

## OVERVIEW GERMANY

### I. INTRODUCTION

The term 'product liability' refers to the liability of manufacturers and suppliers for personal injury or damage to property caused by a defective product. The German law of product liability is today 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 and Article 13 of Directive 85/374/EEC on liability for defective products ('Product Liability Directive')<sup>1</sup> preserves this juxtaposition. Liability in negligence plays the most important role amongst these regimes. Beginning in 1968, the *Bundesgerichtshof* (Federal Supreme Court) has gradually established a distinctive concept of 'producer liability' under general tort law which, although in principle based on fault, effectively implements a form of enterprise liability based on the concept of product defect.<sup>2</sup>

### II. THE PRODUCT LIABILITY REGIME

#### A. CONTRACT

The German law on the sale of goods is covered in §§ 433 ff of the Civil Code ('BGB'). With regard to international transactions, the United Nations Convention on the International Sales of Goods applies.<sup>3</sup> A fundamental reform of German contract law was enacted on 1 January 2002,<sup>4</sup> which also includes implementation of Directive 1999/44/EC on certain aspects of the sale of consumer goods and associated guarantees.

The main legal basis for damage claims in contract is § 280 BGB, which requires breach of a contractual duty. The most relevant breach of a contractual duty with respect to product liability is delivery of a "defective" product (§§ 434, 437 BGB).

#### 1. *Privity of contract*

Breach of a contractual duty, with respect to product liability situations, in most circumstances requires the existence of a contract between the claimant and the defendant. Although the idea of a contract conferring rights on third parties exists in German law (§

---

<sup>1</sup> O.J. 1985 L 210/29

<sup>2</sup> BGHZ 51, 91 ff [Chicken Pest].

<sup>3</sup> United Nations Convention on Contracts for the international sale of goods 1980 (BGBl. 1989 II 588; as amended BGBl. 1990 II 1699); s. Art. 28 EGBGB.

<sup>4</sup> Gesetz zur Modernisierung des Schuldrechts, BGBl. 2001 I p. 3183 ff.

311 III BGB), it is generally not available in product liability claims by a buyer against a manufacturer with whom he did not enter into a contract.<sup>5</sup>

## **2. Defective product**

A product is defective according to § 434 BGB if it is not in conformity with the contract.<sup>6</sup> The concept of defect is therefore primarily based upon a mutual, subjective idea of the product's features. The agreed quality can be higher or lower than the average quality of those products. Where the parties did not (expressly or impliedly) agree on a certain quality, goods will be defective (1) if they are not fit for the purpose expressed to, and recognized by, the seller, or (2) if they are unsuitable for the ordinary use to which products of such kind are normally put.

Unlike under the previous law of sale of goods, the seller is also liable for public statements on the specific characteristics of the product made by the manufacturer (or his representative), particularly in advertising or labeling (§ 434 I 3 BGB). The seller is, however, not liable for public statements if he did not know, or should have known, of those statements, or if he corrects those statements before contracting, or if those statements could not have influenced the decision of the buyer.

## **3. Fault requirement**

Contractual liability for defective products, in principle, requires that the seller was at fault as to the delivery of a defective product. § 280 I 1 BGB, however, in effect sets up a rebuttable presumption that the seller knew, or should have known, of the defective condition of the product. Yet in practice the seller will often be able to rebut the presumption of fault, for it is under no general obligation to check the quality of each product. The seller only has a duty to check that a product is free of defect where such an examination is reasonable in the circumstances. Where the seller grants an explicit guarantee, or explicitly or implicitly assumes responsibility for the quality of the good, he is liable even if he did not know, or should not have known, of the defect (§ 276 I 1 BGB).

## **4. Limitation period**

The limitation period for contractual claims is generally two years from the supply of the defective good (§ 438 BGB). This period is extended to five years if the defect concerns immovable property, or chattels which are normally incorporated into a building.

---

<sup>5</sup> Note, however, that the doctrine of third party contracts has developed since it was rejected by the *Bundesgerichtshof* in the Chicken-pest case (BGHZ 53, 91 ff) with respect to product liability cases. One situation for a third party claim would be, for example, an employee of a manufacturer suing another manufacturer who sold his employer a defective machine through which he became injured.

