Contractual liability only plays a role if a sales agreement between the consumer and the supplier exists (Article 7:24 NCC). The buyer may claim any damages if the product which has been delivered does not possess the qualities which the buyer was entitled to expect. The buyer may expect that the product possesses the qualities necessary for its normal use and the qualities necessary for any special use provided in the contract (Article 7:17 NCC). Supply of a product other than the one agreed does not conform to the contract. The same applies if what has been delivered varies in quantity, size or weight from what has been agreed. Further, where a sample or model was shown or given to the buyer, the product must conform to this sample or model, unless the sample or model was provided only for indicative purposes.

However, if the failure in performance consists of a defect referred to in Articles 6:185-6:192 NCC, the seller is not liable for the damage referred to in those articles unless:

- he was aware or ought to have been aware of the defects;
- he has promised freedom from defects; or
- it relates to damage to things for which pursuant to Articles 6:185-6:192 NCC, there is no right to compensation on the basis of the threshold provided for in these articles, without prejudice to his defences pursuant to the general provisions for damages.

Under contractual liability law, liability to non-commercial consumers cannot be excluded or limited by contractual provisions (Article 7:6 NCC). Although the seller may use general terms and conditions, the other party is only bound by the general terms and conditions if he knows or should have known their contents (Article 6:232 NCC). A clause in a set of general terms and conditions can be annulled if the wording and the contents of such clause are unreasonable for the other party (Article 6:233 NCC). The Articles 6:236 and 6:237 NCC set out contractual stipulations which are strictly forbidden (“black list”) and which are presumed to be unreasonably onerous (“grey list”) respectively.

The “black list” includes:

- a stipulation which totally and unconditionally excludes the other party’s right to enforce performance;
- a stipulation which limits or excludes the other party’s right to set the contract aside; and
- a stipulation which limits or excludes the right which, pursuant to the law, the other party has to suspend performance or which gives the user a more extensive power of suspension than that to which he is entitled pursuant to the law.

The “grey list” includes:

- a stipulation which, taking into account the circumstances of the case, gives the user an unusually long or an insufficiently precise period to react to an offer or another declaration of the other party; and
- a stipulation which materially limits the scope of the obligations of the user with respect to what the other party could reasonably expect in the absence of such stipulations, taking into account rules of law which pertain to the contract.

Before the implementation of the Directive in the Netherlands, product liability claims were generally based on Article 6:162 NCC. This provides that any person who causes injury to another by means of an unlawful act is liable to pay compensation. The term “unlawful act” includes violation of any right or a statutory duty, as well as any act or omission which violates a rule of unwritten law “pertaining to a proper social conduct”. The cases in this respect fall into three categories: manufacturing defects,
inadequate warnings or instructions and design defects. The relevant difference between the strict liability and tort-based liability may lay in the “standard of care”. Under the Netherlands Product Liability Act the producer is liable unless he can exonerate himself by way of certain specific defences. Under general tort principles the possibilities of exoneration are in theory wider, but it is generally believed that it will make no difference in practice.

Since the Directive was implemented in the Netherlands, product liability cases have generally been based on the strict liability system. As a rule, the principles of the directive can only be used with respect to products being put into circulation since 30 July 1988, which is the date the Directive should have been implemented.

1.2 Does the state operate any schemes of compensation for particular products?

No such schemes exist.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

A producer or anyone who might be said to appear to be a producer may be liable for supplying a defective product. In Article 6:187 (2) NCC the definition of producer is given. Producer means the manufacturer of a finished product, raw material or other component parts. In addition, a person who presents himself as the producer of the product is considered as a producer. An entity which connects its name to a product by printing its name or trademark or any other sign on it also falls within the scope of the definition of “producer”. A licensee is regarded as a “producer” if he presents himself as such. Otherwise, he is not a producer in the sense of the product liability regulations. Also the importer may be held liable in respect of defective products. A supplier will not be liable unless he fails to inform the injured person within a reasonable time of the identity of the producer or of the person who supplied him with the product. In the event that the person who supplied the product to the supplier is insolvent, liability will not revert to the supplier himself. If the producer is not known, the supplier may be held liable.

Duty of care in tort can rest on all persons who cause injury to another and may be held responsible for the damages.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In the Commodities Act Decree the recall obligation is included. This recall obligation does, however, not include recall from the end-users. However, it may be considered unlawful not to recall products from the end-users for example when other measures are inadequate.

Article 8(2) of the Product Safety Directive (European Directive 95/374/EEC), which should have been implemented on 15 January 2004 (but still has not been implemented), provides that the competent authorities are entitled to organise, or to require a producer to organise, a recall in the event they consider that the voluntary action taken by the producer is unsatisfactory or insufficient. In such a case, both producers and distributors must co-operate with the authorities and abide by any procedures established by them. This means, that in appropriate circumstances, products must be removed directly from the hands of the consumers.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In general, the party claiming damages bears the burden of proof (Article 150 Court Civil Proceedings (“CCP”)). However, in some circumstances the courts have lessened the burden on the claimant, or shifted it to the defendant, while still requiring the element of fault.

For liability based on tort, fault is required. The claimant has the obligation to provide prima facie evidence that the offender was at fault. A shift of the burden of proof from the claimant to the defendant has been accepted previously in among others, the “Lekkende Waterkruik”—case, where the Supreme Court ordered that the producer of the hot water bottles had to show that sufficient precautions were taken.

However, more recently in the “Du Pont/Hermans”—case the Netherlands Supreme Court did not accept the shift in the burden of proof as such, but ruled in favour of the claimant by stating that the question of fault could only be answered based on the circumstances submitted by the defendant to demonstrate its point of view. This included “evidence put forward by the defendant as to its actions and the reasons for those actions”.

In the “Asbestos”—case, the Supreme Court gave an indication of the extent to which the producer has the duty to investigate risks associated with the product. In this case an employee became ill because of the use of asbestos in the factory of his employer. The decision related to an employer, but it is generally believed that it can also be applied to producers. According to the decision, an employer must explain how he fulfilled his duty of care with respect to the safety. If legislation in that respect is lacking or is insufficiently precise, the danger of any substances to be processed or produced must be investigated. The employer must make enquiries, including if necessary, consulting experts.

For the purposes of an action brought under the provisions of the contractual liability, Article 6:188 NCC stipulates that the claimant bears the burden of demonstrating that the product was defective and that the defect caused the damage to the claimants. Once the claimant has shown that the product was defective, the burden is on the producer/supplier to prove that the defect did not exist when the product was put on the market.

The stipulations of burden of proof apply to both contractual and non-contractual situations. Article 6:192 NCC determines that the liability of the producer cannot be contractually limited. The same applies for sales agreements and general terms and conditions subject to these agreements.

Liability based on stipulations for product liability under Articles 6:185-6:193 NCC is mainly risk liability (i.e. strict liability), but it can be seen to include some “fault” elements. One of those is the issue of the reasonably expected use of a
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2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

One component required for proving a tort has occurred is causation between fault/defect and damage. This causation is established through the test of ‘condicio sine qua non’. The claimant has to prove that there is causal relationship between the fault/defect and the damage. The courts may shift the burden of proof to the defendant. The claimant also has to prove to what extent the defendant is liable. The defendant has only to compensate for damage that can be attributed to the defendant. Whether damage can be attributed is decided on the basis of the nature of the liability or the nature of the damage (Article 6:98 NCC).

Article 6:99 NCC stipulates that if the damage results from two or more events, for each of which a different person is liable, and it has been established that the damage is arisen from at least one of the events, the obligation to compensate for the damage is imposed on each of such persons. A person will only not be held liable if he proves that the damage is not the result of an event for which he is liable.

As stated under question 2.1, the claimant normally bears the burden of proof. The claimant has to prove that there was a fault/defect, that damage occurred and that a causal relationship exists between the defect/fault and the damage. As set out under question 2.1 the courts may lessen the burden on the claimant or shift it to the defendant.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In Article 6:189 NCC it is provided that if, based on 6:185 NCC, more than one person is liable for the same damages, each of them shall be liable for the whole. Thus, all defendants are jointly and severally liable. The same is provided in the general provisions in Article 6:102 NCC. In this respect, it is required that the liability relates to the same type of damage.

Suppliers of “trademark-less” products are considered as producers of the products. Suppliers of these products can only pass on their liability if they inform the injured party within a reasonable time of the identity of the producer or of an upstream supplier (Article 6:187, (4) NCC). The general principles will also apply to trademark-less products.

A producer is only partly liable (i.e. not jointly and severally liable) in situations in which damages can be “divided”, for example if it can be shown that the particular producer only caused one particular part, or type, of the damages.

In the “Des”-case the Supreme Court of the Netherlands rejected the concept of assigning liability by market share and imposed the burden concept of joint and several liability. Thus, regardless of proof that the defendant’s product caused the injury, and regardless of the particular defendant’s share of the relevant Des hormone market at the pertinent time, any prior Des manufacturer can now be held liable in the Netherlands on the basis of joint and several liability for the entirety of the plaintiff’s injury.

The extent of liability as between commercial parties can be limited by contractual clauses. As noted above, the liability of the producer may not be limited or excluded with respect to consumers and Article 6:192 NCC. The same applies in general national law.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Under Dutch case law a producer is obliged to warn if he knows or ought to have known that the product can cause damage. If he fails to warn he can be held liable.

In the “Rockwool”-case, the Supreme Court ordered that a manufacturer in general ought to take such measures, which can be required of a “careful manufacturer”, in order to prevent that the product he brought into the market causes any damage. In Rockwool it was also decided that producer of a semi-finished product has the obligation to warn both the purchasers of the semi-finished product and the purchasers of the end product.

In the “Halcion”-case the Supreme Court decided that a medicine is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account. The consumer is not required to expect additional effects for which he is not warned. The producer is liable if an additional effect arises that was, or could have been, foreseeable and whereby he failed to warn the consumer for the danger of an additional effect occurring.

In the Netherlands the doctrine of the ‘learned intermediary’ theory is not recognised. In the “Halcion”-case the Court decided that Halcion should have warned not only the doctors who prescribed the medicine but also the consumers. Halcion may not have relied on doctors to have sufficient knowledge of the pharmacy to warn the consumers by themselves.
3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer is, according to Articles 6:185-6:192 NCC, not liable if he proves:

- that he did not put the product into circulation;
- that it is to be assumed that the product did not have the defect which caused the damage at the time when the producer put it into circulation;
- that he manufactured the product neither for sale nor for any other form of distribution for economic purposes;
- that the defect is due to compliance of the product with mandatory regulations issued by public authorities;
- that the state of scientific knowledge at the time when the product was put into circulation was not as to enable the defect to be discovered; or
- in the case of the manufacturer of a component, that the defect is due to the design of the finished product or that the component was made according to the instructions of the producer of the final product.

Sellers having a contractual relationship with the consumer may include the defence that the breach of contract consists of a defect referred to in Articles 6:185-6:192 NCC in circumstances in which the seller was not, and ought not to have been, aware of the defect, and had not promised that the product is free from defects.

Producers/suppliers who are sought to be held liable in tort (i.e. based on an unlawful act) can argue that there was no negligence. This argument could succeed if, for example the defect was hidden or latent or otherwise undiscoverable by the producer/supplier at any relevant time prior to the injury.

The general provisions for damages in book 6 NCC provide that in all actions in which there is a failure in the performance of an obligation, damages may be limited or excluded entirely if the injury was caused by the fault or negligence of the consumer.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The development risks defence has been incorporated in Article 6:185 NCC (see question 3.1 above). In the “Sanquin Foundation”-case, the development risks defence was in discussion. The District Court held that for the purposes of assessing whether a blood product is defective, a court must take into account “the extent of safety the public may expect of blood products”. The court decided that the public may expect that blood products are free of HIV in the Netherlands, taking into account the vital interest in such products and the fact that in principle no alternatives exist. (In this context, it was held that the fact that the Foundation had complied with applicable regulations could not support a different conclusion.) However, the District Court also held that the Foundation had acted in compliance with the scientific and technical learning available at the moment of the blood donation and the delivery of it to the claimant, and it was therefore entitled to rely on the “development risks” defence under Article 6:185.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory and/or statutory requirements may be a defence (reference is made to question 3.1). See also the “Sanquin Foundation”-case above.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Although no specific rules exist that it is not possible, it is generally believed that a claimant cannot bring the same claim again based on the same set of facts.

4 Procedure

4.1 Is the trial by a judge or a jury?

There is no jury system in the Netherlands.

In the Netherlands claims must be brought in first instance before the competent District Court, unless the parties have agreed upon a different form of dispute resolution. If the amount claimed is €5,000 or less, a special division of the District Court (the Cantonal division) will deal with the case. In first instance, a case is usually decided by a single judge.

Decisions from the District Courts (including those of the Cantonal division) are subject to appeal to the Court of Appeal. If the amount claimed is less than €1,750 in which case the decision cannot be appealed at all. Usually, a case before the Court of Appeal is decided by a majority decision of a panel of three judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

In the course of court proceedings, the court can appoint experts, either ex-officio or at the request of a party (Article 194 CCP). Before court proceedings are under way, a party can request that the court allows preliminary expert advice on a certain issue (Article 202 CCP). In addition, each party is free to file opinions of its own experts. However, such opinions are considered as coming from party experts (i.e. are taken to be partisan). In the case of conflicting opinions of the party experts, the court usually appoints its own expert. The court can also hear witnesses (Article 163 CCP). In addition, a party can request the court to allow the preliminary hearing of witnesses before court proceedings are under way (Article 186 CCP). However, it is for the judge to assess the evidence.
4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

There are no specific provisions under Dutch law for class actions, group litigation orders or group management proceedings as such. However, multi party actions are in fact available by a number of means. In addition, the Dutch government has recently announced an investigation into whether a system of group actions should be provided.

As a matter of law, there is no limit to the number of claimants who can bring an action and an enormous amount of claimants could simply be added in one action. This will be permitted if there is sufficient connection between the claims of the different claimants. The criteria for determining whether there is “sufficient connection between the claims” are, inter alia, the point in time at which the claim arose and whether the claims concern the same subject matter. Furthermore, the judges take the question of efficiency into account when determining whether the claimants can jointly take action.

Collective actions can be brought by an interest group in the form of a foundation or union, so long as the foundation or union is a legal person and its articles of association provide that one of its objectives is to take care of the (similar) interest of people having suffered damages as a result of a defective product (Article 3:305a NCC). A settlement must be attempted before such an action can be brought, and monetary damages are not available directly through these means. However, the foundation or union can seek a declaration that the producer is liable for damages. On the basis of such a declaration the individual injured persons can then negotiate with respect to their compensation or initiate proceedings before a District Court. In such proceedings, the individual has only to prove that he suffered damages. Furthermore, a group of claimants can give a power of attorney to one party to file the claim on their behalf.

Also test cases do happen, although there is no specific provision for such cases. In such cases the claim will usually be brought by a limited number of injured persons, while for example a consumer organisation co-ordinates the action and pays the costs.

The law does not provide for a formal consolidation of multiple claims. However, if a number of claims regarding the same subject matter is pending before the same court, the court can consolidate the cases on the docket, which means that the various steps in the litigation will take place on the same dates.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

As set out before, collective actions can be brought by an interest group in the form of a foundation or a union such as a consumer association. However, in such action no claim for monetary damages can be made.

4.5 How long does it normally take to get to trial?

It is difficult to estimate the length of time to progress a product liability claim in the first and second instances, because the length of time a case can take before the District Court and the Court of Appeal is highly dependent on whether the court wants to hear witnesses and/or takes expert advice. These are usually the delaying factors.

It is important to know that in Dutch litigation no such thing as a trial (a hearing in which all evidence is presented to the court, followed by a final decision) exists. A hearing before the Dutch courts usually consists only of the oral arguments of both parties summarising their cases. The courts can render interim decisions, which may include partial decisions and/or instructions to the parties regarding the further conduct of the litigation such as an order to prove certain statements, an order that expert advice will be taken etc. However, each case must sooner or later end with a final decision, allowing or denying, in whole or in part, the relief sought. If a lot of witnesses are to be heard and/or extensive expert advice is ordered, a final decision might be rendered within one to two years after service of the writ.

In practice, the length of time of the appeal procedure is usually shorter than in first instance. This is because most of the time no new evidence is introduced in appeal. With the above in mind, the following estimates can be given:

- instance: final decision within one to two years after service of the writ; and
- appeal: final decision within one to 1.5 years after service of the appeal writ.

A Supreme Court appeal takes approximately one and a half to two years after service of the Supreme Court appeal writ until the first decision. This is usually also the final decision. The Supreme Court rarely renders interim decisions.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

There is no trial about preliminary issues in the Netherlands.

4.7 What appeal options are available?

As set out above, claims must be brought in the first instance before the competent District Court (Rechtbank), unless the parties have agreed upon a different form of dispute resolution. There are nineteen District Courts in the Netherlands. Which of those has jurisdiction in a given case will depend on where the defendant resides.

If the amount claimed is €5,000 or less, a special division of the District Court (the Cantonal division) will deal with the case. Decisions from the District Courts (including those of the Cantonal division) are subject to appeal to the Court of Appeal (Gerechtshof) as of right, unless the amount claimed is less than 1,750 in which case the decision cannot be appealed at all.

There are five Courts of Appeal in the Netherlands and which of those has jurisdiction to hear an appeal depends on which District Court rendered a first instance decision. Decisions from the Court of Appeal are subject to appeal to the Supreme Court (Hoge Raad). The Supreme Court appeals are limited to points of law and points of insufficient
motivation (that is: allegations that the Court of Appeal did not provide sufficient reasons for their decision, or that their reasoning was incomprehensible).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Every issue in dispute, legal or factual, must be decided by the court. In the course of proceedings the court may order either ex officio or at the request of a party that expert advice must be taken on certain issues (usually technical or medical issues if it is a product liability case). Before court proceedings are under way, a party can request that the court allows preliminary expert advice on a certain issue. In addition, each party is free to file opinions of its own experts. However, party experts are taken to be partisan. In the case of conflicting opinions of the party experts, the court usually appoints its own expert, although the court will not be bound by that experts’ advice.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There is no formal pre-trial in the Netherlands or other kind of discovery as such.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Under Dutch procedural law each party has the obligation to disclose the entire truth. A party can request the production of certain documents, and the court may draw adverse inferences from non-disclosure or incomplete disclosure. The court may also order a party to submit certain evidence. Usual forms of evidence include documents, witness statements and expert opinions.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

A cause of action for damages based on a contract of sale cannot be brought after two years from the time the buyer becomes aware of the identity of at least one of them more than three years previously, since the cause of action against the producer becomes barred by the lapse of three years (Article 6:191 NCC). The broad definition of “producer” and the fact that the product liability provisions allow the injured person to claim from any of several producers means that the answer is generally favourable for the injured person.

In cases brought under the product liability provisions, often several persons can be considered “producers” of one and the same product. Then, the question arises whether each product can invoke expiry of the limitation period if the injured person “became aware, or should reasonably have become aware” of the identity of at least one of them more than three years previously, since the cause of action against the producer becomes barred by the lapse of three years (Article 6:191 NCC). The broad definition of “producer” and the fact that the product liability provisions allow the injured person to claim from any of several producers means that the answer is generally favourable for the injured person.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In the case of concealment or fraud it is likely that the courts will order that it is contrary to reasonableness and fairness to invoke a time limit.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Claimants can recover what is known as damages in kind (for example replacement of products). They can also, in certain circumstances, get advance payment of damages in summary proceedings. Advance payment might be awarded by the judge in the summary proceedings if the view is that
it is likely that damages will be awarded in the proceedings on the merits and if the claimant has an urgent interest in obtaining advanced payment.

Damages for death can be claimed only by those persons referred to in Article 6:108 NCC. These include the spouse, the registered partner and the children of the deceased, at least up to the amount of the maintenance to which they are entitled by law; other relatives by blood or marriage of the deceased can claim damages provided that at the time of his death the deceased maintained them.

Damages for personal injury, which include physical and mental injury, are recoverable under Article 6:107 NCC. These include for example hospital costs and costs for future care. In principle, only the injured person should be compensated for such damages. However, a third party (other than an insurer), who has incurred such costs for the benefit of the injured person is also entitled to compensation, provided that the costs would have been recoverable by the injured person himself.

Mental injury refers to illness and harm which is not triggered by physical injury. Damages for mental injury can be claimed only in respect of unlawful acts (that is in tort). Article 6:190 NCC (the Netherlands Product Liability Act) is limited to personal injury of a physical nature and does not include mental injury. However, the term “personal injury of a physical nature” is construed to include illness and harm which is a consequence of a physical injury, and could include pain and suffering related to that physical injury.

Non-material damages can also be claimed in the Netherlands in respect of unlawful acts, pursuant to Article 6:106 NCC. The damages should be “fairly assessed” and largely relate to damage to the claimant’s honour, reputation or right to privacy. Generally, very modest amounts are awarded for non-material damages in the Netherlands.

Reasonable costs made to avoid or limit damages (costs of mitigation) can also be claimed based on 6:96 NCC. Punitive damages are not available in the Netherlands.

### 6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No case law exists in this respect in the Netherlands. It is unlikely that a court would grant a claim in the Netherlands in such a case, unless one can prove that the reasonable costs of medical monitoring are the consequence of the damages.

### 6.3 Are punitive damages recoverable? If so, are there any restrictions?

In the Netherlands punitive damages are not recoverable.

### 6.4 Is there a maximum limit on the damages recoverable for death or personal injury under the provisions of the Netherlands Product Liability Act and there are no set limits on recovery under national provisions.

However, based on Article 6:109 NCC, the court can limit damages, taking into account the type of liability at issue, the legal relationship between the parties and the financial capacity of both parties. It is generally accepted that the courts must be very restrictive in applying Article 6:109 NCC to limit recovery. As the courts have freedom to determine the level of damages to be paid, there can be no real indication of the level of damages to be expected. The court will consider what is reasonable in the circumstances.

### 7 Costs / Funding

#### 7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The unsuccessful party is usually ordered to pay the legal costs of the successful party (Article 237 CCP). The costs to be paid are fixed by the court, according to a scheme, which is based on the “value of the case”, i.e. the amount claimed. The costs as fixed by the court are usually much lower than the actual costs. The successful party has no action at his disposal to claim the remaining part of his legal costs. This system has been criticised for a long time, but it is not expected to change in the near future.

#### 7.2 Is public funding e.g. legal aid, available?

Pursuant to the Acts on Legal Aid (Wet op de Rechtsbijstand), people with an income of less than approximately €2,000 per month have a right to legal aid paid by the State if certain criteria are met. Those criteria are inter alia: the legal interests must concern the Netherlands and the costs of the legal aid must be in reasonable proportion to the interest of the case. The aid consists of the payment of most of the individuals own legal fees. The individual always has to pay a small amount himself. In addition, he has to pay the court fees and, in the event he loses the case, the other parties’ costs, as ordered by the court.

#### 7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2 above.

#### 7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency and conditional fee arrangements and even “no win no fee” arrangements with lawyers are to some extent allowed, particularly in personal injury cases. However, in practice only a limited number of lawyers will accept these arrangements. The vast majority of lawyers work on the time-spent fee basis only.
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Lovells’ product liability lawyers are supported by dedicated Science and Project Management Units.

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Chapter 34

Poland

1 Liability Systems

1.1 What systems of product liability are available (i.e., liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault-based, or strict, or both? Does contractual liability play any role?

Product liability claims in Poland may be made under any of three concurrent legal regimes: strict product liability, fault-based tort liability or the law of contract.

Strict liability

Strict product liability was introduced into Polish law in 2000 when new provisions implementing Directive 85/374/EEC were added to the Civil Code (articles 4491-11). These apply to damages caused by products put into circulation in Poland as of 1 July 2000. The Polish legislator decided to use the term “liability for dangerous products” instead of “liability for defective products” in order to avoid confusion with warranty claims under contracts of sale. However, the definition of a dangerous product in the Polish Civil Code is equivalent to that of a defective product in the Directive: any product which does not provide the safety one may expect taking into account normal use of the product. Circumstances existing at the time when the product was put into circulation, in particular concerning its presentation and the information provided to consumers on its properties, shall be used to decide whether the product is dangerous.

Under the strict liability regime, anybody who produces a dangerous product in the course of his business shall be liable for any damage caused by that product to anybody else. The scope of recovery for damage to property under this legal regime is limited (see question 6.1).

Tort

Before the provisions on strict liability were introduced in the Polish legal system, product liability claims could (and indeed still can) be based on the traditional law of tort. Polish law has a very broad notion of tort: “everybody who by his fault caused a damage to another person is obliged to redress it”. The Supreme Court has developed a concept whereby the marketing of a dangerous product constitutes a tort. Causing damage to human health or property is an unlawful act, and lack of due diligence amounts to negligence. The jurisprudence has drawn distinctions between design, production, information and monitoring defects.

Although product liability under the law of tort is generally fault-based, the Supreme Court has significantly eased the rules concerning proof of fault. The Court has accepted that the introduction onto the market of a dangerous product in and of itself indicates negligence. Moreover, a concept of an anonymous, organisational fault (rather than the personal fault of a defined individual) with objective elements has been applied in product liability cases. Consequently, this system has in practice been very similar to the strict liability regime provided for in the Directive.

Contract

If there is a contractual relationship between the injured person and the person providing the product, product liability claims may be based on the law of contract. Delivery of a dangerous product amounts to non-fulfilment or improper fulfilment of contractual obligations. A defective product is one which is not in conformity with a contract and therefore warranty claims can play an important role in product liability cases.

1.2 Does the state operate any schemes of compensation for particular products?

No such schemes exist in Poland.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the strict liability regime, responsibility for a dangerous product rests on:

- the producer, i.e. any person who produces the product in the course of his business;
- the producer of material, raw material or a component part of a product (unless the exclusive cause of the damage was defective construction or instructions given by the producer);
- the own brander (any person who presents himself as the producer by placing his business name, trade mark or another distinguishing designation on the product), or
- the importer (any person who, in the course of his business, introduces into domestic trading a product originating from a foreign country).
The liability of the abovementioned persons is joint and several.

If the producer, the own brander or the importer are not known to the injured party, any person who sells a dangerous product in the course of his business shall be liable for damages caused by that product unless he informs the injured party of the name and address of any of those persons or of his own supplier. The time limit for providing this information is one month from notification of the damage.

In product liability claims brought under the law of tort, it is usually the producer who has been held liable for damages caused by a product. In the case of imported goods, importers have also been held liable for such damages. There have also been cases in which liability was found to rest with the seller alone or together with the producer.

### 1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A producer’s obligations do not end once the product is on the market. He is obliged to monitor his products and to take appropriate measures when he has received information on risks associated with a product which is already on the market. He has a duty to warn of these risks and, if a mere warning is inadequate, even to withdraw or recall the product from the market. A product recall obligation follows from the General Product Safety Act (which implements Directive 2001/95/EC). It can also be ordered by a competent authority, e.g. the President of the Office for Competition and Consumer Protection.

Claims for failure to issue warnings or to recall products may be made under the law of tort. It is also possible to bring a preventative action in which the court can order that the producer prevent a possible occurrence of anticipated damage by e.g. recalling the dangerous product.

### 2 Causation

#### 2.1 Who has the burden of proving fault/defect and damage?

Under the strict liability regime, the claimant must prove the damage, the defect in (or dangerous feature of) the product, and the causal link between the damage and the defect. Some commentators have expressed the opinion that the claimant does not need to prove the defect as the occurrence of damage itself indicates that the product was defective.

Under the law of tort, the claimant must prove an unlawful act by the defendant, fault on the part of the defendant, the damage and the causal link between the damage and the defendant’s act. However, in product liability cases the requirements on claimants to prove all the elements of the tort have been eased (see question 1.1). It is assumed that there was negligence on the part of the producer if he put a dangerous product on the market. It will usually be sufficient for the claimant to prove that the product was defective.

Under the general law of contract, the claimant must prove the non-fulfilment or improper fulfilment of contractual obligations, the damage and the causal link between the two. For warranty claims under the law of consumer sales, the claimant must prove that the goods were not in conformity with the contract.

#### 2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Under Polish law, the causal link must be adequate. It means that a person liable to redress the damage is liable only for normal effects of the action or omission which caused the damage. In product liability cases under the traditional law of tort, the Supreme Court accepted that it is sufficient for the claimant to show a high degree of probability that the causal link exists.

#### 2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If several persons caused the damage, their liability is joint and several. This means that the claimant may claim full compensation from any one (or some, or all) of them and full compensation by one of them sets the others free from those claims. The degree to which each of them contributed to the emergence of the damage is relevant only for the purpose of mutual settlements amongst them. The person who paid the damages may demand from the remaining persons a refund of an appropriate part according to the circumstances of the case, usually according to the fault of a given person and the degree to which he contributed to the emergence of the damage.

There is no concept of market share liability under Polish law.

#### 2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account; only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Product information and warnings are relevant for the evaluation whether the product was dangerous at the time when it was introduced on the market. Such information
determines the expectations of the consumer as to the safety of the product. If a risk caused by the product could have been reduced by appropriate warnings, the lack of warnings makes the product dangerous. This triggers the strict product liability when the product has caused a damage. It is worth noting that before the strict liability regime was introduced, Polish courts accepted that a failure to sufficiently warn - which subsequently caused a damage - constitutes a tort.

The content of necessary product information and warnings depends on the ultimate product user. Different information standards apply to products addressed to professionals and to consumers. Polish law does not know the principle of “learned intermediary”. However, some legal commentators express the opinion that if a product can be obtained only through a professional intermediary, the requirements to warn the ultimate consumer shall be less stringent.

### 3 Defences and Estoppel

#### 3.1 What defences, if any, are available?

Under the strict liability regime, the defences are as follows:
- the producer did not put the product into circulation;
- the product was put into circulation other than in the course of business of the producer;
- the dangerous properties of the product occurred after it had been put into circulation, unless they resulted from a cause inherent to the product;
- the dangerous properties of the product could not be foreseen on the basis of the state of scientific and technical knowledge at the time the product was put into circulation;
- the dangerous properties of the product are due to compliance with the provisions of law, or
- in case of the manufacturer of a component, the damage was caused solely by the defective construction or instructions given by the producer.

Under the law of tort, due to the specific shift in the burden of proof developed by the jurisprudence in product liability cases, the defendant may prove that there was no fault on his part.

Under the law of contract, the defendant may prove that the non-fulfilment or improper fulfilment of the contract was due to reasons that were not attributable to him.

In any case, the defendant may prove that the injured person has contributed to a certain extent to the emergence or increase of the damage. Under the general rule of Polish civil law, this will have an influence on the amount of compensation, which shall be correspondingly reduced in such a case. If the only cause of the damage was an act of the injured party or a third party or a force majeure, the defendant may argue that there is no causal link between the defect in the product and the damage.

The lapse of the limitation period is also a defence which can be used under each liability regime (see question 5.1).

#### 3.2 Is there a state of the art/development risk defence?

- Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

A state of the art defence is available under the strict product liability regime. It is for the producer to prove that the dangerous properties of the product could not have been discovered, taking into account the state of scientific and technical knowledge at the time the product was put into circulation. It is an objective test; the actual knowledge of the producer should be of no importance.

#### 3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The fact that the manufacturer complied with regulatory and/or statutory requirements does not as such amount to a defence. It is only when the dangerous feature of the product is due to the application of provisions of law that the manufacturer can avoid liability.

#### 3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Under Polish law, any judgment has the effect of res judicata only between the parties to the proceedings with regard to the subject matter of the court’s decision and the underlying facts. A claimant is prevented from claiming the same damage again unless some new facts have come to light which did not constitute a basis for the original judgment (in particular, facts which occurred after the date of the judgment).

As the judgment is res judicata only between the parties to the original proceedings, a different claimant can litigate issues of fault, defect or causation in separate proceedings against the same defendant based on the same facts and issues which were decided by the court in an earlier case. Issue estoppel does not apply in respect of third parties.

### 4 Procedure

#### 4.1 Is the trial by a judge or a jury?

The first instance trial is by one or - in exceptional cases - three professional judges.

#### 4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No. The judge assesses all evidence himself. The court cannot call anyone to sit with the judge (or judges) and
4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

In Poland, there is no class action procedure as in the US. A multiple claim procedure is available whereby several claimants may bring their claims in a single action when the claims are of the same kind and are based on the same factual and legal issues. The court has to be jurisdictionally competent to try each individual claim and all the claims together. However, even in this sort of multi-party litigation the court still determines each claim individually.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Regional consumer ombudsmen and non-governmental organisations listed in a regulation of the Minister of Justice can bring claims in favour of citizens in matters of consumer protection. The issue of whether their authorisation to act for a consumer also encompasses product liability claims has not yet been resolved. So far, the prevailing opinion in the literature and in the jurisprudence is that these entities can only pursue claims arising out of contracts between a consumer and a professional. Hence, claims based on tort law or the strict liability regime would not be covered by their competence if there is no contractual link between the injured party and the defendant.

4.5 How long does it normally take to get to trial?

The length of time between filing a statement of claim and the first hearing depends on the workload of the relevant court and the complexity of the case. Usually it can take three to twelve months, and sometimes even longer, from the commencement of the proceedings until the date of the first hearing.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court may issue a preliminary judgment in which it decides whether a claim is grounded in principle (based on issues of law and fact). The decision with respect to the actual amount of the claim will be taken at a later stage. The court is obliged to wait until the preliminary judgment becomes final before it can issue a judgment on the amount of the claim.

4.7 What appeal options are available?

All first instance judgments can be appealed and no permission of any court is required at this stage. The court of second instance decides issues of law and fact. It has a right to rehear the case and to make its own findings on the basis of evidence collected at both instances. However, in practice the review is usually limited to the question of whether the decision of the court of first instance was correct. The court of second instance may affirm, repeal or vary the first instance judgment.

The possibility of filling a cassation at the Supreme Court from a judgment of the court of second instance is limited. The Supreme Court reviews only issues of law. It accepts to hear a case if the matter contains an important issue of law or raises serious doubts, or if inconsistencies in jurisprudence, or if the underlying proceedings were invalid for procedural reasons, or if it finds the cassation to be manifestly founded. There is also a minimum value limit for disputes which can be subject to cassation (PLN 50,000 (approx. €12,000), or PLN 75,000 (approx. €18,000) in cases between businesses). If the matter is not capable of being challenged by a cassation, there is a possibility to apply for declaring a final judgement inconsistent with the law. Such a declaration enables the plaintiff to claim compensation from the State if a damage was caused to him/her by that defective judgement.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

If a matter requires special (e.g. technical or scientific) knowledge, the court appoints experts to present a written or oral opinion. Even if a judge has special knowledge on a given subject himself, he is obliged to appoint an expert. This is because a judge cannot replace an expert in civil proceedings, and because parties have a right to ask questions and challenge the results of an expert opinion.

Private expert opinions may also be presented by the parties. However, they have the same value as private documents, i.e. they are only evidence that a given person made a statement contained in the document, and as such they do not present a source of special knowledge for a judge.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There are no requirements regarding the pre-trial stage under Polish law (except for cases between businesses) and it is not common for parties to exchange witness statements or private expert opinions before trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Upon an order of the court (which may be issued during the proceedings), any party may be obliged to present a document which is in his possession and which constitutes evidence in respect of any issue relevant to deciding the case. The court usually orders such discovery at the request of an opposing party. Before the commencement of proceedings, submission of certain documents can be
ordered by way of securing the evidence where there is a risk that it will be impossible or very difficult to obtain such evidence in the future. The Supreme Court has stated that the purpose of securing the evidence is not to allow a potential claimant to evaluate the prospects of his claim. The claimant does not have any claim for disclosure as such, and there is no general pre-trial discovery procedure.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist (see question 5.2 below).

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The limitation period for claims under the fault-based law of tort and under the strict product liability provisions is three years from the day when the injured party learned or - acting with due diligence - could have learned about the damage and the identity of the person liable for it.

A claim in tort becomes time-barred after ten years from the event that caused the damage, regardless of whether the damage has manifested itself within that time. Under the strict product liability regime, the ten-year limitation period begins to run on the day when the producer put the product into circulation.

Warranty claims under consumer sales contracts can be made when the lack of conformity becomes apparent within two years from the delivery of the good. A consumer's claim is time-barred after the later of the two year period since delivery of the good and the one year period since he or she discovered the non-conformity in the good. Furthermore, the claim will expire if the consumer has not notified the seller of the non-conformity within two months of having discovered it.

In case of warranty claims under non-consumer sale contracts, the claim will expire if the buyer has not notified the seller of the defect within one month of the date when he or she has discovered or - acting with due diligence - could have discovered it. As for sale contracts between businesses, a warranty claim will expire if the good has not been examined in a customary time after the delivery and the buyer has not notified the seller of the defect without undue delay.

If claims are made under the general law of contract, the limitation period is ten years (but three years for businesses) from the moment when the claim has become due.

Special rules regarding the lapse of a limitation period apply to persons who do not have full capacity to perform acts in law (minors or incapacitated persons) and who do not have a statutory representative (parent, guardian or curator). In relation to such persons the limitation period cannot end earlier than two years after the appointment of a statutory representative or the cessation of the cause for such appointment. The same applies to persons with mental disability who are eligible for full incapacitation.

The lapse of a limitation period is a defence which may be invoked by the defendant. The court considers the lapse of the limitation period only if it is expressly invoked by the defendant, and will not consider it ex officio. The court generally has no discretion in this respect. However, in exceptional cases, the court may rule a limitation defence inadmissible based on the general clause of article 5 of the Civil Code, according to which one cannot make use of one’s right if it would be contrary to the socioeconomic aim of that right or to good custom.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In case of concealment or fraud, the limitation defence would be ruled inadmissible on the basis of article 5 of the Civil Code (see question 5.2).

Claims under consumer sales contracts can be made despite the lapse of the time limits described above if the seller knew about the non-conformity of the product and did not draw the consumer’s attention to this fact.

The lapse of the time limits described above will also be of no relevance for warranty claims under non-consumer sale contract if the seller maliciously concealed the defect or represented and guaranteed that the defect does not exist.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under Polish law, compensation always includes monetary damage, while non-monetary damage can be recovered only in instances where express provision has been made for it. Monetary damage includes both actual damage (damnum emergens) and lost profits (lucrum cessans).

Under the law of tort, compensation is recoverable for damage to property and personal injury. Compensation for personal injury includes both monetary damage (all expenses related to the injury, e.g. costs of medical treatment and maintenance, as well as lost income, annuity or a single indemnity, and the cost of training for a new occupation) and non-monetary damages specified in the Civil Code. Compensation for non-monetary damage in the form of pain and suffering is not obligatory. It is in the discretion of the court whether to grant it or not. Refusal to grant it must, however, be objectively justified. There are also certain types of damages which can be recovered in case of death of the injured party. Persons to whom the deceased either owed a statutory duty of maintenance or voluntarily and permanently supplied with maintenance can claim annuity. The court may also award appropriate compensation to the closest family members of the deceased if their living standard has considerably deteriorated as a result of the death.

Under the strict product liability regime, the scope of damages recoverable for personal injury is the same as under the law of tort. There are some differences as far as recovery for damage to property is concerned. Strict liability covers only damage to items which are ordinarily intended for personal use and which the injured party has used mainly for...
such purpose. Compensation cannot be recovered for
damage to the product itself or for profits which the injured
person could have derived from the use of the product.
Damage to property is recoverable only if the value of the
claim exceeds the minimum threshold of €500. If it does,
the full amount of damage can be recovered.
Under the law of contract, only monetary damage can be
recovered. This includes damage to property and to the
product itself.

6.2 Can damages be recovered in respect of the cost of
medical monitoring (e.g. covering the cost of
investigations or tests) in circumstances where the
product has not yet malfunctioned and caused
injury, but it may do so in future?
There have not been any cases including medical monitoring
claims in Poland. Under the existing liability regimes, actual
damage must occur in order for compensation to be
recovered. In preventative litigation, the court can order that
certain steps be taken in order to prevent the occurrence of
threatened damage or that security be given by way of
depositing a certain amount of money with the court. This,
however, would not include the recovery of costs of medical
monitoring before any damage had occurred.

6.3 Are punitive damages recoverable? If so, are there
any restrictions?
There are no punitive damages in Polish law.

6.4 Is there a maximum limit on the damages
recoverable from one manufacturer e.g. for a series
of claims arising from one incident or accident?
There is no maximum limit on recoverable damages in
Polish law.
It is worth noting that the amounts of compensation awarded
by Polish courts are much lower than in the US or Western
Europe due to lower standard of living.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or
other incidental expenses; (b) their own legal costs
of bringing the proceedings, from the losing party?
As a rule, the losing party will be ordered to cover all
necessary costs of the successful party. This includes court
fees, other justified expenses and legal costs. The legal costs
are limited to the fees of one attorney which are calculated
on the basis of the value of the claim according to the scale
provided for in the law. The statutorily recoverable legal
costs usually do not cover the full amount of actual
expenditure on legal services.

7.2 Is public funding e.g. legal aid, available?
Yes, public funding is available in Poland.

7.3 If so, are there any restrictions on the availability of
public funding?
Legal aid is available to claimants who cannot afford to
finance the costs of proceedings, provided that their claim is
not manifestly ungrounded. A claimant has to file a
statement of his family relations, property and income in
order to obtain a waiver of court fees. Claimants who have
been exempted from court fees (in whole or in part) can also
be granted representation by an attorney paid by the State.
(Accepting such an appointment is a duty of every attorney.)
The quality of such legal representation is, however, usually
not sufficient to handle complex cases which usually require
special expertise.

7.4 Is funding allowed through conditional or
contingency fees and, if so, on what conditions?
According to their code of ethics, Polish attorneys should
not work on a “no win, no fee” basis.
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Chapter 35

Portugal

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

The Portuguese Product Liability Act was approved by Decree-Law 383/89, of 6 November, and amended by Decree-Law 131/2001, of 24 April (which implemented, respectively, Directive 85/374/EC of the Council, of 25 July, and Directive 1999/34/EC, of the European Parliament and Council, of 10 May) and it specifically regulates the liability of the producer arising from damages caused by defective products (the Product Liability Act). Such liability arises directly from law irrespectively of the existence of fault from the manufacturer.

In addition to the Product Liability Act, cases of product liability may also result from the application of provisions on consumers' protection, such as Decree-Law 67/2003, of 8 April (which implemented Directive 1999/44/EC of the European Parliament and Council, of 25 May) on the compliance of goods with the terms foreseen in the purchase and sale contract executed between a professional seller and a consumer (the Protection of Consumers Provisions).

Finally, a note should also be made to the traditional liability regimes foreseen in the Portuguese Civil Code, according to which liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty may also arise based on tort or contractual liability (both of which are fault based).

1.2 Does the state operate any schemes of compensation for particular products?

There are no compensation schemes for particular products operated by the Portuguese State (there are a few indemnity funds created by the State, which, however, are not aimed directly to provide compensation for damages caused by defective products).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the Product Liability Act, respondents may be the manufacturer of a finished product, of a component part or of raw material and those who present themselves as the producer of the product by putting their respective name, trademark or other distinguishing signal on the product.

For this purpose, those also deemed as manufacturers are (i) any entity which imports into the European Community a product for sale, hire, leasing or any form of distribution in the course of the respective business; or (ii) any supplier of the product, whenever the manufacturer or importer in the European Community cannot be identified, unless if, once notified in writing, such supplier informs the injured party, within 3 months, in writing, the identity of each of said manufacturer or importer or of any other predecessor supplier.

The “retail” supplier may be liable, in particular under the Protection of Consumers Provisions, but also under the traditional contractual liability.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Decree-Law 69/2005 on safety guarantees of products (which implemented Directive 2001/95/EC of the European Parliament and Council, of 3 December) sets that recall of products should be triggered (i) when other actions reveal to be insufficient to prevent the risks posed by the product; (ii) following instructions issued by the relevant authorities in charge of market control; and (iii) in the cases in which the manufacturer considers it necessary.

Failure to recall represents a misdemeanour that may be prosecuted by the General-Inspection for Economic Activities; in addition, anyone suffering damages (either from the supply of the defective product or from the failure to recall) may bring a claim for damages based on the systems briefly described in question 1.1 depending on the specific constraints of each case.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In principle, under Portuguese law, the burden of proof lies with the party alleging the right. The burden of proof of hindering, modifying or terminating facts of a right lies with
the party against whom the claim is directed.

Under the Protection of Consumers Provisions there are several legal presumptions, which may cause the reversion of the burden of proof.

Under the traditional systems of tort and contractual liability there are some cases of legal presumptions of fault, causing the reverse of the burden of proof, the most common of which is in contractual liability (fault is presumed).

### 2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Although no solution expressly exists in Portuguese legislation, consistent case-law of higher courts has adopted the so-called theory of the adequate causation, under which the claimant must show that damages would not probably be suffered if the relevant (damaging) fact had not occurred.

### 2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

According to the Product Liability Act, the producer may only be held liable for the damages caused by defective products that such producer puts in circulation.

If several entities are responsible for the damages, they shall be jointly and severally liable vis-a-vis the claimant. In the internal relations, the specific circumstances of the case need to be considered; in case of doubt, liability shall be divided in equal shares.

### 2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Paragraph 1 a) of Article 26 of Decree-Law 69/2005 determines that failure to supply relevant information (both by manufacturers and intermediaries) to consumers enabling them to evaluate the risks inherent to a given product, when the same are not immediately recognisable, constitutes a misdemeanour sanctioned with a fine. Similarly, paragraph 1 d) of the same Article establishes that failure of the producer to inform distributors of results of control and supervision tests is also a misdemeanour punishable with a fine. The application of fines does not prejudice product liability sustained under any of the systems referred to in question 1.1 above, provided the respective pre-requisites are met.

Regarding the principle of the “learned intermediary”, it should be noted that supplying information to an intermediary does not discharge the manufacturer from its information obligations towards the consumers.

### 3 Defences and Estoppel

#### 3.1 What defences, if any, are available?

Under the Product Liability Act, the manufacturer ceases to be liable if it is able to show that:

- i) he did not put the product into circulation;
- ii) having regard to the circumstances, it is reasonable to admit that the defect did not exist at the time when the product was put into circulation;
- iii) the product was neither manufactured by him for sale or any form of distribution for economic purposes nor manufactured or distributed by him in the course of his business; or
- iv) in case of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Whenever a faulty conduct of the injured party concurs to cause the damage, the court may, attending to all circumstances, reduce or disallow the liability of the producer. In any event, damages arising from nuclear accidents and covered by international conventions in force in Portugal are not subject to the Product Liability Act.

To avoid the application of the Protection of Consumers Provisions, the seller should allege and evidence, namely, that:

- i) the good was in compliance with the contract;
- ii) although existing a lack of compliance, at the time the contract was concluded, the consumer was aware, or could not reasonably be unaware of such lack of compliance;
- iii) although existing a lack of compliance, the same has its origin in materials supplied by the consumer; or
- iv) the lack of compliance only appeared after the guarantee period.

Defence against tort and contractual liability should be conducted by challenging the fulfilment of the respective pre-requisites, including but not limited to relevant causation determined as referred in question 2.2.

#### 3.2 Is there a state of the art/development risk defence?

Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The fact that the state of scientific and technical knowledge at the time when the manufacturer put the product in
circulation was not such as to enable the existence of the defect to be discovered is one of the ways for the manufacturer to exclude his liability. Nevertheless, the burden of proof of the relevant facts remains vested in the manufacturer.

### 3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Yes. Should the manufacturer be able to show that the product’s defect is due to compliance with mandatory regulations issued by public authorities, liability is excluded.

### 3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The general rule under Portuguese law applies in the sense that re-litigation is not possible. However, cases where a claim differs from any other (predetermined by the merits) even if only on the factual grounds, the purpose of the claim or the identity of the parties (e.g. of the claimant) do not qualify as “re-litigation” and should be heard by the court.

In addition, according to Portuguese law there is no rule of binding precedent, and even if precedent from higher courts tends to be persuasive, a court may in any claim drift away from previous judicial decisions passed in relation to similar cases.

### 4 Procedure

#### 4.1 Is the trial by a judge or a jury?

In product liability civil cases (claims for damages), the trial is always conducted by a judge. In Portugal only in some criminal cases is it possible to request that the trial is heard by a jury (which is not frequent, even because the only role of the jury is to advise the judge and not to decide).

#### 4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes. Whenever the facts under discussion cause difficulties of a technical nature to arise which solution depends on a special knowledge not held by the court, the judge may designate a competent expert to assist the final hearing and render the necessary advice.

In addition, at any stage of the proceedings, the court has the possibility to request technical reports on the matters in discussion.

#### 4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

The Portuguese legal system foresees a procedural mechanism named “acção popular” which is close to a class action, and where a common interest and grievance may cause a representative judicial proceeding beneficial to all of the parties represented therein.

Such claims, however, have not been commonly used in civil lawsuits, and are still viewed in Portugal as a procedural form of action somehow tailored to defend public interests, such as environmental, mainly under administrative law.

#### 4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes. In principle, claims can be brought to court by representative bodies on behalf of a number of claimants, such as consumer associations.

#### 4.5 How long does it normally take to get to trial?

In a regular lawsuit in a court of first instance allowing two degrees of appeal, it may usually take more than one year before starting the trial, namely because of the large number of cases assisted by each judge and the difficulties in reaching a settlement before trial, which leads to significant problems concerning date scheduling.

The total duration required for a decision to be passed in such a lawsuit may reach 3 or 4 years (in particular if there are witnesses to be heard in foreign countries by rogatory letter and if expert advice is required).

#### 4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

After the written stage of the proceedings (exchange of pleadings), the court summons the parties for a preliminary hearing. In this stage of the process the discussion of prejudicial matters that affect the court’s understanding or ability to rule on matters brought to suit may occur.

If the court considers that a prejudicial matter raised by the defence (e.g. incompetence of the court, or that the claim is already ruled by a final decision on the merits) is self-evident, the case may be dismissed immediately. In these cases prejudicial matters relate only to matters of law.

In cases where the evidence presented by the parties is undeniable and self-evident the judge may simply decide on the merits also at this stage. In these cases, issues may relate to matters of law as well as of fact.

Other options concerning the possibility of the court trying preliminary issues, the results of which determine whether the remainder of the trial should proceed, consist of the parties’ invitation to a legal transaction, thus putting an end to the case.
4.7 What appeal options are available?

The final award and the interim decisions passed by the first instance court may be subject to appeal, with two degrees of jurisdiction, depending on the value of the claim. While both issues of fact and of law may be brought before the Court of Appeal (2nd instance court), the Supreme Court of Justice (3rd instance court) deals only with issues of law.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Further to the reply to question 4.2, whenever special investigation procedures are required, experts may be appointed by the parties or the court, being the parties heard in respect of the appointment of the experts. Should the parties agree on the appointment, the judge shall proceed accordingly, unless he has grounds to doubt the expert’s skills.

Failing an agreement on the expert, each party shall appoint an expert and the judge shall appoint the third.

The court is never bound by the depositions and opinions from experts.

Technical and expert opinions may also be attached to the lawsuit at any time.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Witnesses normally testify orally during the final hearing, but, under certain circumstances, they may be heard in advance. If there is the danger that testifying may become very difficult or impossible for a certain individual, such individual may testify before the trial and even before the lawsuit is filed.

On the other hand, expert reports are submitted to court before the final hearing, but whenever any of the parties requires it or the judge demands it, the experts shall come to the final hearing to render clearance, under oath, over some specific issues.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Documentary evidence should be produced, whenever possible, during the written phase of the lawsuit, but is also allowed until the end of the hearings before the first instance court.

It is also possible to request the court to order the other party to produce specific documents, specifying which facts are to be proved by such documents. The other party becomes under the obligation to present the relevant documents, unless the same alleges not to have them. In such case, the requesting party may evidence the untruthfulness of that allegation. On the other hand, if the requested party alleges that the document existed but was destroyed or lost, the same has to provide evidence that it was not by its fault that the document disappeared.

If a party refuses to present a document, the court is free to interpret such refusal. Furthermore, the burden of proof regarding the fact that was supposed to be evidenced through the document is reversed.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Under the Product Liability Act the right to recover damages is limited for a period of 3 years from the date of awareness by the injured party, or the date when the injured party should have become aware, of the damage, the defect and the identity of the manufacturer.

On the other hand, according to Decree-Law 67/2003, the purchaser must inform the seller of the lack of compliance within 2 months from the date on which the purchaser detected it (in case of real estate properties this period of time is extended to 1 year). Rights granted to the purchaser under this regime may be exercised when the lack of compliance becomes apparent and for a period of 2 years as from the delivery of the good (in case of a second-hand good, this period of time may be reduced to 1 year by mutual agreement of the parties) (in case of real estate properties, this period of time is extended to 5 years). All the rights and remedies available to the purchaser under this regime expire within 6 months following the notice of defect provided to the seller.

In case of tort, a judicial claim to recover damages should be brought within a period of 3 years from the date on which the injured party became aware of such right, even if without knowing the identity of the responsible party and the full extension of the damage. Said limitation is without prejudice to the ordinary statute of limitations of 20 years as from the date of the damaging fact applying to the right to recover damages.

Finally, according to the general rule on contractual liability, the purchaser must inform the seller of the defect within 6 months following delivery of the product and until 30 days following the date on which the purchaser became aware of the defect. In certain commercial transactions, such deadlines may be reduced to 8 days for claiming defects of the products supplied.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Although the concept of concealment is not contemplated by Portuguese law (as it is not the concept of discovery), in case the injured party fails to exercise a right, as a result of an intentional conduct (“dolo”) of the damaging party, namely, if such intentional conduct misleads the injured party, the running of the period of limitation is suspended.
6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the Product Liability Act, the manufacturer may be liable for death or personal injury and damages to any property or product other than the defective product, provided that the same is ordinarily intended for private use or consumption and the injured party mainly used it for that purpose.

The Protection of Consumers Provisions impose not only remedy of defective products supplied to consumers (by way of repair or replacement of the product, reduction of price or termination of the contract), but also the right to recover personal or property damages caused by the supply of defective products or services.

According to the traditional regimes of tort and contractual liability all damages suffered may be recovered - including to the product itself, bodily injury, mental damage, damage to property - provided the claimant is able to establish all pre-requisites for the purpose, including, but not limited to, relevant causation.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The mere possibility of causing damages is not sufficient to sustain liability. On the other hand, provided that its results prove that the product had a defect and caused a damage (even if not liquidated), including the cost of medical monitoring, this may be recovered, being the respective amount liquidated in the phase of enforcement of the judicial decision.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable under Portuguese law. Moral damages are recoverable, but compensations granted for such damages are normally relatively low.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Under Portuguese law, there is no maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from the same incident or accident.

The original version of the Portuguese Liability Act included as maximum limit on the damages recoverable from one manufacturer of the amount of PTE 10,000,000 (roughly €50,000); such maximum limit was, however, eliminated in the amendment of the Product Liability Act operated by Decree-Law 131/2001.

In turn, a minimum threshold of liability still exists in the Product Liability Act applying to damages in products, which are only recoverable to the extent they exceed the value of 500 euros.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

According to the “loser pays rule”, the defeated party must bear all the costs of the lawsuit, meaning the winning party recovers all expenses borne throughout the lawsuit.

Typically each party bears its own lawyer’s fees. Reimbursement of these expenses occurs only in cases of litigation in bad faith (faulty behaviour during the proceedings).

7.2 Is public funding e.g. legal aid, available?

Yes. Legal aid may be granted on the grounds of economical insufficiency and in different forms, from the exemption of court fees to the appointment of an attorney.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is granted merely on the basis of economic need.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are not allowed by the rules of the Portuguese Bar Association, being impossible to establish that fees will amount to a certain percentage of the value of the claim in dispute or that they will entirely depend on the outcome of the case.

Attorney’s fees should be determined by pre-defined criteria, mainly the time spent with the case and the complexity of the issue in discussion, as well as the importance of the service provided, the wealth of the client and the results obtained. However, part of the lawyers’ fees may be dependent on the success of the proceeding. Such success fees are considered a bonus and not a substitute for the normal fee for the service provided by the lawyer.
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Chapter 36

South Africa

Hofmeyr Herbstein & Gihwala Inc.

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Product liability may arise whenever a product supplied by a distributor or manufacturer contains a defect which causes damage either to person or property.

The manufacturer or designer of a product can be held liable for loss or damage caused as a result of the use of his product, either on the basis of contract or on the basis of delict (unlawful conduct).

The liability is fault based. The strict liability principle has not been adopted in South Africa. The Appeal Court again confirmed on 28 March 2003 that a manufacturer may not be held strictly liable in delict for harm caused by defective manufacture (Wagener v Pharmacare Ltd. and Cuttings v Pharmacare Ltd.).

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any such schemes.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The manufacturer may be held liable based on the doctrine of liability for negligence regardless of contractual privity. In Cooper and Nephews vs Visser 1920 AD the Appeal Court accepted that if the manufacturer’s negligence had caused the loss, it could be sued despite the absence of privity between it and the purchaser.

The distributor will not be held liable in terms of product liability principles.

The retail supplier may be held liable contractually although there will often be no privity of contract between the seller and the ultimate consumer who suffers damage or loss as a result of a defect in the product sold. Such consumer may be left remediless, unless the consumer can prove a breach of warranty of some kind.

The same principles apply for the importer, whether in the capacity of a manufacturer or retail supplier.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Certain safety requirements or minimum standards may have been prescribed in regard to certain products by law often through standards authorities such as the South African Bureau of Standards (SABS) and other regulatory products. It is important for products to comply with such standards and in the event of failure or non-compliance, an obligation could exist to recall such products. A claim for failure to recall will be based on delict and liability follows only if the omission was in fact wrongful; and this will be the case only if in the particular circumstances a legal duty rested on the manufacturer to act positively to prevent harm from occurring and he failed to comply fully with such duty. The causing of damage by means of conduct in breach of a statutory duty is prima facie wrongful.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The claimant must prove that the product is defective or faulty and as a result thereof caused the damage.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

South African Delictual Law distinguishes between factual and legal causation. According to the Appellate Division, the “but for” test applies with regard to factual causation. Different from factual causation is legal causation, which deals with the remoteness of damages and therefore no liability.

A claimant will therefore have to prove that the increased risk to which he/she was exposed to, without any warning about the existence of the risk, caused the harm. The increased risk must be causally connected with the injury
suffered. Without proof of such nexus, the claimant will be unsuccessful.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

It should be ruled by the court that the claimant did not prove his case and the claim should be dismissed. The doctrine of contributory negligence applies in South Africa and may play a role to distribute liability between various parties.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn about inherent or hidden dangers in a product does give rise to liability for the manufacturer. Warnings on a label or instructions in a brochure will be necessary in certain circumstances where the possibility of damage is foreseeable. The manufacturer should know the product it manufactured and must therefore be able to foresee the likelihood of certain events which may cause damage, as long as such events are not too remote.

The manufacturer should inform and warn the ultimate consumer in the event of the product manufactured reaching the consumer in its final form. In such event it should not be necessary for the intermediary to warn further. One would expect of the manufacturer not to supply information to an intermediary which is of a warning nature and not also to warn the end user of such possible danger. Especially if the product is in its final format and already packed and sealed to be on sold to a customer. In the event of an intermediary receiving information from a manufacturer and the intermediary is of the view that the consumer should be warned about an additional danger contained in the information received from the manufacturer, then the intermediary should either not supply the product further on in the chain or it should ensure somehow that the consumer becomes aware of such information about the product. The intermediary cannot just ignore information at its disposal which should be made available to the next entity in the chain of supply.

3 Defences and Estoppel

3.1 What defences, if any, are available?

- The product is not defective and was not used as intended or recommended or prescribed.
- Conclusive state of the art prior tests done.
- Absence of negligence.
- Contributory negligence.
- Consumer contracted out of the right to sue.

If the defendant pleads that the defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

No. It will only be a defence in criminal proceedings. In civil proceedings compliance with legislation will not be a defence to prevent damages being awarded against a party.

3.2 Is there a state of the art/development risk defence?

Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

No. It will only be a defence in criminal proceedings. In civil proceedings compliance with legislation will not be a defence to prevent damages being awarded against a party.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Any claimant may, within the law of prescription, claim damages independent of other similar claims lodged. Each case will be treated separately. Different claimants could have suffered different hardship and the facts of each case may also be different.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

4 Procedure

4.1 Is the trial by a judge or a jury?

Trials are heard by a judge. South Africa does not have a jury system.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, courts in South Africa do not have that power.
South African Law at present does not recognise the class action as a form of procedure to institute action. However, a draft bill making provision for group or class actions has been published for comment. It is, however, not unusual for actions to be brought in South Africa by a number of people with the same interests and where their claims are substantially based on the same facts.

**4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?**

No. Only if the claimants ceded their right, title and interest to such body.

**4.5 How long does it normally take to get to trial?**

It depends in which legal jurisdiction the action was brought. On average it takes approximately one to one and a half years for a matter to be brought to trial.

**4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?**

A court will hear points in limine and special pleas, for example, prescription of a claim first before it entreats the merits of the matter. Parties may also agree to split the merits of the case and quantum of damages of the claim and hear the merits of the case first, thus resulting in the saving of legal costs if the claimant does not succeed in proving the merits of its case.

**4.7 What appeal options are available?**

An automatic appeal from the lower court (Magistrates Court) to the Supreme Court is available. From the judgment of a single judge an appeal to an appeal tribunal of three judges sitting in the Supreme Court is available. However, leave to appeal is required from the single judge. If leave to appeal is not granted, a petition to the Chief Justice will have to be made to obtain leave to appeal. A further appeal from the three judges is available to the Appeal Court.

**4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?**

A court will not appoint experts of its own accord. The parties to the action are entitled to present expert evidence. The nature and extent of the expert evidence are not restricted but a summary of such evidence must be made available to the counter party before the trial commences.

**4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?**

South Africa does not have the deposition procedure.

**4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?**

In terms of our discovery procedure, a party is obliged to make full disclosure of all documents, tape recordings and correspondence relevant to the case and make copies of same available to the other side. The discovery procedure is usually completed by the time the first pre-trial meeting is held a few weeks before the trial commences.

**5 Time Limits**

**5.1 Are there any time limits on bringing or issuing proceedings?**

Yes, certain time limits do exist.

**5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?**

A debt arising from delict or contract prescribes three years after it originated and therefore action must be instituted within such three-year period. Prescription shall commence to run as soon as the debt is due. A debt shall not be deemed to be due until the creditors have knowledge (or ought reasonably to know) of the identity of the debtor and of the facts from which the debt arises. The completion of prescription will be postponed in the event that the person against whom the prescription is running is a minor, or is insane, or is a person under curatorship. It is not within the discretion of the court to apply time limits. In terms of certain Acts of Parliament, periods of notice have been prescribed, and limits of time have been fixed within which actions must be brought.

**5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?**

Prescription will not commence to run in the event of the concealment of facts or a fraudulent act, preventing a claimant from having full knowledge of the facts on which its claim arises.

**6 Damages**

**6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?**

The following types of damages are recoverable: damages for breach of contract; damages for pain and suffering; patrimonial damages such as loss of income; medical...
expenses and damage to property.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No they cannot.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

No, South African Law does not recognise punitive damages.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the amount of damages recoverable provided that the damages claimed from the respective parties are proven by the claimant.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Yes, court fees are recoverable on a party and party scale which provides that the successful party is entitled to recover the court fees in terms of the High Court Rules as per a taxed bill of costs, subject to the discretion of a Taxing Master. In the event that an order as to attorney and client costs is granted by the court, the successful party will be entitled to recover their own legal costs according to the Court Rules from the losing party as per the taxed bill of costs, subject to the discretion of a Taxing Master. In the event that an order as to attorney and own client is granted, the successful party will be entitled to recover all legal costs including the costs of their attorney.

7.2 Is public funding e.g. legal aid, available?

Yes, public funding is provided by institutions such as the Legal Aid Board, the Legal Resource Centre and certain Legal Aid Clinics.

7.3 If so, are there any restrictions on the availability of public funding?

Yes. A means test exists for the purpose of determining the indigence of an applicant for aid. In civil matters the income and assets of the applicant and/or his/her spouse are both taken into account to qualify for aid. However, certain restrictions exist regarding the types of claims and financial assistance is often not provided for monetary claims for damages based on contract and delict.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are allowed in South Africa. However, the “success fee” may not exceed the normal fee by more than 100%, provided that, in the case of claims sounding in money, the total of any such success fee payable by the client to the legal practitioner, may not exceed 25% of the total amount awarded or any amount obtained by the client in consequence of the proceeding concerned, which amount may not for purposes of calculating excess, include any costs.
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- Commercial Litigation (High Court and International);
- Arbitrations;
- Telecommunications;
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- Product Liability;
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Today, this rich historical and cultural mix of the firm in many ways reflects the South African Nation’s diversity. Hofmeyr brings together a diversified collection of legal skills and talents covering most aspects of the law. Drawn together in one cohesive unit, the 43 partners and 280 staff, located in Gauteng and the Western Cape, reflect the full spectrum of the South African Nation.

A number of partners of Hofmeyr have served as Presidents of the Law Society. No fewer than 4 of the firm’s partners have served as acting Judges of the High Court of South Africa over the past three years. Being as enterprising as our clients, we are determined to make things happen, giving a business lead, not just a legal opinion.
1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Defects in products can arise from breach of duty of care (fault-based products liability) or they may be fortuitous (strict products liability).

In the first scenario, notice that in Spain negligence is both a civil and a criminal tort, and product liability cases can be solved either by civil or criminal courts, depending on the action. A practical rule of thumb distinction can be introduced:

- If the defendant’s faulty behaviour caused serious personal injury, criminal law would be paramount. The criminal court would decide about both criminal and civil liabilities, and a general principle of respondeat superior would apply to the latter.
- If only property damages occur, the case will be decided in accordance with civil liability rules, as set out in the Spanish Civil Code, even though criminal law cannot be a priori excludable.


Contractual liability only applies in case of damages to the defective product itself. The parties to the contract can use the contractual remedies in force, if the statute of limitations has still not run. Statutory consumer law limits the parties’ freedom of contract by establishing legal warranties (sect. 5.1 of Directive 1999/44/EC of the European Parliament and of the Council, of May 25, 1999, on certain aspects of the sale of consumer goods and associated guarantees, and sect. 9 of the Spanish Act 23/2003: two years of mandatory warranty for lack of conformity, for new products; and at least one year for used products).

A useful guide covering (civil) products liability case law before 1 Oct 2004 can be consulted in www.indret.com (Pablo Salvador Coderch (ed.) Guía InDret de jurisprudencia sobre responsabilidad de producto. 4ª edición, November 2004).

1.2 Does the state operate any schemes of compensation for particular products?

Up to now, only for civil liability cases arising from the use of tainted blood: Spanish Royal Decree 9/1993 of May 28, 1993 (patients infected in public hospitals with HIV derived from tainted blood). Spanish Act 14/2002 of June 5, 2002 (patients infected in public hospitals with HCV); and Catalonia Act 3/2000 (37th additional disposition, patients residents in Catalonia infected with HCV in public Catalan hospitals). All these provisions subject the benefits of the scheme to the prior renouncing of actions against the public administration, authorities and civil servants.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

The manufacturer and the importer to the European Union are primarily liable (sect. 1 LRCPD). The dealer is only liable if he fails to identify the manufacturer (sect. 4.3).

The manufacturer of the defective component of a product is also liable (sect. 2 of the Council Directive 85/374 and sect. 4.1b LRCPD). The victim may sue both the manufacturer of the final product and of the component, who will be jointly and severally liable (sect. 7 LRCPD).

The existence and scope of a right of contribution between the manufacturer of the final product and of the component is governed by the general law of contracts (breach of contract and aliud pro alio) and tort law (in case of personal injury).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

According to section 4.3b of the Spanish Royal Decree 1801/2003 of December 26, 2003 (implementing Council Directive 2001/95/CE), manufacturers have a duty to recall marketed products as soon as they know or should know that the products present safety risks to the consumers.

Under section 6.1 of this Royal Decree, if manufacturers and
Causation

2.1 Who has the burden of proving fault/defect and damage?

In products defective by negligence of the manufacturer defendant, the historical principle according to which proof of negligence had to be introduced by the plaintiff has been superseded by case law and now a presumed negligence standard with a defence of proving the inexistence of negligence governs most cases.

In strict products liability, and according to section 5 of LRCPD, the plaintiff bears the burden of proving the defect, the harm, and causation.

Section 217.6 of the Spanish Civil Procedure Act (Spanish Act 1/2000 of January 7, hereinafter LEC) introduced the principle of the cheapest cost avoider, which in practice means that courts often shift the burden of proof of the inexistence of the defect to defendants. Same happens, along the lines of res ipsa loquitur, in relation to the causation requirement. The plaintiff still has to introduce evidence enough about the defect itself.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In civil jurisdictions, burden of persuasion is “More Probable than Not”, that’s to say, Preponderance of the Evidence.

Specific tests in order to ascertain the existence of the defects of the products and congenial to products liability have been introduced by the Council Directive 85/374 and sect. 3 LRCPD. In Spain, a Consumer Legitimate Expectations test prevails over a Risk-Utility one. Even though, the second test is waved by defendants in most design defects and failure to warn cases.

The LRCPD considers all circumstances which might cause damage. Therefore, increased exposure to risk if harm materialised would be certainly considered by the court as one of the relevant factors. Whether exposure alone would be enough, will be a matter of regulation for the court. The LRCPD enables the parties to introduce evidence about co-causation or comparative negligence, and Spanish case law reads the products liability statute as a strict liability standard with a defence of comparative negligence.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Multiple injurers are jointly and severally liable in front of the victim (Sect. 7 LRCPD). A right of contribution among them governs the internal relationship: each co-injurer has to pay in the internal relationship according to their individual contribution to cause the harm. A pro rata principle applies as a default rule.

Alternative causation cases are not unknown under Spanish law, and the defendant will be jointly and severally liable for the harm caused. Market share liability has never been formalised as a general principle. In practice, however, presumed causation or alternative causation doctrines might produce similar results.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Inadequate instructions or warnings give rise to liability when risks of harm posed by the product could have been avoided or, at least, reduced if the manufacturer had given adequate warnings, and the omission renders the product unsafe. Appropriate warnings exclude liability (S.Ct., 1st Ch., May 22, 2001). Whether the foreseeability of risk and the reasonableness of the warning requirement play a role is controversial. Case law excludes liability if the victim disregards clear instructions of use (fireworks: S.Ct., 1st Ch., October 5, 1983; cfr. S.Ct, 1st Ch., December 19, 1994: lack of warnings and instructions). In Spain doctrinal analysis is rather skeptical to the well founded U.S. Restatement of the Law Torts, Third: Products Liability thesis that supports the idea that failure to warn cases should be handled under a Negligence rule.

As a matter of rule, clear and effective information has to be supplied to the final buyer and remain accessible to the end-user. Even though a learned intermediary rule governs medical drugs and devices subject to medical prescription, adequate warnings must be given to the end-user (Appeals Court, Valencia, November 22, 1997).

Defences and Estoppel

3.1 What defences, if any, are available?

The defendant can oppose that (i) he had not marketed the
product (sect. 6.1.a LRPCD); (ii) the defect did not exist when the product was marketed (sect. 6.1.b); (iii) the product had not been manufactured to be marketed (sect. 6.1.e); (iv) the product was manufactured complying with mandatory regulations (sect. 6.1.d); or (v) when the product was marketed, it conformed to the state of art (sect. 6.1.e, subject to the exceptions of sect. 6.3: see question 3.2 below).

Under all circumstances, the manufacturer or importer of a component may allege that the defect inheres exclusively to the design of the product that incorporates the component or the inadequate warnings given by the manufacturer of the integrated product (sect. 6.2).

A comparative negligence defence is always available (sect. 9).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

State of art is always a defence for public entities (Spanish Act 13/1992 of September 26, sect. 142, as amended by Spanish Act 4/1999). The defence is also generally available for private defendants except for medical drugs and devices, and food (for human use or consumption, sect. 6.3 LRPCD). The defendant bears the burden of proving that the defect was not discoverable at the time the product was marketed (sect. 6.1).

The manufacturer is under the duty of monitoring successive state of the art changes: if the defect becomes discoverable after the time of (first) supply, the manufacturer is obliged to warn consumers, to report the authorities and, according to the circumstances, to recall the product.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

No. Compliance with mandatory regulatory requirements is a defence (sect. 6.1.d) LRPCD), but even in this case, the manufacturer has a duty to warn the relevant regulatory agency if he knew or should have known that the regulation itself was defective.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Most re-litigation cases relate to failed criminal claims: the plaintiff filed a claim before a criminal court which decided for the defendant, but left open the possibility of assessing (civil) negligence or strict liability before a civil court.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is by a Judge. There are no juries in Spanish civil proceedings.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, it has no such a power. Please see our answer to question 4.8 below in relation to court appointed experts.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Section 11 of the LEC grants legal standing to certain groups of consumers and users, differentiating three situations:

i) Consumers and Users Associations have legal standing to defend the rights and interests of its associates and the Association, as well as the general interests of the consumers and users.

ii) When a group of consumers or users that are identified or can be easily identified, has been damaged, the LEC grants legal standing to (i) Consumers Associations; (ii) legal entities incorporated with the object to defend or protect consumers and users; and (iii) the groups of consumers or users harmed.

iii) When the individuals affected by the damage are not identified or easily identified, legal standing is granted solely to the Consumers Associations which, according to the law, are deemed “representative”.

Any consumer belonging to the class has legal standing to take part in the proceedings initiated by the class action (sect. 13.1 LEC).

In addition, section 15 LEC provides that the class actions brought to court, once they have been admitted, shall be made public through the media in order to call to the proceedings to all the individuals who belong to the class. When the individuals of the class are identified or can be easily identified, the claimant must inform them of the filing of the claim prior to the general call (sect. 15.2 LEC).

Class actions are not frequently brought.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

As stated above, claims can be brought by Consumers and Users Associations and by groups of consumers or users.

4.5 How long does it normally take to get to trial?

The length of the proceedings is to a large extent determined by the Court of First Instance in charge of the case. Generally speaking, the trial takes place between 6 and 18 months since the filing of the claim.
4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

There is a specific stage in the civil proceedings, the preliminary hearing, which takes place after the filing of the answer to the claim, in which the court will examine any circumstances that may hamper the valid continuation and finalisation of the process.

The issues to be decided by the court at the preliminary hearing are: (a) lack of competency to stand trial or lack of representation; (b) res judicata; (c) absence of joinder, (d) inadequacy of the procedure; and (e) legal defects in the claim or the eventual counter claim, due to a lack of clarity or precision regarding determination of the parties or of the claim (sect. 416 LEC).

Issues of fact cannot be brought at this stage of the proceedings.

As mentioned in question 4.1, trial by jury is not permitted.

4.7 What appeal options are available?

There are three appeal options available under LEC.

i) Recurso de reposición (sect. 451 and ff LEC). Motion against interlocutory decisions and non-final rulings. The motion is decided by the same court which issued the appealed decision.

ii) Recurso de apelación (sect. 455 and ff LEC). Appeal against final rulings and judgments issued by Courts of First Instance. The appeal is decided by the Court of Appeal.

iii) Recurso de casación (sect. 477 and ff LEC). Cassation appeal against judgments issued by Courts of Appeal is decided by the Spanish Supreme Court, and is limited to three cases: (i) when the judgement was issued for the protection of fundamental rights; (ii) when the amount involved exceeds €150,000; or (iii) when the resolution of the Court of Appeals has “cassational” interest.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Both parties are entitled: (i) file jointly with their respective pleadings (statement of claim and answer to the claim) the expert reports they deem convenient for the defence of their interests (sect. 336 LEC); or (ii) request from the court the appointment of an expert (Sect. 339 LEC).

The court may also ex-officio appoint an expert in the limited cases established in section 339.5 LEC, among which product liability is not included.

There are no restrictions on the nature or extent of expert evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

As a general rule, there is not pre-trial deposition. Only in exceptional circumstances, the LEC provides for anticipated evidence (sect. 293 and ff LEC) and measures to secure evidence (sect. 297 and ff LEC). Provided that these circumstances are met, factual or expert witnesses may be required to testify.

As mentioned above, as a general rule expert reports are filed jointly with the pleadings of the parties and, therefore, are exchanged prior to trial. Witnesses testify at the trial and there are not witness statements that are exchanged before that moment.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Section 328 LEC provides for the obligation to disclose documents that are not at the disposal of the other party, on the latter’s request. The documents to be disclosed should be identified.

Third parties are obliged to disclose documents only if the court considers their content essential for the judgement to be issued (sect. 330 LEC).

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, there are different time limits, depending on the applicable law.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

i) Spanish Act 22/1994, of July 6 (LRCPD). Time limit is three years from the time when the injured party suffered the harm provided that the person responsible for the said harm is known.

ii) Spanish Act 26/1984, of July 19, Consumers Protection Act (LGDCU). If the LRCPD is not applicable (according to its Final Provision 1), and when the individual who suffered the damage can be considered a consumer or user, in terms of article 1.2 of the LGDCU, articles 25 to 28 of this Law are to be applied. The LGDCU does not lay down an express time limit for bringing actions under Sections 25 to 28. In default thereof, the case law resorts to the general rules under the Spanish Civil Code: i.e. 15 years if the liability is contractual (sect. 1964 CC) and one year if the liability is in tort (sect. 1968.2 CC). If the liability is both contractual and non-contractual, time limit is considered to be 15 years.

iii) Section 1902 Spanish Civil Code. Damages other than those above must follow the general regime of the Civil Code: 15 years for contractual liability (1964 CC) and one year for non-contractual liability (1968.2 CC).

As a general rule, time limits start when all consequences of the damage are definitely known.

Age and condition of the claimant do not affect the
calculation of any time limit. As regards discretion of the courts to disapply time limits, generally speaking the courts tend to favour the plaintiff when determining the *dies a quo*.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment and fraud may affect the running of time limits if they prevent the plaintiff from knowing the “responsible” party of the damages produced.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under LRCPD, property damage (excluding harm to the product itself) and personal injuries can be recoverable, but not pain and suffering (sect. 10.1), which are covered by the general Civil Code provisions (sect. 10.2). Damages to the product itself are governed by the law of contracts. Loss of profit is recoverable, but not economic loss (controversial). Harms derived from nuclear incidents are not covered by the LRCPD (sect. 10.3).

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The plaintiff has a cause of action if he or she can introduce enough evidence about increase of risk derived from a potential defect of the product. But mere apprehension or speculation is not enough.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are unknown to the Spanish courts and also contrary to the European *Ordre Public* (sect. 24 of the Proposal for a Regulation of the European Parliament and the Council on the law applicable to non-contractual obligations, “ROME II”), but if the manufacturer is found to have acted wilfully or even negligently and the product caused personal injuries, the Public Prosecutor and the victim (or relatives if death occurred) may file criminal actions.

In addition to that, case law includes many instances in which pain and suffering awards are used to (over)compensate victims of egregious torts, especially in cases of intentional torts and gross negligence. Pain and suffering is also used by the courts to justify a substantial award when the court is persuaded by the existence of damages, but the evidence introduced by the plaintiff is poor.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The global civil liability that can be imposed to the producer for the same defect in the same product is limited to a maximum amount of € 63,106,270.96 (sect. 11 LRCD).

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party is entitled to recover costs from the losing party, provided all claims made by the latter are dismissed and unless the court finds that the case presented serious factual or legal doubts (sect. 394.1 LEC).

Recoverable costs are: (i) fees paid by the successful party to its lawyer and court agent; (ii) fees paid to experts and other costs related to other persons who have intervened in the proceedings; and (iii) court fees, if any, and other incidental expenses (sect. 241 LEC).

Recoverable costs are determined by the court clerk (sect. 243 LEC).

Concerning attorney’s fees, the only legal limit is established in a third of the amount involved in the case, unless the court declares that the losing party behaved in a reckless manner (sect. 394.3 LEC). Nevertheless, attorney’s fees are usually calculated taking into account the guiding criteria established by the bar associations.

7.2 Is public funding e.g. legal aid, available?

Article 119 of the Spanish Constitution provides for public funding when the law so establishes it or when the litigant proves lack of economic resources to litigate. Spanish Act 1/1996 of January 10th on Free Public Legal Aid and its Regulation 2103/1996 of September 20th develop such a Constitutional principle, and state the requirements, contents and administrative proceedings to obtain free public legal aid.

7.3 If so, are there any restrictions on the availability of public funding?

Availability of public funding is limited to individuals whose income do not exceed certain limits and to Associations declared of public interest providing they prove lack of economic resources to litigate.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The Advocacy General Statute does not allow conditional or contingency fees. It nevertheless allows that a part of the attorney’s fees is subject to the result of the proceedings (sect. 44 Spanish Royal Decree 658/2001, of June 22, Advocacy General Statute).
Acknowledgement

Laura Camarero and Juan-Antonio Ruiz, associates at Cuatrecasas, have also contributed in the drafting of this chapter.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

The Swedish Product Liability Act (1992:18) ("PLA") specifically concerns liability arising from personal injury or damage to consumer property caused by a defective product. The PLA is based on EC-directive 85/374/EEC and provides for strict liability, i.e. no finding of negligence is required. The injured party need only prove that the product was defective and that the injury occurred as a consequence thereof.

More general principles of liability can be found in the Torts Liability Act (1972:207), which provides for liability based on negligence. The Torts Liability Act supplements the PLA as lex generalis. Further and since the PLA does not apply to damage caused to property used for business purposes, the Torts Liability Act provides for product liability in that area.

In addition, there are acts regulating certain specific areas, such as e.g. electricity, environment and explosive goods. These acts supplement the PLA as lex specialis and provide for strict liability.

Contractual liability may play a part e.g. in the relation between consumers and retailers/service providers. In addition to the liability primarily provided for manufacturers under the PLA, the Consumer Sales Act (1990:932) and the Consumer Services Act (1985:716) give a consumer the possibility to claim compensation from retailers/service providers for damages to consumer property caused by defective products and services. Contractual liability may also play an important part as a basis for recourse in business relations, e.g. when a business has had to provide compensation due to product liability and wishes to reclaim those costs from its supplier in turn of the defective product.

1.2 Does the state operate any schemes of compensation for particular products?

The state operates compulsory insurance schemes under the Patient’s Compensation Act (1996:799) for injuries caused by medical treatments and the Traffic Compensation Act (1975:1410) for traffic-related injuries. A private Pharmaceutical Insurance Scheme covers product liability for pharmaceutical products. In addition, the Swedish social security insurance system compensates loss of income and expenses for medical care up to a certain level. A particular social insurance covers damages due to work-related injuries.

By these various schemes of compensation, the scope for damages in product liability cases is effectively limited.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the PLA the responsibility is primarily imposed on the manufacturer of the defective product. The definition of a “manufacturer” is broad and may include the manufacturer of a finished product, the manufacturer of a component part, and any person who, by putting his name, trade mark or other distinguishing feature on the product, can be deemed to have represented himself as its manufacturer. An importer, who brings a product into the European Economic Space ("EES"), will also be considered primarily liable on terms equal to a manufacturer.

In addition, anyone having supplied a defective product - e.g. a retailer or wholesaler - may be held secondarily liable, if none of the above primarily liable parties can be identified. This liability applies if the secondarily liable supplier fails to inform the injured person, within one month from the date of the claim, of the identity of someone primarily liable or of the secondarily liable supplier being next in the supply chain. This opportunity, to avoid product liability by referring liability onward, is only available to suppliers with secondary liability.

If two or more manufacturers can be held liable for the same defect, they are liable jointly and severally.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A revised Product Safety Act (2004:451) ("PSA"), incorporating the directive 2001/11/95/EEC into Swedish national law, entered into force 1 July 2004. The PSA applies to goods and services which are supplied on a commercial basis and which are designed to be used by consumers or can be expected to be used by consumers. A manufacturer who
has supplied a dangerous product must, without delay, recall the product from the distributors holding it, if required in order to prevent injuries. If such a recall is not sufficient to prevent injuries, the manufacturer shall also recall the products directly from the consumers holding it. A manufacturer, who intentionally or by negligence fails to comply with the duty to recall dangerous products, may be liable to pay penalties. The Swedish Consumer Agency generally supervises the application of the PSA and may apply for such penalties to be imposed.

The fact that a recall is carried out does not relieve the manufacturer from possible liability in damages according to the PLA.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The injured party must prove the defect, the damage and the causal relationship between the two. He or she must also prove the scope of damage suffered.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The ordinary standard of proof under Swedish law applies. This standard is relatively demanding and it will generally not suffice to merely prove causation on the balance of probabilities. To fulfil the ordinary standard of proof can be difficult in cases where there may be several, possible causes for an injury, involving complicated technical and scientific issues over which experts may have different opinions. For such cases the Supreme Court has established a rule, which eases the burden of proof for the claimant. According to the rule, it is sufficient for the claimant to present a causal relationship, which is clearly more probable than any other explanation for the injury presented by the defendant. The causal relationship presented by the claimant must also be plausible in itself, taking all circumstances into account.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

It is unclear what the Swedish position would be if a claimant cannot prove or even make probable which one of several possible producers have manufactured the defective product. The principal rule is that the claimant has the burden of fully proving his or her case. As mentioned under question 1.3 above, if the manufacturer of a product cannot be identified, each supplier of the product can be held secondarily liable. The purpose of this rule is to provide protection to consumers and to minimise the risks that no liable entity can be identified. Division of liability on the basis of market share is not a concept generally recognised in Swedish law.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

According to the PSA a manufacturer of a product or a supplier of a service is obliged to provide the consumer with such information on safety issues that may required in order for the consumer to assess the risks of the product or service and to protect him- or herself from such risks. Failure to provide adequate safety information may lead to a product being considered “defective” and thus provide basis for liability under the PLA. The extent and the type of information required may vary due to the circumstances. Factors to be considered are the type of product and the range of its uses. Another important factor is the range of potential users and the skills of these users. If the product is to be used mainly by adult professionals or by small children, this substantially affects the requirements of the safety information.

Furthermore, a manufacturer who has put a product on the market, which later proves to be dangerous, shall according to the PSA immediately inform about the risks which the product might pose. The information shall be given in an appropriate form to the consumers concerned, either in the form of direct messages or through advertisements or similar published information. The information shall also be given to the supervising authorities.

Although no supporting precedent exists, Swedish law would likely recognise the principle of the “learned intermediary”, at least within certain specific fields, such as e.g. a doctor prescribing medicine to a patient. However, the precise extent to which the duty to supply safety information could be discharged through a “learned intermediary” is unclear. (For example, although a doctor is under a duty to assist a patient in making an informed choice with regard to medication and thus to provide certain safety information, the manufacturer is also obliged to provide such information directly to the patient in the form of a package insert included with the medication. If the manufacturer fails to provide such information, he may not be able to rely on the doctor’s duty to inform as a full defence).

3 Defences and Estoppel

3.1 What defences, if any, are available?

A manufacturer can avoid liability if he is able to prove:

- that he did not put the product into circulation in any
kind of business activity;

- that, having regard to the circumstances, it is probable
  that the defect which caused the injury did not exist at
  the time when the product was put into circulation by
  the manufacturer (i.e. the defect has arisen due to
  subsequent misuse, lack of maintenance or tampering
  with the product);

- that the defect is due to compliance of the product
  with mandatory regulations issued by the authorities;

- that the state of scientific and technical knowledge
  ("state of the art") at the time when the manufacturer
  put the product into circulation was not such as to
  enable the existence of the defect to be discovered; or

- that the defect and associated risk is of a nature
  generally known and accepted by society in relation to
  the product ("systemic defence"). This may apply to
certain very specific product categories, such as e.g.
alcoholic beverages, tobacco or medicinal products
with publicly disclosed side-effects.

In addition to the abovementioned the liability of the
manufacturer may be reduced or disallowed, if he can prove
that contributory negligence by the injured party has played
a part.

Finally, the manufacturer will not be held liable if the
claimant is unable to prove the existence of a defect, an
injury and a causal relationship between the two.

3.2 Is there a state of the art/development risk defence?
Is there a defence if the fault/defect in the product
was not discoverable given the state of scientific
and technical knowledge at the time of supply? If
there is such a defence, is it for the claimant to
prove that the fault/defect was discoverable or is it
for the manufacturer to prove that it was not?

Swedish law provides for a state of the art / development risk
defence (see question 3.1 above, fourth bullet-point). It is
for the manufacturer to prove that the state of scientific
and technical knowledge at the time when he put the product into
circulation was unable to discover the existence of the
defect.

3.3 Is it a defence for the manufacturer to show that he
complied with regulatory and/or statutory
requirements relating to the development,
manufacture, licensing, marketing and supply of the
product?

Swedish law provides for compliance with mandatory
requirements as a defence (see question 3.1 above, third
bullet-point). It is important to stress that referring to other,
non-mandatory, regulations issued by public authorities or
others, for example technical standards, does not necessarily
relieve the manufacturer of liability.

3.4 Can claimants re-litigate issues of fault, defect or
the capability of a product to cause a certain type
of damage, provided they arise in separate
proceedings brought by a different claimant, or does
some form of issue estoppel prevent this?

There exists no form of issue estoppel under Swedish law
preventing a different claimant from re-litigating issues of
fault in a new proceeding. Procedural principles of res
iudicata will, however, prevent the same claimant from re-
litigating the same issue against the same counterparty.

4 Procedure

4.1 Is the trial by a judge or a jury?

The trial is - as in almost all civil matters in Sweden - by
judge. In civil litigation the trial in the District Court is by
one to three professional judges and in the Court of Appeal
by three to five professional judges. Finally, if leave to
appeal is granted, the trial in the Supreme Court is by three
to seven professional judges.

4.2 Does the court have power to appoint technical
specialists to sit with the judge and assess the
evidence presented by the parties (i.e. expert
assessors)?

Yes, the court has the power to appoint technical specialists.
This is, however, very rarely done.

4.3 Is there a specific group or class action procedure
for multiple claims? If so, please outline this. Are
such claims commonly brought?

On 1 January 2003 a new Swedish Act on Class Actions
came into force allowing class actions to be brought before
Swedish courts. This means that one plaintiff may litigate
on behalf of a passive group of class members, who -
although not being parties to the proceedings in the formal
sense - will nevertheless be bound by the court’s decision.
Class actions are not, as of yet, commonly brought in
Sweden and no such action has, (again) as of yet, been
finally adjudged.

Three forms of class actions are allowed under the new act.
Any person or entity may initiate a Private Class Action
provided that such person or entity has a claim of its own
and is a member of the class. Further the law provides for
Organisational Class Actions, meaning that certain
organisations may bring class actions without having a claim
of their own. Such actions may be initiated by consumer-
and labour organisations and must, as a general rule, concern
disputes between consumers and providers of goods or
services. Moreover, the law provides for Public Class
Actions whereby an authority appointed by the Government
may act as plaintiff and litigate on behalf of a group of class
members.

The act is based on a so-called “opt in” solution. This means
that a class member must choose whether or not he wishes to
be included as a member of the class. Only class members
who have given written notice to the court and thus chosen
to “opt in”, will be allowed to participate in the proceedings
as passive members of the class.

In order for a class action to be permitted questions of fact
must be common or similar to the entire class. Although the
threshold for fulfilling this requirement is set rather low, a
class action should not be permitted if there are substantial
individual differences between the claims within the class.
The law also requires that a class action is the best
alternative compared to other forms of procedure such as
joinder of claims and the “pilot case” model. In addition, the class must be well defined and the plaintiff must be suitable to represent the class.

Judgements in class actions are subject to appeal to the same extent as decisions in normal legal proceedings. Any member of the group may file an appeal. If an appeal is made, the Court of Appeal will consider the special prerequisites required for class actions. If the court finds that the prerequisites for a class action are not fulfilled, the appeals will be dealt with as individual cases.

The new law provides that the current rules on costs in the Procedural Code apply also to a class action. Thus, cost should follow the event. However, the passive class members have, as a general rule, the right to a fee and the number of other cases depending on a number of factors, such as e.g. the complexity of the case, the skill of counsel, the use of delaying tactics, the efficiency of the judge and the number of other cases pending before the particular court. As a general rule, it will take at least 1-2 years before parties can expect to go to trial before a court of first instance.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

If the court considers it to be appropriate, it can decide to try certain issues in a separate judgement. Generally, the court will only adopt such an approach if it believes that, in so doing, it may dispose of all or a substantial part of the case. Questions to be tried and determined in such a separate judgement can either be issues of fact, which are of significance to the final outcome of all or part of the case, or certain matters of law, which are in need of clarification.

Product liability cases are tried by professional judges only (see question 4.1 above).

4.7 What appeal options are available?

District court judgements may be appealed to the Court of Appeal without restriction, except in cases where the amount claimed is very small. Appeal to the Supreme Court is only available after having been granted leave. For the Supreme Court to grant such leave, it is generally required that the case involves an issue, the outcome of which could have a significant value as legal precedent for the larger legal community.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint an expert to assist on technical issues or issues requiring specialist knowledge. However, this is rarely done. Instead the parties usually appoint and instruct such experts themselves. In general, there are no restrictions on the nature or extent of expert evidence. However, if the evidence is deemed clearly unnecessary, it may be rejected by the court.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Under Swedish procedural law there are no pre-trial depositions of witnesses or exchange of witness statements. Experts are, however, generally required to submit a written statement outlining their evidence prior to the trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

There is no duty on a party to disclose documentary evidence to the other party prior to proceedings being commenced (pre-trial discovery). During the preparatory stage (see question 4.5 above), each party will invoke and submit the written evidence on which he or she intends to rely at the main hearing. In addition, a party may request the court to order documents to be produced by the other party (or a third party). Such a request will generally be granted,
provided it concerns sufficiently specified documents or categories of documents and is accompanied by a declaration explaining how the particular document may be relevant as evidence to the requesting party’s case.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

According to the PLA, an injured party, who wants to recover damages, has to file a suit before court within three years from the day on which he or she became aware of, or should reasonably have become aware of, (a) the deficiency in the product; (b) the injury; and (c) the causal relationship between the two. A claim must further, at the latest, be filed within ten years from the day on which the manufacturer put the particular product into circulation. Finally, the general law on torts stipulates a time limit of ten years to commence legal proceedings, calculated from the negligent act or omission causing the injury.

Personal circumstances, such as age or physical condition, will generally not excuse an injured party from failing to adhere to prescribed limitation periods and the court can not exercise any discretion in applying such periods.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Issues of concealment or fraud will not generally affect the running of any time limit, save where such concealment or fraud effectively postpones the fulfilment of requirements for the time period to start running (see the understanding required from the injured party in order for the three year limitation period to start running in question 5.2 above).

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

- Damage to the defective product itself is not covered by the PLA. In order to recover such damages the claimant has to refer to contractual liability for the sale of goods.
- The PLA stipulates that personal injuries are covered by the act and will be compensated. According to general tort law, the expression personal injury includes both physical as well as mental injuries, including death.
- Damage to property (excluding the defective product itself) is compensated under the PLA, though there are two notable restrictions. First, the property has to be of the type ordinarily intended for private use and de facto used by the injured person mainly for such private, non-commercial purposes. Second, an amount of SEK 3,500 is deducted from the damages.

According to general torts law based on negligence, damage to property may be compensated without the abovementioned restrictions.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The position under Swedish law is unclear on this point. However, provided the existence of a defect in the product can be proven, it is possible that a producer may be held liable for costs of medical monitoring undertaken to detect and limit possible injuries. One of several prerequisites would be that a sufficiently direct link can be established between the defect and the monitoring measures taken.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Damages are exclusively compensatory under Swedish law. Punitive damages are not available.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit or ceiling for damages. If the damages are considered unreasonably burdensome, the manufacturer may, however, be able to assert that the damages should be limited. Such a limitation will only apply in exceptional cases, when the damages are significantly higher than what would be considered a normal risk in the manufacturer’s line of business.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Court fees and legal costs (including attorney’s fees and costs for evidence) are, as a general rule, fully recoverable from the losing party.

7.2 Is public funding e.g. legal aid, available?

For consumers, generally, insurance covers legal fees up to a certain level. Legal aid exists, but is subjected to considerable limitations in respect of product liability issues.

7.3 If so, are there any restrictions on the availability of public funding?

Yes (see question 7.2 above).
7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are generally not allowed under the rules of the Swedish Bar Association. However, to some extent it is possible to have fee arrangements, allowing a somewhat higher fee to apply if the assignment is successful and a lower fee to apply if it is not. As described in question 4.3 above, so-called “risk agreements” are allowed in Swedish class action suits. A claimant may thereby agree with his counsel that the fee should be dependent on the outcome of the case. A risk agreement requires approval of the court. If the court has approved a risk agreement, the payment specified by the agreement can be paid out of the means won by the group in the proceedings.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

The Swiss Product Liability Act (“PLA”), enacted on January 1, 1994, largely adheres to the principles of EC Directive 85/374, and provides for the strict liability of a manufacturer, importer or supplier for death, injuries, damages or destruction of an object for private use caused by a defective product. The liability of a producer to an injured person may not be limited or excluded by contract (Article 8 PLA).

Pursuant to Article 11(1) PLA, the PLA does not replace statutory provisions on tort and contractual liability. Thus, an injured person may base a claim either on the provisions of the PLA or on the statutory provisions governing implied warranty, general contractual liability and/or extra-contractual tort liability, including liability of the principal for acts of his subordinates, and tort liability of a real estate owner (particularly Articles 197 et seq., Article 97, Articles 41 et seq. and Articles 55 and 58 of the Swiss Code of Obligations; “CO”). While direct damages for breach of an implied warranty in a sales agreement is (exceptionally) based on the strict liability of the seller, indirect damages resulting from breach of an implied warranty and tort damages can only be recovered based on fault.

A claim for product liability can also be brought based on the civil responsibility of a real estate owner for damages emanating from the property (Article 679 of the Swiss Civil Code; “CC”), or it can be based on the contractual responsibility of the contractor for the quality of his work (Articles 368 et seq. CO). Product liability-related relief may also be sought based on federal statutes that regulate specific kinds of resources, activities, industries and crafts, and which contain provisions on product liability. These include Article 27 of the Electricity Act, Article 28 of Motor Vehicle Traffic Act, Article 1 et seq. of the Federal Act on the Liability of Train and Steam Ship Transportation Enterprises and the Swiss Post, Article 59a of the Environmental Protection Act, Article 37 of the Explosives Act, Article 33 of the Pipelines Act and each of the applicable regulations and ordinances.

The alternative statutory provisions discussed above are important as they remain the basis for claims that are beyond the scope of the PLA, including claims for damages to objects of commercial or professional use (the PLA applies only to products for private use), for damages less than the statutory minimum of 900 Swiss Francs provided for by Article 6(1) PLA, for damages resulting from agricultural and hunting equipment that have not yet been subject to processing as defined under Article 3(2) PLA, for the equitable compensation of pain and suffering (mental damage) and, finally, for purposes of evaluating causal connection.

1.2 Does the state operate any schemes of compensation for particular products?

Switzerland does not operate any schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Under the PLA any person that meets the statutory definition of a “producer” is strictly liable for its defective product. Under the statute, a “producer” includes the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part (Article 2(1)(a) PLA), any person who presents itself as a producer by putting its name, trademark or other distinguishing feature on the product (Article 2(1)(b) PLA), and any person who imports into Switzerland a product for sale, hire, leasing or any form of distribution in the normal course of business. Under the PLA responsibility for a fault or defect also falls on the producer of a defective raw material or the maker of a defective component (Article 2(1)(a) PLA). The PLA further provides that where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer, unless it informs the injured person, within a reasonable time period, of the identity of the producer or of the person(s) who supplied it with the product (Article 2(2) PLA). The same applies in the case of an imported product, if such product does not properly indicate the identity of the importer (Article 2(3) PLA).

Apart from the PLA (see above question 1.1), applicable tort and civil law, including relevant case law, generally provides
for the fault-based product liability of tortfeasors, real estate owners, sellers, and contractors, and specifically establishes the fault-based product liability of manufacturers, retailers, wholesalers and distributors, as well as component manufacturers. Federal statutes regulating specific resources, activities and industry sectors (see above question 1.1) generally establish a liability regime based on the principle of causation.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The PLA does not specifically provide for the recall of defective products, nor for the issuance of a warning to consumers following the discovery of a defect. Nor does it provide that the liability of the producer be limited as a result of a recall.

Based on the applicable case law of the Federal Supreme Court, a duty to recall may, in appropriate circumstances, be found under general civil and tort law. In this respect, it is a generally accepted principle in Swiss law that a producer (in the broad sense of the term; see above question 1.3) has a duty to observe the use of his products and to take reasonably appropriate measures to prevent accidents if he discovers a source of danger. Swiss doctrine further maintains that a duty to recall may also arise under Articles 2, 3, 7 and 9 of the Swiss Unfair Competition Act (“UCA”) by reason of the deception of competitors and consumers, such as the placement into commerce of a product that has a hidden defect or does not comply with applicable product or safety standards.

A properly-executed recall and/or a warning directed to consumers and/or users of a distributed product, while not discharging the producer from liability, may reduce the damages in any subsequent action. Moreover, in the event that an injured party keeps the defective product despite a recall or uses it in disregard of a proper warning, the producer may be able to assert a defence of contributory negligence.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The injured person must prove that the defendant is a producer within the meaning of Article 2 PLA.

The general provisions of the CO apply to proving a defect, the causal relationship between the defect and the damage, and the amount of damage by virtue of Article 11(1) PLA. For damage claims brought under the PLA or under other provisions of tort law, the burden of proof is on the party requesting relief (Article 42(1) CO); for damage claims based on a breach of contract, the burden of proof for the absence of fault is on the party in breach (Article 97 CO).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

To decide whether the defendant’s conduct played a sufficient role in bringing about the damage, Swiss courts apply the theory of adequate causation and examine the course of events as a whole. An act is considered relevant for this purpose only if every day experience shows that it normally leads to the type of damage that occurred. The theory of adequate causation allows Swiss courts to set limits on liability where the chain of causation has been interrupted by independent causes or by events for which the defendant is not responsible. If the damage results from an extraneous cause of this kind, the effect under Swiss law is to exonerate the tortfeasor in whole or in part.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Where two or more persons are liable for the same damage, Article 7 PLA provides that these persons shall be liable jointly and severally. There is no established jurisprudence applying market-share liability in Switzerland.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Pursuant to Article 4(1)(a) PLA, a product is defective when it does not provide the safety which a person is entitled to expect, taking all of the circumstances into account, including the presentation of the product. A product is thus deemed to be defective if the information given by the producer is inadequate or necessary information is absent. Failure to adequately warn gives rise to liability. According to doctrine, however, if the danger of a product is well known or obvious, warnings are not required and the product is not deemed to be defective by reason of such danger. Furthermore, a producer is not liable if his product was safe but the consumer did not respect the warnings which were correct, complete, sufficiently precise and comprehensible.

The PLA does not specifically provide for the principle of “learned intermediary”, nor does it provide that the liability
of the producer will be limited if information is supplied to such a “learned intermediary”. In such a case, the normal standard of adequate causation would be applied to the specific facts of the case. In the case of pharmaceutical products, however, the Federal Act on Therapeutical Products provides that product information shall be provided to the consumer in the product packaging.

### 3 Defences and Estoppel

#### 3.1 What defences, if any, are available?

A producer can rely on six statutory defences under the PLA. A producer is not liable if he proves: (i) that he did not put the product into circulation (Article 5(a) PLA); (ii) that the defect which caused the damage did not exist at the time when the product was put into circulation (Article 5(b) PLA); (iii) that the product was neither manufactured for sale or any other form of distribution with a financial purpose, nor distributed by the producer in its normal course of business (Article 5(c) PLA); (iv) that the defect occurred due to compliance with mandatory regulations and standards issued by the public authorities (Article 5(d) PLA); (v) that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered (Article 5(e) PLA); and (vi) (in the case of a producer of raw material and/or component manufacturer) that the defect is attributable to the design of the product in which the component or material has been incorporated to the instructions given by the manufacturer of the product (Article 5(2) PLA).

Outside of the scope of the PLA (see above question 1.1), applicable case law of the Federal Supreme Court establishes a variety of defences to product liability claims, including contributory negligence or wilful misconduct on the part of the injured person, the voluntary and lawful consent or acceptance of the injured person to the injury, the objectively unforeseeable use of a product inconsistent with its purpose and with the instructions issued by the producer, and, similar to Article 5(e) PLA, a state-of-the-art defence. According to article 43 et seq. CO, a Swiss court may reduce compensation in cases of contributory negligence, and refuse compensation in cases of wilful misconduct or gross negligence.

#### 3.2 Is there a state of the art/development risk defence?

Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Both within and outside of the scope of the PLA, the producer (in the broad sense of the term; see above question 3.1) is not liable if it proves that the state of scientific and technical knowledge at the time when it put the product into circulation was not such as to enable the existence of the defect to be discovered (Article 5(e) PLA and case law; see above question 3.1). The producer has the burden of proving that the defect was not discoverable at the time of supply.

#### 3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under the PLA the producer (in the broad sense of the term; see above question 1.3) is not liable if it proves that the defect is due to compliance of the product with mandatory regulations issued by the public authorities (Article 5(d) PLA; see above question 3.1).

#### 3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Claimants can re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant.

### 4 Procedure

#### 4.1 Is the trial by a judge or a jury?

Switzerland does not have a system of trial by jury for civil litigation and therefore all cases are tried before a judge. Litigation is generally conducted in writing (exchange of briefs, including proposed means of evidence).

#### 4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not have the power to appoint technical specialists to sit with the judge or assess the evidence presented by the parties. However, some courts, especially the Commercial Courts that exist in some cantons, will designate lay judges specialised or experienced in the technical field or industry pertinent to the case at hand.

#### 4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

Swiss procedural regulations do not provide for class actions, but it is possible in certain circumstances to file claims as a group of plaintiffs, or against a group of defendants. While applicable procedural regulations on this point vary considerably among the different cantonal jurisdictions, generally, claims of a group of plaintiffs are admitted if they are directed against the same defendant and if the cause of action is sufficiently similar or identical. Conversely, for a claim against a group of defendants to be admitted all defendants must be subject to the jurisdiction of the same competent court and the cause of action must be sufficiently similar or identical.
4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Group actions may be permitted when they further judicial efficiency and economy. The independence of the legal relationship characterising each of the group members, however, is not affected by these circumstances. The effect of a judgment is independent for each member of the group and judicial acts of each member of a group are attributable only to each such member. Where efficient, the members of the group may appoint a joint counsel and form an association to bring a lawsuit on behalf of its members. The association must have legal personality; its members need to have the legal capacity to bring the lawsuit on their own; the members must have assigned their rights to the association; and the constitution or statutes of the association must stipulate the protection of the interests of its members.

Under the UFA relief in connection with the anti-competitive placing of a defective product into commerce (such as the demand for a recall; see above question 1.4) may also be sought by professional and industry sector associations and consumer protection associations on behalf of their members, and by the Federal authorities if it can be established that the defect of the product is detrimental to Switzerland’s image abroad (Article 10 UFA).

4.5 How long does it normally take to get to trial?

Each canton has its own civil code of procedure and judicial practice and thus the average time to get to trial varies among the cantons. In cantons such as Zurich or Geneva, it typically takes approximately two months from the filing of a complaint to get to trial. However, provisional measures may be obtained provided that the injured party/plaintiff can show a prima facie case, urgency, and irreparable harm.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Preliminary trials do not exist in Switzerland.

4.7 What appeal options are available?

Most cantons are divided into jurisdictional districts with a District Court operating as the tribunal of first instance. Generally, judgments rendered by a District Court may be appealed to the cantonal High Court which is the second instance court. In some cantons, the cantonal High Courts or Courts of Appeals can review the facts of the case as well as the law; in most cantons, however, the Higher Court or Court of Appeals may only examine whether the lower court has correctly applied the law.

Judgments rendered in civil matters by the cantonal High Courts or Courts of Appeal may be appealed to the Federal Supreme Court if the amount of the judgment exceeds 8,000 Swiss Francs (Article 46 Federal Act on the Organization of the Judiciary (“OJA“)). The Federal Supreme Court is the sole federal judicial court and the highest court in Switzerland. Appeals to the Federal Supreme Court are limited to questions of law. Unless there is a breach of federal rules of evidence, the Federal Supreme Court is bound to the findings of the cantonal courts as regards the facts and will not rule ultra petita (Article 63(1) and (2) OJA).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint independent experts to address technical questions and parties may introduce expert evidence. The judge is free to determine the weight to be given to expert evidence and generally will give greater weight to the opinion of a court-appointed expert, who is considered to be impartial, than to a party-appointed expert.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Pre-trial depositions do not exist in Switzerland. Witness statements and expert reports are usually introduced during the trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Common law pre-trial discovery procedures do not exist in Switzerland. There is no obligation to disclose documentary evidence before the commencement of evidentiary proceedings.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Claims for the recovery of damages brought under the PLA are subject to a three-year statute of limitations. Article 9 PLA provides for a relative statute of limitation, which begins to run from the day on which the plaintiff becomes aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer. Article 10 PLA further provides for an absolute statute of limitation which bars any claim brought after the expiration of a period of ten years from the date on which the producer put into circulation the product which caused the damage.

Claims for recovery of damages based on sales warranties are subject to a statute of limitation of one year after the delivery of the purchased goods (except where defects were wilfully concealed (Article 210 CO)). Other claims for recovery of damages are generally subject to a statute of limitation of ten years from the day on which the amount becomes due (Articles 128 et seq. CO). Claims based on tort are barred one year from the day on which the plaintiff becomes aware or should reasonably become aware of the damage and of the identity of the liable producer, or ten years after the commission of the tortuous act (Article 60 CO).
The limitation period set by these statutes of limitation may be interrupted upon the recognition of the damage and the ensuing debt by the producer, by the initiation of enforcement proceedings, or by the filing of a claim against the producer.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

The time limits vary depending on whether the liability is based on the PLA (see above question 5.1). In general, the age or the condition of the claimant will not affect the calculation of the time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

With regard to claims for the recovery of damages brought under the PLA, the statute of limitation of Article 9 PLA (see above question 5.1) takes into account the issues of concealment or fraud as it only begins to run from the day on which the plaintiff discovers or should have discovered the defect and the identity of the producer. Pursuant to Article 10 PLA (see above question 5.1), however, any claim brought after the expiration of a period of ten years from the date on which the producer put into circulation the product which caused the damage is barred, even if the plaintiff was prevented from discovery of the defect and the identity of the producer because of concealment or fraud.

According to jurisprudence, if defects were wilfully concealed claims for recovery of damages based on sales warranties are no longer subject to a statute of limitation of one year (Article 210(1) CO) but of ten years from the date of the delivery of the goods.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Pursuant to Article 1 PLA, the damage caused by death or by personal injuries and damage to, or destruction of, any item of property other than the defective product itself (Article 1(1)(a) and (2) PLA) are recoverable if the damaged property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for his own private use or consumption (Article 1(1)(b) PLA). Furthermore, the PLA provides for a statutory minimum of 900 Swiss Francs (Article 6 PLA).

Damages for pain and suffering (mental distress) are not recoverable under the PLA, but can be claimed by the injured party or his close relatives as an equitable remedy pursuant to general tort law (Article 47 CO). The amount of the damage award is within the reasonable discretion of the judge; it will be determined according to the nature and seriousness of the injury, the effect and duration of the suffering and the degree of fault of the tortfeasor, but usually leads to rather modest awards which are paid out in a lump sum.

Swiss tort law further permits the recovery of damages that result from a relative’s death (bereavement damages), including burial costs, medical expenses, and the loss of financial support to the persons related to the deceased (Article 45 CO).

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

While there is no established Swiss jurisprudence on claims for the cost of medical monitoring in the absence of an injury, according to some authors such costs might be claimed even in the absence of the occurrence of an injury, based on the civil law principle of unjust enrichment under Articles 62 et seq. CO, although in the authors’ view this is doubtful.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Awards of punitive damages or exemplary damages are unknown and even considered a violation of Swiss public policy. Pursuant to Article 135(2) of Swiss Private International Law Act (“PILA”), Swiss courts must refuse the award of punitive damages even if the payment of such punitive damages is provided for by the applicable foreign substantive law.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable from one manufacturer

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Court fees must be advanced by the plaintiff prior to the commencement of the proceedings and can ultimately be recovered from the losing party. The losing party must pay all or a portion of the legal costs of the winning party. If neither party prevails, the court may divide the court fees and leave each party to bear its own legal costs.

7.2 Is public funding e.g. legal aid, available?

A party can be exempted from paying court costs if it can establish prima facie that is has a valid case on the merits and that it is unable to pay the court fees and attorney costs. Such a party has the right to nominate an attorney without charge, who is then remunerated by a cantonal-appointing authority.
7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Under the cantonal laws and/or bar regulations, fee agreements must always provide for a remuneration which covers the attorney’s costs and expenses. In certain cantons, however, it is possible to agree on a share in an eventual result of the litigation.

Marc Palay is an American-trained lawyer who has practiced for more than a decade in the Geneva office of Winston & Strawn. He has an extensive background in U.S. and transnational litigation and international arbitration, with particular focus on complex product liability, intellectual property, securities, fraud, construction, competition and trade disputes. In the product liability arena, Mr. Palay has coordinated the defence of such actions in a number of jurisdictions throughout Europe, the Middle East and Asia and has been chosen by his peers for inclusion in the International Who’s Who of Product Liability lawyers. Mr. Palay also has extensive experience drafting and negotiating commercial, license and distribution agreements, and counsels clients on a wide variety of international commercial and trade matters.

Mr. Palay is an experienced trial lawyer who practices before a wide variety of international judicial, administrative, and arbitral forums, while at the same time continuing to represent European and multinational firms before state and federal courts throughout the United States.

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For 150 years, Winston & Strawn LLP has made it a goal to provide clients with the highest quality legal representation. With nearly 900 attorneys and offices located in major business centres around the world, including Chicago, New York, Washington, D.C., Los Angeles, San Francisco, Geneva, Paris, and London, we are well positioned to effectively serve our clients’ needs in the global economy.

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Winston & Strawn’s Geneva, Switzerland office is home to the firm’s prominent international arbitration and international product liability practices. Winston & Strawn’s practice in Geneva also encompasses transnational corporate, commercial, and financial matters. Fluent in English, French, German, Spanish, and Italian, our Geneva attorneys handle issues in virtually every jurisdiction of Western and Eastern Europe, Africa, and the Middle East, and have substantial experience in many Asian jurisdictions as well.

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Chapter 40

Ukraine

Proxen & Partners

Oleg Shevchuk

1 Liability Systems

1.1 What systems of product liability are available (i.e., liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Prior to 1 January 2004, the product liability system was principally based on the Law of Ukraine No. 1023-XII of 12 May 1991 “On Protection of Consumers Rights” (Pro Zakhyst Prav Spozhivachyv), which invoked liability of sellers and manufacturers towards a consumer (defined as an individual purchasing, ordering, using or intending to purchase or order goods (works, services) for his own everyday use). Since the enforcement on 1 January 2004 of the new Civil Code of Ukraine (Tsivilniy Codeks Ukrayny) broader interpretation of the product liability system is available:

A seller, a manufacturer of goods, a performer of works (services) is obliged to reimburse the damage caused to physical person or legal entity as a result of design, technological, compound or other defects of goods, works (services), as well as inadequate or incomplete information thereon.

This broader interpretation authorises not only consumers but also any third person to bring a product liability claim. New law remains relatively untested in court practice. Product liability may include liability towards a person, his property as well as reimbursement of moral damages, which are understood to be personal sufferings of an individual and/or abasement of honour, dignity and business reputation of a physical or legal entity. Strict liability theory is usually employed. Product liability may be based on tort as well as on contract.

1.2 Does the state operate any schemes of compensation for particular products?

In practice, there is no scheme of compensation operable by the state for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Both the manufacturer and the seller bear the responsibility for a product defect.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The manufacturer has to suspend production and the seller has to cease sale of a product, which is proven to cause or may cause damage to life, health, or property of the consumer or environment.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

It is the general principle of the civil proceedings that each party must prove those facts, which it uses as a basis or in support of its claim/defence. A burden to prove defect and damage will usually fall on a person invoking liability of manufacturer and/or seller.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Strict liability theory is usually employed. The claimant has to prove:

a) Illegal actions by the seller or manufacturer, which implies that: i) the product has design, technological, compound or other defect; and/or ii) inadequate or incomplete information was provided.

b) Damage, which may include damage towards: i) property; or ii) person.

c) Causation between the illegal actions and damage.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

It is the burden of the claimant to prove that the seller or
manufacturer is the one who sold or produced the product. A claim cannot be brought to an abstract manufacturer.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A product liability claim can be brought if provision of inadequate or incomplete information about a product caused damage to a person. The law does not differentiate between the liability of a manufacturer and a seller. A claimant may choose to file a claim against the manufacturer or the seller or both. The principle of "learned intermediary" is not known in Ukrainian legal system. At the same time the seller cannot invoke the manufacturer's failure to warn the seller as a basis for avoidance of liability.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defendant has to prove lack of any of the elements referred to in question 2.2 above.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There is no consistent court practice or clear guidance of the law in this respect. Fault element is not to be proven by the claimant. Therefore, it is mostly likely that the manufacturer (seller) may be held liable irrespective of whether the defect was discoverable or not.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

There is no consistent court practice or clear guidance of the law in this respect. It is usually assumed that a product cannot be defect if it complies with regulatory or statutory requirements. It is a burden of the claimant to prove that the product is defective.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The case may be re-litigated due to:

a) new facts, which include:

i) facts, which are material for the case but the claimant was not aware and was not able to aware of them;

ii) deliberately untrue witnesses' statements, expert's opinion or translation; forged documents or material evidence, provided any of the above caused unfair court decision as proven by the court judgement in force;

iii) criminal acts by parties, other persons taking part in the case or by the judge(s) while considering the case, as proven by the court judgement in force;

iv) repeal of a court decision or a document of other competent organ, which was the basis for the court to decided the case; and

v) the law used by the court while deciding the case is proven to be contradicting to the Constitution.

b) exceptional circumstances, which means that after appeal review of the case by the Supreme Court of Ukraine:

i) application of the same provision of law by different courts appeared to be inconsistent;

ii) application of the law was in contradiction to the Constitution; and

iii) international court authority, whose jurisdiction is recognised by Ukraine, judged that decision in the case was in violation of international undertakings of Ukraine.

4 Procedure

4.1 Is the trial by a judge or a jury?

One judge usually hears the case. No jury is available for product liability cases.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

A court on its own initiative or granting request of a party may engage an expert to give his opinion on certain matters relevant for the case. An expert opinion is not binding on the court, which takes it into account in line with other proves and evidences presented by the parties.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

“Class action” in its classic meaning is not available. However, it shall be noted that consumer associations are authorised, inter alia, to bring a claim that actions of a seller
or a manufacturer towards an uncertain number of consumers are illegal and request that such actions be ceased. If the claim is granted the defendant shall announce the court decision through mass media or otherwise make consumers aware thereof. Such court decision has a binding effect in litigation by a consumer if such action(s) is the subject matter of a claim.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, see for instance question 4.3 above.

4.5 How long does it normally take to get to trial?

The time it takes from claimant’s petition to first hearing of the case depends on the complexity of the case and workload of the judge; it may take in practice from a couple of days to a couple of weeks or longer. The procedural law sets forth an impracticable seven-day period for the judge to take actions in preparation of the trial (extendable to twenty days for complex cases) and a seven to fifteen-day period to complete the trial. The new procedural law expected to come into force late 2005 or early 2006 establishes a ten-day period for the judge to decide on acceptance or rejection of the claimant’s filing and a two-month period to complete trial (extendable to three months for complex cases).

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court is not authorised to try preliminary issues, the result of which determine whether the remainder of the trial should proceed.

4.7 What appeal options are available?

Court decision comes into force following expiry of the term for appeal. The court decision may be appealed to a court of appeal within a one-month period starting on the date immediately following the date the decision is announced. A court decision, which was subject to an appeal procedure, and a decision of a court of appeal may further be appealed to the Supreme Court of Ukraine within one month following the announcement of decision of a court of appeal. The new procedural law pending enforcement will slightly change the term for appeal, but the options will be the same: a decision of the court may be appealed to a court of appeal and, if appealed to a court of appeal, to the Supreme Court of Ukraine.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Procedural status of an “expert” will only be bestowed upon the person appointed by the court. A party may use its own expert opinion having status of written evidence or statements of third parties. Admissibility of such opinion is at discretion of the court, which may reject it if it is not relevant for the case or inappropriate means to prove those facts for which such opinion is used.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Existing procedural law is not detailed in this regard leaving it much to the discretion of the court. Usually, no pre-trial deposition is available.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Each party shall present the evidences supporting the claim/defence. A party may seek the court’s assistance in obtaining evidences. Motion for documents disclosure shall detail: the nature of written evidence requested; why such evidence should be in possession of that person; and the circumstances which are to be proven by the document.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Damage is recoverable if it is caused before use-by date of a product or, if no such date is available, within ten years from the manufacture date. Damage shall also be recoverable if a person was not informed about things which are to be taken after use-by date, and consequences of their failure to be taken.

Statute of limitation is usually three years (for a claim on product defect based on the contract - one year) from the date when a person gets to know or is able to get to know about infringement of his right or the person who infringed his right. The court may dismiss the case following motion of the other party that the claim is brought upon expiry of the statute of limitation, unless the court finds that there is a good excuse for the limitation period being missed.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Age or condition of the claimant does not affect the calculation of any time limits. The court has discretion in applying the statute of limitation.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

There is no direct causation between concealment or fraud with the time limits referred to in question 5.1 above.
6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damage to product, property, person and moral damage are recoverable.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The plaintiff needs to prove existence of damage. Therefore, no protection for hypothetical damage is available.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not available.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party may recover court fees and other incidental expenses, such as amounts to be paid to witnesses or experts, costs due to reviewing evidences at site, expenses for searching the defendant, etc. The losing party may also be required to pay the fees of the successful party’s advocate. Such fees may be up to five per cent of the awarded amount but not bigger then the applicable tariffs. An advocate’s “applicable tariff” is a phenomena of the soviet system, which does not exist in Ukraine any more. The court practice on reimbursement of legal costs is variable.

7.2 Is public funding e.g. legal aid, available?

No public funding is available in product liability cases, although some consumer associations and other public organisations availing some assistance to plaintiffs, in a form, for instance, of free legal aid, is available on case by case basis.

7.3 If so, are there any restrictions on the availability of public funding?

There is no restriction on the availability of public funding.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

There are no limitations with regard to conditional or contingency fees.

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The practice of Mr. Shevchuk focuses M&A, while he is also actively involved in advising on foreign investments, banking, finance and arbitration.

The Law firm “Proxen” was formed in 1990 in Kyiv, Ukraine. It is the first private law firm in Ukraine that obtained a license for legal practice from the Ministry of Justice. Today Proxen is one of the biggest and most experienced law firms in the country. Professional expertise in such areas as (in alphabetical order) foreign investments, international borrowings, investment disputes, litigation, M&A, and privatisation enables the firm to meet the highest demands of both domestic and international clients. In 2003 it opened a new office operating under the name “Proxen & Partners”.

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Chapter 41

USA

Shook, Hardy & Bacon LLP

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

Product liability claims may be brought under theories of strict liability, negligence or breach of warranty. A plaintiff bringing a product liability claim must prove that a product was defective due to an unreasonably dangerous condition or characteristic. There are three categories of product defect: (1) design defect; (2) manufacturing defect; and (3) warnings defect, i.e., failure to adequately warn of risks and dangers associated with product use. A product liability plaintiff may recover for injuries to the person, including death, and damage to property.

1.2 Does the state operate any schemes of compensation for particular products?

In limited circumstances, compensation systems have been set up and operated by the federal government. For example, in 1986, Congress created the National Vaccine Injury Compensation Program to compensate individuals or families of individuals who have been injured by childhood vaccines. To obtain compensation, a party must file a claim with the U.S. Court of Federal Claims. A physician then reviews the claim on behalf of the government to determine whether it meets the criteria for compensation. The initial decision regarding the amount of compensation is made by a “special master.” A party may appeal the special master’s decision to the Court of Federal Claims and then to the Federal Circuit Court of Appeals. A party may sue the manufacturer of a vaccine only if the vaccine is not covered by the National Vaccine Injury Compensation Program or, for vaccines covered by the programme, only after the party has sought relief through the National Vaccine Injury Compensation Program and been denied compensation or received an award the party rejects.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

In most jurisdictions, product liability claims may be asserted against any entity involved in making a product available to the consumer, including manufacturers, wholesalers, distributors and retail suppliers of the product. Some jurisdictions have so-called “innocent seller” statutes or case law that protect retailers from liability arising out of their sale of defective products provided certain conditions are met, such as the availability of jurisdiction over the manufacturer, the availability of adequate remedy against the manufacturer, lack of knowledge of the defect by the seller, and inability by the seller to discover defectiveness of the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A majority of jurisdictions have held that, in the absence of a statutory requirement or action by a governmental regulatory authority, a manufacturer has no duty to recall a product or take steps to remedy defects discovered after the product has already been sold. However, courts in a minority of jurisdictions, including Arkansas, Colorado, Delaware, Hawaii, Illinois, Iowa, Kansas, Louisiana, Minnesota, New Jersey, New York, North Carolina, Texas, Washington, and Wisconsin, have held that a manufacturer does have a post-sale duty to recall or repair a product.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Generally, the plaintiff bears the burden of proving all elements of a product liability claim. Although the elements of a strict liability claim vary according to state law, a plaintiff typically must prove: (1) that the defendant’s product caused or contributed to cause the plaintiff’s injury; (2) that the product was defective, i.e., unreasonably dangerous, at the time of the plaintiff’s injury; (3) the defective condition of the product existed at the time the product left the hands of the defendant; and (4) that the defendant’s product was the proximate, or legal, cause of the plaintiff’s injury. Under the negligence theory, a plaintiff must prove these elements and that the defendant knew or should have known of the alleged product defect.
A plaintiff must prove both actual and proximate causation. Actual causation entails two components, general and specific causation. To establish general causation, the plaintiff must prove that the defendant’s product is capable of causing the type of injuries alleged. To establish specific causation, the plaintiff must prove that the particular injuries in the plaintiff. Generally, to establish actual causation, a plaintiff must offer expert testimony that, to a reasonable degree of medical probability, the defective nature of the defendant’s product caused or substantially contributed to cause the plaintiff’s alleged injuries.

To establish proximate causation, also referred to as legal causation, a plaintiff must establish that the injury is the natural and probable consequence of the defendant’s conduct. The concept of proximate causation acts as a limit on the extent of a defendant’s liability. A defendant may not be held liable for every consequence that follows the defendant’s action; rather, the defendant’s liability is limited to the natural and probable consequences of its action or inaction.

**2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?**

In the majority of jurisdictions, a plaintiff bears the burden of proving that the defendant manufactured the product that caused the plaintiff’s injury. However, a few jurisdictions have adopted market share liability. It was first adopted by the California Supreme Court in a 1980 case involving the synthetic estrogen drug diethylstilbestrol, also known as DES, which was manufactured by as many as 300 manufacturers between the 1940s and the 1970s. Market share liability has subsequently been adopted in at least five other jurisdictions in the United States, including Florida, New York, Michigan, Washington and Wisconsin.

Under market share liability, a plaintiff may recover injuries caused by a product identically manufactured by more than one manufacturer even though it is not possible to determine the identity of the manufacturer of the particular unit that caused the plaintiff’s injury. The legal requirements for recovering under the market share theory of liability vary in each of these jurisdictions. For example, in California, a plaintiff must join a “substantial share” of manufacturers and each defendant can be held liable for its share of the market unless it proves it could not have manufactured the product that actually caused the plaintiff’s injury. In New York, a plaintiff must also join a “substantial share” of manufacturers and each defendant may be held liable for its share of the national market. However, because the New York court adopted market share liability as a method of apportioning defendants’ liability according to their alleged total culpability, a defendant may not exculpate itself even if it can show that it did not manufacture the product that actually caused the injury. In Florida, the plaintiff must show that she has made a genuine attempt to identify the manufacturer responsible for her injury, but has no burden to join a substantial share of manufacturers. Each manufacturer joined as a defendant in Florida is presumed to have an equal market share (as determined by the number of defendants in the case) unless it proves that its actual market share was less.

**2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?**

Where liability is premised on a defendant’s failure to warn of risks or dangers associated with use of a prescription drug, the learned intermediary doctrine provides that the defendant manufacturer discharges its duty by warning the prescribing physician of the dangers associated with use of the product. It is then the learned intermediary’s responsibility to warn the user. The learned intermediary doctrine applies in cases involving prescription drugs because these products can only be obtained through a licensed physician, who is in a superior position to understand and evaluate the warnings in light of the patient’s medical condition and background. The learned intermediary doctrine has also been held to apply in cases involving heavy industrial equipment where an employer acts as the intermediary in instructing employees regarding safe use of the product.
caused the injury and that the defendant engaged in wrongful conduct.

Statutes of Repose
In contrast to statutes of limitation, statutes of repose provide that a claim will be barred if not brought within a specific number of years after the product was manufactured or sold, regardless of when the plaintiff’s injury occurs. Time periods for statutes of repose are typically longer than statutes of limitation, but the “discovery rule” generally does not apply to statutes of repose. Thus, statutes of repose are viewed as an absolute time bar on a claim.

The Learned Intermediary Doctrine
See question 2.4 above.

Intervening and Superseding Cause
A defendant in a product liability action may assert as a defence that the plaintiff’s injury was caused by the intervening conduct of a party other than the defendant. The intervening conduct may be that of another defendant, of a non-party or of the plaintiff himself (see Comparative Fault/Contributory Negligence below). However, intervening conduct is generally a defence to a product liability claim only if the conduct is also a “superseding cause.” Most courts hold that intervening conduct is a superseding cause where the conduct is such that a manufacturer could not be expected to guard against such conduct in the design of the product. Examples of intervening, superseding causes include failure to properly maintain a product, negligent use of the product, use of a product for a purpose not intended or reasonably foreseen by the manufacturer, failure to inspect a product, failure to follow instructions regarding the installation of a safety device, failure to comply with a product recall, alteration of a product, or criminal action.

Comparative Fault/Contributory Negligence
Formerly, many jurisdictions completely barred recovery by a plaintiff where the plaintiff’s own negligence caused, or contributed to cause, the plaintiff’s injury. Most jurisdictions no longer bar recovery by a plaintiff who is contributorily negligent; rather, they apply comparative fault under which the plaintiff’s recovery is reduced if the plaintiff’s own negligence caused, or contributed to cause, the plaintiff’s injury. Some jurisdictions impose “pure” comparative fault to reduce a plaintiff’s recovery by the percentage of fault attributed to the plaintiff’s negligence. Other jurisdictions apply “modified” comparative fault, which reduces a plaintiff’s recovery by the percentage of fault assigned to the plaintiff. However, under comparative fault, if the plaintiff’s own conduct contributed to the injury, some jurisdictions impose “pure” comparative fault to reduce a plaintiff’s recovery by the percentage of fault attributed to the plaintiff’s negligence. Other jurisdictions apply “modified” comparative fault, which reduces a plaintiff’s recovery by the percentage of fault assigned to the plaintiff. Under this system, a plaintiff may not recover if his fault is equal to that of the defendant(s). In other jurisdictions applying “modified” comparative fault, a plaintiff may recover provided that the percentage of fault attributed to her does not exceed the percentage of fault attributed to the defendant(s). Thus, a plaintiff may still recover where the plaintiff’s fault is equal to that of the defendant(s).

Assumption of the Risk
In many jurisdictions, it is a defence to a product liability claim if the plaintiff knew of a product defect, recognised the danger posed by the product, but nevertheless proceeded to use the product and was injured. This defence is different from contributory negligence in that it applies a subjective standard, i.e., what the plaintiff actually knew, rather than the objective standard applied to a contributory negligence determination, i.e., whether the plaintiff acted as a reasonable person under the circumstances.

Pre-emption
Where a governmental or regulatory body has promulgated rules and regulations regarding product safety, some courts hold that product liability claims that, if successful, would require additional conduct by the manufacturer, are preempted by the governmental or regulatory rules and regulations.

Compliance with Governmental Standards
See question 3.3 below.

State of the Art
See question 3.2 below.

3.2 Is there a state of the art/development risk defence?
Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

In negligence actions, the fact that a product was manufactured according to the state of the art, i.e., the level of scientific and technical achievement in the relevant field, is relevant evidence that the manufacturer exercised due care. Evidence that a manufacturer complied with the state of the art may also be relevant in strict liability cases, particularly in a design defect case, where such evidence may be relevant to determine the feasibility of an alternative design, consumer expectations or the standard for design defect. State of the art evidence is, however, inadmissible in some jurisdictions, including Illinois, Montana, North Dakota, and Pennsylvania. Generally, in jurisdictions where evidence of the state of the art is admissible, the burden of proof is on the defendant to prove that it complied with the state of the art. However, in jurisdictions that require a plaintiff asserting a design defect theory to offer proof of a safer, feasible alternative design, the burden of demonstrating the relevant state of the art is on the plaintiff.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

In a majority of jurisdictions, a manufacturer’s compliance with regulatory and statutory requirements is evidence of due care or lack of defect, but is not conclusive. In a small number of states, including Arkansas, Colorado, Kansas, North Dakota, Tennessee, Utah and Washington, a manufacturer’s compliance with regulatory and statutory requirements creates a rebuttable presumption that the product is not defective. In Michigan, a manufacturer of a prescription drug is not liable and the product is not...
defective or unreasonably dangerous if the drug and its labelling were approved by the United States Food and Drug Administration (FDA).

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A plaintiff is not estopped from litigating issues of fault, defect or the capability of a product to cause a certain type of damage where another plaintiff has unsuccessfully litigated the same issue(s). However, in some circumstances, where an issue is decided against a defendant in one proceeding, the defendant may be precluded from re-litigating the issue in future proceedings involving different plaintiffs.

4 Procedure

4.1 Is the trial by a judge or a jury?

In both federal and state court, either party may demand a trial by jury. Most federal juries are comprised of six persons and two alternates and verdicts must be unanimous. State court juries are commonly comprised of 12 persons and the number of jurors required to render a verdict varies. In some states, unanimity is required, while others require nine of 12 or 10 of 12. In state courts using six-person juries, some require five of six jurors to render a verdict.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

A federal court may appoint a “special master” who may serve as a referee, auditor, examiner or assessor to assist the court with complicated issues. Rule 53(b) of the Federal Rules of Civil Procedure provides that reference to a master “shall be the exception and not the rule.” Where trial is by jury, a master may be appointed only where the issues are complicated. Where trial is by a judge, the court must show that some “exceptional condition” requires appointment of a master, except in matters of account and difficult computation of damages.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

A federal court may “certify” or allow a class action to go forward if the requirements of Rule 23 of the Federal Rules of Civil Procedure are met. Rule 23(a) provides that four prerequisites must be satisfied for a suit to be certified as a class action. First, the class of parties must be so numerous that joinder of all members of the class is impracticable. Second, there must be questions of law or fact common to all members of the class. Third, the claims or defences of the parties who wish to bring the claim on behalf of the class must be typical of the claims or defences of the class. Finally, the parties who wish to bring the claim on behalf of the class must be capable of fairly and adequately protecting the interests of the class.

If the four prerequisites are satisfied, Rule 23(b) provides that an action may be allowed to proceed as a class action in the following three circumstances: (1) the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the defendant, or adjudications with respect to individual members of the class would be, as a practical matter, dispositive of the interests of other members of the class who are not parties to the action or would substantially impede or impair their ability to protect their interests; (2) the defendant has acted or refused to act on grounds generally applicable to the entire class; or (3) questions of fact or law common to the members of the class predominate over questions affecting only individual members and a class action is superior to other methods for the fair and efficient adjudication of the controversy.

Rule 23(b)(3), directs the court to consider the following factors in making a determination whether common questions of fact or law predominate over individual issues and whether a class action would be superior to other methods for adjudication of the controversy: (a) the interests of members of the class in individually controlling the prosecution of separate actions; (b) the extent and nature of any litigation concerning the controversy already commenced by members of the class; (c) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (d) the difficulties likely to be encountered in the management of the class action.

If a court determines that the provisions of Rule 23 are satisfied, it may certify the proposed class and allow the representative plaintiffs to litigate the case as a class action. Typically, the representative plaintiffs must provide notice to potential members of the class that they may opt out of the class and pursue their claim individually. If a class member fails to “opt out” of the class, the class member becomes part of the class action and is bound by its result.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Generally, a representative organisation, such as a consumer association, has no standing to file a product liability claim for injuries sustained by its members. However, some such organisations file petitions with governmental regulatory authorities requesting that the regulatory authority take action against manufacturers, such as requiring a recall of the product or imposing additional safety standards.

4.5 How long does it normally take to get to trial?

The length of time it takes to for a case to get to trial varies by jurisdiction. In the federal courts, during the 12-month period ending March 31, 2004, the overall median time to trial was 21.9 months. See Statistical Tables for the Federal Judiciary, March 31, 2004 <http://www.uscourts.gov/caseload2004/tables/C05mar04.pdf>. However, there is great variation within the federal courts during this period, ranging from only 9.0 months in the Western District of
Wisconsin and 9.9 months in the Eastern District of Virginia, 32.0 months in the Northern District of New York, and 37.0 months in the Western District of New York. See id.
The length of time it takes to get to trial in state court varies by jurisdiction, but comprehensive statistics are unavailable.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Judges in federal and state courts may use summary judgment procedure to dispose of specific issues or an entire case prior to trial. Rule 56 of the Federal Rules of Civil Procedure and comparable rules in state courts allow a court to enter summary judgment as to specific issues or the entire case where no genuine issue of material fact exists and the judgment may be entered as a matter of law. Courts may use summary judgment proceedings or other pretrial hearings to make determinations regarding the admissibility of expert testimony. Where expert testimony is held inadmissible, these proceedings, referred to as “Daubert hearings” in federal court, may make trial unnecessary if a party is unable to meet their burden of proof without expert testimony.

In contrast to summary judgment, courts may also hold separate trial proceedings regarding preliminary issues, the result of which determine whether it is necessary to try remaining issues. Rule 42 of the Federal Rules of Civil Procedure and comparable rules in state courts allow a court, where convenient or to avoid prejudice, or where conducive to expedition and economy, to order the separate trial of any claim or any separate issue. In such proceedings, the court may go beyond matters of law and make findings of fact. Additionally, the constitutional right of the parties to trial by jury applies in the separate proceedings. Commonly known as “bifurcation,” this procedure is frequently sought by defendants facing claims for punitive damages to prevent the jury from considering issues such as the defendant’s wealth and other prejudicial evidence irrelevant to the determination of liability and actual damages. In such instances, defendants typically request that the court try issues related to liability and actual damages first and then, only if actual damages are awarded, to consider evidence relevant to punitive damages in a separate proceeding.

4.7 What appeal options are available?

Before appealing a judgment or order to an appellate court, a party may request, by motion, that the court that entered the order or judgment reconsider its order or judgment in limited circumstances, such as where new evidence has been discovered that could not have been previously discovered or where fraud has been committed upon the court.

Appeals may generally be taken only from a “final decision.” See 28 U.S.C. §1291. A “final decision” is one that settles the rights of the parties and disposes of all issues in the case. There are, however, exceptions under which an “interlocutory appeal,” which is an appeal from a decision that is not final, may be taken. Such instances include orders granting or denying injunctions, orders involving a controlling question of law if an immediate appeal will advance the ultimate termination of the litigation, orders constituting a clear abuse of discretion where the court’s legal duty is plainly established, reference of an issue of state law to a state appellate court and other limited circumstances. See 28 U.S.C. §1292. Additionally, an order granting or denying certification of a class action, although not a final decision, may be appealed pursuant to Rule 23(f) of the Federal Rules of Civil Procedure.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Parties may present expert testimony in both federal and state courts where such testimony will be helpful to the judge or jury in evaluating the evidence. The admission of expert testimony in federal courts is governed by Rule 702 of the Federal Rules of Evidence. Rule 702 provides that an expert may testify if the expert is qualified by knowledge, skill, experience, training or education and if the expert’s proposed testimony is based upon sufficient facts or data, is the product of reliable principles and methods and if the principles and methods have been reliably applied to the facts of the case. Additionally, in evaluating the qualifications of experts and the reliability of expert opinions, federal courts are guided by the U.S. Supreme Court’s decision in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). The Daubert decision sets forth several factors to guide courts in determining whether an expert’s opinions are reliable, including whether the expert’s method or theory has been tested, whether the method or theory has been subjected to peer review and publication, the rate of error of the technique or theory, the existence of standards and controls applicable to the method or theory, and whether the method or theory has been generally accepted in the scientific community.

State courts have rules similar to Rule 702 and many apply the Daubert decision. However, some state courts still apply the “general acceptance” standard set forth in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), which was rejected by the Supreme Court in Daubert. Under the Frye test, an expert’s opinion is admissible if the technique employed by the expert is “generally accepted” as reliable in the relevant scientific community.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

In both federal and state courts, parties may take the pre-trial depositions of factual and expert witnesses. Rule 30 of the Federal Rules of Civil Procedure limits the length of a deposition to one day of seven hours, unless otherwise agreed by the parties. State court rules regarding depositions vary by jurisdiction, but typically allow broad latitude for the deposition of both factual and expert witnesses.

Rule 26(a)(2) of the Federal Rules of Civil Procedure requires all parties to disclose the identity of all experts that may be used at trial, including a written report containing a complete statement of all opinions to be expressed and the reasons and bases in support of the opinions, the data or other information considered by the expert in forming the opinions, exhibits to be used in support of the opinions, the
qualifications of the expert, including a list of all publications authored by the expert within the preceding ten years, the compensation to be paid to the expert, and a list of all other cases in which the expert has given testimony at deposition or at trial in the previous four years. State court rules regarding the disclosure of expert reports vary by jurisdiction.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

The Federal Rules of Civil Procedure and comparable rules in state courts are designed to prevent parties from “ambushing” adversaries at trial with unknown evidence. Accordingly, parties are required to disclose information to be used at trial, including documentary evidence, before trial begins. Rule 26(a)(1) requires all parties, at the outset of a case, without awaiting any discovery requests, to provide copies or a description by location and category of all documentary evidence the party may use to support its claims or defences. Moreover, the parties are under a continuing obligation to supplement their disclosure of such information as it becomes known to them throughout the case.

Rules 26 through 37 of the Federal Rules of Civil Procedure provide numerous discovery tools which a party may use to obtain relevant information from an adverse party. Parties may discover information relevant to the case by taking depositions of factual and expert witnesses, propounding written interrogatories, requests for production of documents and things, requests for admissions, and physical and mental examinations of a party.

Finally, federal courts and most state courts require the parties, in advance of trial, to exchange written witness and exhibit lists, as well as copies of all exhibits that may be used at trial.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

A plaintiff must file suit within the applicable statute of limitations. Statutes of limitation applicable to product liability actions vary by jurisdiction and may range from one year to six years.

A suit is commenced when the plaintiff files the complaint, also called a petition in certain jurisdictions, which contains the relevant allegations and a request for relief. When the complaint is filed, a summons is issued commanding the defendant to appear before the court to answer the complaint. Rule 4(m) of the Federal Rules of Civil Procedure provides that a complaint will be dismissed if the plaintiff does not serve the complaint and the summons on the defendant within 120 days of issuance of the summons. A defendant must answer the complaint within 20 days of service of the summons and complaint. State courts have similar rules and similar timeframes, although the time to answer is 30 days in many jurisdictions.

Alternatively, a plaintiff in federal court may request that a defendant waive the requirement of formal service of the summons in order to avoid the costs associated with such service. If a defendant refuses to waive formal service and plaintiff subsequently serves the defendant with the complaint and summons, the defendant must pay the expenses associated with formal service of the summons. Where a defendant agrees to waive service of the summons, the defendant has 60 days after signing the waiver of service to answer the complaint, rather than the usual 20 day period in which to answer where formal service is made. After the plaintiff files the complaint and the defendant files its answer, federal courts and most state courts issue scheduling orders that govern the discovery, pre-trial and trial phases of the case.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

Statutes of limitation begin to run when a claim accrues. The time of accrual varies depending on jurisdiction, but generally a claim accrues when a plaintiff has been injured and knows the cause of his injury. Statutes of limitation are “tollled” or suspended where a plaintiff has not reached the age of majority, is mentally incapacitated or, in some jurisdictions, is imprisoned. The limitations period begins to run again when the plaintiff reaches the age of majority, when the mental incapacitation is lifted or when the period of imprisonment ends.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Statutes of limitation are commonly tolled where a defendant commits an ongoing fraud that prevents the plaintiff from realising that he or she has been injured.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In a product liability claim, a plaintiff may recover for personal injury and wrongful death, including pain and suffering, medical expenses, loss of income, loss of financial support and loss of consortium. A product liability plaintiff may also recover for damage to property, including damage to the product itself and damage to other property. Finally, a product liability plaintiff may recover punitive damages, which are discussed below.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Product liability defendants have been ordered to pay for medical monitoring of plaintiffs to detect the future development of latent injuries or diseases. There is, however, a recent trend against medical monitoring in the absence of physical injury.
6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are recoverable in product liability actions in most jurisdictions. A plaintiff typically must prove, by clear and convincing evidence, that a defendant acted willfully, wantonly or with malice in order to recover punitive damages. In numerous jurisdictions, punitive damage are not recoverable unless actual damages are awarded.

The United States Supreme Court has recently struck down a punitive damages award that was 145 times the amount of the compensatory damages award on the ground that such an award was an arbitrary deprivation of property in violation of the defendant’s constitutional right to due process. State Farm Mutual Automobile Insurance Co. v. Campbell, 538 U.S. 408 (2003). The Court noted that any award ten times the amount of compensatory damages or larger would likely be unconstitutional on due process grounds. The Court also held that certain factors, such as the defendant’s wealth or conduct unrelated to the injury at issue, may not be considered in determining the amount of a punitive damages award.

Numerous jurisdictions have enacted limits on the amount of punitive damage awards, including Colorado, Connecticut, Florida, Kansas, Oklahoma, Texas and Virginia. Additionally, some states require that portions of punitive damage awards be paid to the state, including Georgia and Iowa.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is not a limit on the amount of monetary damages recoverable from one manufacturer. However, some states limit the number of punitive damage awards, but not the amount, to one award that may be recovered from a single defendant for any act or omission, regardless of the number of claims that arise.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Rule 54 of the Federal Rules of Civil Procedure provides that a prevailing party may recover costs other than attorneys’ fees as a matter of course unless the court directs otherwise. “Costs” are defined by 28 U.S.C. §1920 to include fees of the court clerk, fees of court reporters for transcripts necessarily obtained for the case, fees for printing, witness fees (limited under 28 U.S.C. §1821 to $40 per day plus mileage and reasonable travel expenses), copying costs and fees of court-appointed experts and translators.

Attorneys’ fees are generally recoverable only where specifically authorised by a statute creating a cause of action, such as claims of alleged civil rights violations, and are typically not recoverable in product liability suits.

7.2 Is public funding e.g. legal aid, available?

Although a criminal defendant is entitled, under the Fifth Amendment to the United States Constitution, to the effective assistance of legal counsel, which requires federal and state governments to pay the costs of securing such counsel for indigent defendants, no corresponding right to counsel exists in civil cases.

There are, however, a variety of sources of legal aid, both public and private to assist indigent litigants in prosecuting their cases. A major source of such legal aid comes from the various state bar organisations. Additionally, attorneys are generally encouraged and expected to provide a portion of their services pro bono, i.e., free of charge, to indigent clients.

7.3 If so, are there any restrictions on the availability of public funding?

Because of the numerous and diverse nature of sources of legal aid in the United States, it is not possible to provide a comprehensive overview of restrictions applicable to the provision of legal aid. Virtually all sources, however, have specific income thresholds beyond which legal aid will not be provided.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are allowed in the United States. Various conditions and ethical considerations apply in each jurisdiction, but most jurisdictions allow contingency fees of up to 30-40% of the judgment awarded to a party, provided that the parties enter into a fee arrangement in advance.
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A resourceful and integrated firm, SHB operates as one firm worldwide. SHB’s offices are strategically located in Kansas City, Missouri; Geneva; Houston; London; Miami; Overland Park, Kansas; Orange County, California; San Francisco; Tampa; and Washington, D.C.

The firm’s emphasis is resolving litigation matters for private and public companies of all sizes—locally, regionally, nationally and internationally. Cited by Business Week as “the law firm of choice for many companies plagued by high-stakes and often controversial product-liability woes,” SHB is internationally recognized as the litigation firm to be hired to defend complex commercial, antitrust, employment, environmental, ERISA, product liability and mass tort litigation.

SHB attorneys have extensive experience in winning major trials in courts across the country, including the U.S. Supreme Court and the U.S. Courts of Appeals. Many of our attorneys have been recognized for their outstanding professional skills and abilities.
Chapter 42

Venezuela

Macleod Dixon

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role?

There are three (3) main sources which define Venezuela’s product liability system: (i) Article 117, Constitution of the Bolivarian Republic of Venezuela (“CBRV”); (ii) the Consumer and User Protection Law (“CUPL”), published in the Official Gazette on May 4, 2004, which establishes a general framework for product liability and seeks to uphold the consumers’ rights; and (iii) Article 1185, Venezuelan Civil Code (“VCC”), which establishes tort liability. Under the aforementioned sources, we believe it is possible to sustain product liability in respect of damage either to persons or to property. Depending on the nature of the claimant-defendant relationship, contractual or tort liability shall proceed and, in many cases, both types of liability may be joined in a single claim.

Even though product liability has not been a widely discussed topic in Venezuela, a few commentators and our courts’ case law have defined product liability as fault based on Article 1185 of the VCC. Fewer Venezuelan commentators support a strict liability thesis, based upon Article 1193 of the VCC, which in some ways follows the USA and French currents for product liability. However, strict product liability has not been recognised by our courts; on the contrary, many arguments have arisen against a strict liability thesis in this field.

According to Article 2 of the CUPL, provisions of such law are of public policy. Moreover, Article 87 (1) of the CUPL establishes that clauses included in an adhesion contract that exonerate, lessen or limit product liability are to be considered null and void. Thus contractual liability may only be regulated by the parties if limitations do not infringe upon the rights of consumers as provided in the CUPL.

1.2 Does the state operate any schemes of compensation for particular products?

Apart from the general regime for the defence of consumers’ rights provided for in the CUPL and the VCC, there are no special compensation regimes for consumers for any particular products. Nonetheless, some laws do provide for special administrative or criminal liability of manufacturers and distributors (for instance, the Medicines Law and the Law for the Pharmacy Profession).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the “retail” supplier or all of these?

Pursuant to Article 93 of the CUPL, producers, manufacturers, assemblers, importers, merchants with registered brands, distributors, retailers, and anyone who participates in the distribution chain, shall be considered jointly and severally liable for any civil compensation arising from damage caused by products or services rendered.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Pursuant to Article 9 of the CUPL, if a product is determined to be a considerable threat or risk to health (even if used properly), and provided that the consumer has not been adequately informed of such threat or risk, the provider shall, without prejudice of any liabilities, proceed to: (i) recall the product from the market; (ii) substitute the product with another different product; or (iii) replace the product at his own cost.

Notwithstanding the above, the provider cannot be forced to recall the products himself, but may be fined if he does not comply with this obligation. In such case, a court may appoint a third party to recall the products, at the provider’s own cost.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

We have previously stated that two (2) different positions coexist in Venezuela regarding product liability: (i) a dominant current, which sustains that product liability is fault based; and (ii) a minor current, which sustains that product liability should be considered strict. In our opinion, and following the dominant current, the claimant (i.e. the consumer) must prove that the fault/defect of the product,
and any damage arising from it, are attributable to the negligence, imprudence or lack of expertise of the defendant (i.e. culpa). Indeed, pursuant to Article 506 of the Venezuelan Code of Civil Procedure (“CCP”), each party has the burden of proving his own pleadings. This has been recognised as a general principle in Venezuela.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In Venezuela, only direct and verifiable damage may be awarded compensation. Thus the claimant must prove (i) the actual existence of an injury; (ii) that the injury is the direct consequence of the claimant’s exposure to the product; and (iii) that the defendant’s conduct did not meet the bonus pater familia standard in manufacturing or distributing the product. The bonus pater familia constitutes a general standard of diligence required in the execution of obligations.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability is not recognised in Venezuela as a possible solution in distributing concurrent liabilities. As stated previously, pursuant to Article 93 of the CUPL, all intervening parties within a determined chain of supply shall be jointly and severally liable for any obligations arising from any fault/defect in their distributed products. Thus the consumer can request total compensation for any damage suffered from anyone involved in the chain. Pursuant to Article 13 of the CUPL, anyone from the chain of supply who has paid compensation to a consumer for fault/defect of any distributed products, shall have the right to recover any compensation paid from the individual or legal entity actually responsible.

On the other hand, according to Article 1195 of the VCC, whoever has compensated the damage in its entirety, shall have an action against each of the co-obligated individuals for an amount which shall be established by the judge in accordance with the seriousness of the fault committed by each one of them. Should it be impossible to determine the extent of each individual’s liability, liability shall be shared equally amongst them.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of “learned intermediary” under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Pursuant to Article 6 (3) of the CUPL, consumers have the right to be informed, among other things, of the risks, composition and contraindications of any product. Each individual involved in the production and distribution chain is under the obligation to provide the necessary information, advice or warnings about the product.

According to Article 8 of the CUPL, the manufacturer or provider of the product shall immediately inform the authorities and the public about any risks or dangers concerning a product. Information must be provided through means adequate to promptly inform the public, at the sole cost of the manufacturer or provider.

Should the manufacturer or provider fail to inform the consumer about any risks or dangers involved in the use of their products, the manufacturer or provider shall either recall or replace the product at their sole cost. Besides this, the manufacturer or provider will only be subject to administrative liability (i.e. fines set by the competent administrative body).

We have no principle of learned intermediary in Venezuela. The supply of information from each of the individuals involved in the distribution chain must be enough to reach the ultimate consumer. No discharge of this duty seems to be applicable under the CUPL.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under Venezuelan law, elements constituting a tort are (i) inexcusable non-compliance with an obligation; (ii) existence of actual and reparable damage; and (iii) causal relationship between the inexcusable non-compliance and the alleged damage. Even though the claimant is the one bearing the burden of proving the existence of the aforementioned elements, the defendant may bring any available defence tending to demonstrate otherwise.

a) The defendant may plead that no fault can be attributed to him. Thus the defendant may prove that he always maintained prudent and diligent conduct by meeting the bonus pater familia standard which, in turn, weakens the claimant’s plea that the defendant’s fault was the direct cause of the damage suffered.

b) Pursuant to Articles 1271 and 1272 of the VCC, the
defendant may exempt himself from contractual liability for damage, by proving that non-compliance originated from a non-attributable cause, including an unforeseen event or force majeure.

c) Venezuelan commentators and case law have recognised contractual liability exemptions in tort cases, by extending Article 1193 of the VCC to all cases of tort. Article 1193 establishes that an individual may exempt himself from liability for damage, provided that he proves that the damage was due to (i) the victim’s own fault; (ii) a third party’s conduct; (iii) an unforeseen event; or (iv) force majeure.

In order for non-attributable causes to exempt the defendant from product liability, such causes must (i) absolutely bar the defendant from complying with his obligations; (ii) be unforeseeable and unavoidable; and (iii) not be attributable to any extent to the defendant’s fault.

d) When in the presence of contractual liability, the defendant may bring any defence arising from any liability restrictions set forth in the agreement. Under the CUPL and to protect the consumers, certain limitations to such restrictions apply, mainly when in presence of an adhesion contract. Therefore, it is possible that certain clauses within the agreement be considered null and void.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Pursuant to Article 1274 of the VCC, only that damage which was foreseeable or foreseeable at the time of the execution of an agreement, may be compensated. The latter clearly applies to contractual liability, but there is no legal argument to sustain that such provision may be extended to damage arising from tort.

Pursuant to Article 506 of the CCP, should the defendant bring this defence, he will have the burden of proving that the fault/defect was not discoverable.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory and/or statutory requirements may assist the defendant in demonstrating that he was diligent in manufacturing, marketing or supplying the product. Nonetheless, pursuant to Article 12 of the CUPL, authorisation granted by the State to a manufacturer to commercialise goods which may prove to be dangerous for the health of the population, shall not exonerate the manufacturer from any liability due to damage caused by the defective products. Thus compliance with regulatory and/or statutory requirements per se will not exonerate the manufacturer from liability.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

There is no issue preclusion or estoppel by judgement in Venezuela. Therefore, adjudication by a court of material issues shall not be binding upon third parties or even the same parties in any subsequent proceedings. All controversial matters shall be the object of proof by the party carrying such burden, irrespective of such matters having been discussed and settled in previous trials.

Nonetheless, according to the res judicata rule contained in Article 49 of the Constitution of the Bolivarian Republic of Venezuela (“CBRV”); Article 1395 of the VCC; and Article 273 of the CCP, parties to a claim are barred from re-litigating the same claim or cause of action, if such claim has been adjudged by a final judgment rendered by the competent court. For the res judicata rule to apply, elements constituting the second claim (i.e. thing sued; cause of action; parties involved and their quality as claimant and defendant), must be identical to those of the original claim.

4 Procedure

4.1 Is the trial by a judge or a jury?

According to the CUPL, consumers injured by defective products can claim reparation either before the Autonomous Institution for the Defence and Education of Consumers (“INDECU”) or before the courts.

Consumers may try for mediation, conciliation or arbitration through the Conciliation and Arbitration Chamber of the INDECU. These proceedings are conducted by one mediator or arbitrator. The arbitration award shall be binding upon the parties and, in the case of non-compliance with its terms, may be enforced by a court of law.

Article 168 of the CUPL establishes that trial proceedings shall be carried out in accordance with the CCP’s Oral Trial, irrespective of the amount claimed and provided that no special procedure exists. The Oral Trial is meant to be an expeditious procedure, as opposed to common written trial proceedings, and is carried out before a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The Oral Trial established in Article 859 of the CCP, makes no reference to the judge having the power to appoint expert assessors. Nonetheless, Articles 401 and 514 of the CCP expressly grant the judge the power to “order an expert to assist the court upon certain issues, or to elaborate further or explain issues which were discussed in trial.” Articles 401 and 514 seek to assist the judge in clarifying uncertain issues after the parties have presented their evidence. We believe the judge of an Oral Trial may have this power, provided the use of such power does not go against the oral nature of the proceedings.
4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

According to Article 26 of the CBRV, and Article 80 of the CUPL, collective and class rights are recognised to exist and deserve the State’s protection. Nonetheless, neither a special procedure exists in Venezuela to try class actions, nor definition of collective or class rights has been much developed. Indeed, due to the somewhat recent recognition of collective rights in Venezuela (CBRV-1999; CUPL-2004), collective claims are not commonly brought in our country; however, such claims may become more frequent in the future.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Article 80 of the CUPL allows for collective claims to be brought when class rights are at stake. Article 76 (2) of the CUPL grants duly constituted consumer associations the right to represent consumers’ collective rights before administrative or judicial bodies. Both the INDECU (Article 110 of the CUPL) and the Public Defender’s Office (Article 281 Venezuelan Constitution), also have the power to bring collective claims on behalf of consumers. However, the aforementioned entities may only bring claims regarding criminal and administrative liability.

4.5 How long does it normally take to get to trial?

There are no pre-trial proceedings in Venezuela. Thus trial procedure begins as soon as the claim is filed with the competent court.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Pursuant to Article 866 of the CCP, the defendant may bring preliminary issues (for example, lack of jurisdiction, lack of standing, formal deficiencies in the lawsuit, res judicata, the existence of a legal prohibition on admitting the proposed claim, etc.) to the attention of the court. Depending on the preliminary issue and its recognition by the court, the remainder of the trial may or may not proceed. Under Venezuelan law, preliminary issues relate only to matters of law, and are decided by the trial judge pursuant to a special procedure established in the CCP.

4.7 What appeal options are available?

Pursuant to Article 878 of the CCP, decisions from the Trial Court may be appealed before the Court of Appeals. Decisions from the Court of Appeals may, in turn and depending on the amount of the claim, be appealed through a cassation writ before the Supreme Tribunal of Justice.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As stated in question 4.2 above, pursuant to Articles 401 and 514 of the CCP the judge has the power to order an expert to assist the court upon certain issues, or to elaborate further or explain issues which were discussed in trial. According to Articles 451 and in accordance with the CCP, the parties also have the right to present expert evidence. Under Venezuelan law, expert evidence is restricted to issues of fact.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There is neither pre-trial conference nor pre-trial discovery in Venezuela. All the evidence is presented and studied at the trial hearing.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

As stated above, there are no pre-trial procedures (including pre-trial discovery) under Venezuelan law.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Pursuant to Article 1977 of the VCC, all personal actions (including, in our opinion, actions for product liability) have a ten-year statute of limitations period, unless otherwise provided in special cases. Article 1525 of the VCC establishes a special regime for contractual liability arising from defective products. Thus depending on whether it is real estate or goods, a one-year or three-month limitation period would apply (40 days when dealing with animals). However, due to the protective pro-consumer nature of the CUPL, we believe Article 1525 of the VCC would not apply to cases governed by the CUPL.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

As stated above, time limits on bringing a product liability claim are based on the ten-year statute of limitations period. The statute of limitations period is not conditioned by the claimant’s age or situation, and courts have no discretion to ignore it.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Issues of concealment or fraud do not affect the running of the statute of limitations period.
6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

All damage referred to in this question are recoverable in Venezuela, provided that the injury is the immediate cause of a contractual breach or tortious act on the part of the defendant or any of the co-obligated individuals or legal entities.

Three types of damage are recoverable in Venezuela: (i) compensatory damage ("daños emergentes"), a decrease in the claimant’s assets directly and immediately attributable to the contractual breach or tortious act; (ii) loss of profits ("lucro cesante"), deprivation of earnings to which a claimant was entitled, and which may be seen as non-increase of assets; and (iii) pain and suffering (moral damages), an emotional or non-material injury to an individual.

Furthermore, Venezuelan commentators have been developing a thesis allowing for the possibility of recovering damages from a so-called “loss of opportunity”. Loss of opportunity would constitute a future damage, and its reparation is justified by the claimant having been deprived of the “opportunity” of obtaining a profit.

Pursuant to Article 1275 of the VCC, consequential or indirect damage is not recoverable in Venezuela.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

In Venezuela, only direct and actual damages are recoverable, meaning that: (i) the injury must exist by the time damages are claimed; or (ii) the damages must be the direct consequence of a real and existing injury. Thus eventual or speculative damages may not be recovered.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

In Venezuela, only damages intended to compensate the injured party for any loss or aggravation suffered may be recovered. Damages are not meant to either punish the defendant or set an example to the community. Thus punitive damages are not recoverable.

As stated in question 6.1 above, damages for pain and suffering are recoverable in Venezuela. As opposed to actual damages which tend to compensate the claimant for his loss of property, damages for pain and suffering seek to compensate the claimant for mental anguish, laceration of his feelings, shame or degradation. This may appear to be some kind of punitive damages; however, damages for pain and suffering are meant to compensate the claimant’s loss, and not to punish the defendant’s wrong. Compensation goes to the injured party and not to the State.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no limit. Any claimant would have the right to file suit for damages to the extent necessary to compensate his loss, and irrespective of how many claims arise from the same wrong.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Pursuant to Article 274 of the CCP, both court fees (or other incidental expenses) and the successful party’s own legal costs of bringing the proceedings may be recovered from the losing party. According to Article 286 of the CCP, recoverable legal costs are limited to thirty percent (30%) of the amount claimed. Each proceeding, appeal or incidental proceeding thereof must be considered separately in establishing court fees and legal costs.

7.2 Is public funding e.g. legal aid, available?

There is no public funding or legal aid available in Venezuela. The interested party must provide/pay any fees or legal costs arising from the proceedings.

7.3 If so, are there any restrictions on the availability of public funding?

See answer to question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The party may contract professional legal services through conditional or contingency fees. Nonetheless, lawyers are prohibited from obtaining payment of their fees directly from the court’s adjudication to their clients (prohibition of the cuota litis agreement). In other words, an agreement whereby the client assigns his lawyer a percentage of any compensation obtained in trial, is null and void under Venezuelan law.
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Macleod Dixon is a 240-lawyer international firm, focused for nearly a century on providing advice to clients globally. With offices in Calgary, Caracas, Rio de Janeiro, Moscow, Almaty, Atyrau and Toronto, we have developed a reputation for our ability to provide top-quality legal advice.

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