<sup>6</sup> See also Article 2 of the Directive on consumer goods and associated guarantees (1999/44/EC).

Where the seller knew of the defect, the limitation period is usually three years starting with the time at which the buyer became aware of the defect and the damage.

## **B. TORT**

Product liability in tort comprises liability for breach of a general duty of care (*Verkehrspflicht*) under § 823 I BGB and breach of statutory duty (*Schutzgesetz*) under § 823 II BGB.

### **1. Breach of a duty of care**

Most product liability claims have, so far, been brought on the basis of a breach of a duty of care. It is here that the case law of the *Bundesgerichtshof* on product liability comes into play. The main feature of this case law is that the claimant does not have to prove fault on behalf of the manufacturer (or his employees) but only that the product was defective at the time of marketing. In this context, the *Bundesgerichtshof* has identified three types of defects: *manufacturing defects*, *design defects* and *instruction defects* (failure to warn/provide proper product information).<sup>7</sup>

If the claimant can prove the existence of a defect, it is for the manufacturer to show that it did everything necessary and reasonable to discover and avoid the defect. Contrary to the situation under the Product Liability Directive, however, the claimant in principle needs to prove that the product was already defective at the time of marketing. This may be different where the manufacturer, due to intrinsic, particular risks in the manufacturing process, is bound to ensure the safe state of the product before it leaves the premises.<sup>8</sup>

### **2. Breach of statutory duty**

Manufacturers are also liable for intentional or negligent *breach of a statutory or regulatory provision* meant to protect other persons. It makes no difference whether the provisions are based on federal, state or EC law. Important examples of such provisions can be found in the Appliances and Product Safety Act, the Food Act, the Drug Act, the Medical Devices Act and the Criminal Code.<sup>9</sup> While the claimant here needs to prove

---

<sup>7</sup> BGH 51, 91 ff. (*Chicken Pest*) manufacturing defect [LINK]; BGHZ 67, 359 (*Floating Switch*) design defect [LINK]; BGHZ 116, 60 (*Toddler Tea*) instruction defect [LINK]; but see also BGHZ 80, 186 (*Derosal*) instruction defect

<sup>8</sup> BGHZ 104, 323 (*Lemonade Bottle*); BGH NJW 1993, 528 (*Sparkling Water Bottle I*); BGH NJW 1998, 2611 [LINK]

<sup>9</sup> Geräte und Produktsicherheitsgesetz, Lebensmittel- und Bedarfsgegenständegesetz, Arzneimittelgesetz, Medizinproduktegesetz und Strafgesetzbuch [give full references for each].

the breach of a statutory/regulatory duty, it will usually be for the defendant to show that this breach did not occur through fault.<sup>10</sup>

### 3. *Post-marketing duties*

Post-marketing duties of producers exist as general duties of care (negligence) and statutory duties. The manufacturer's duty of care does not end with the marketing of the product. The courts have always stated that manufacturers are obliged to monitor their products and take appropriate measures, including warnings and recalls, if dangers become apparent subsequent to their marketing. Failure to do so constitutes breach of a duty of care and thus a potential ground for liability.<sup>11</sup> In a modification of its defect-focused case law in negligence (see above), the *Bundesgerichtshof* maintains that there is no shift in the burden of proof regarding breach of such a post-marketing duty, i.e. the claimant needs to show that the manufacturer should have discovered the risk in question through product monitoring and testing.<sup>12</sup>

While post-marketing duties in the past were mainly the domain of negligence, the transposition of the revised General Product Safety Directive (2001/95/EC) will shift the focus further towards breach of statutory duty. Under the transposition legislation, the Appliances and Product Safety Act (*Geräte- und Produktsicherheitsgesetz, GPSG*),<sup>13</sup> manufacturers are under a duty to place only safe products on the market (§ 4 GPSG). Suppliers are required not to place products on the market which they know or should know, given the information and experience they have, are unsafe (§ 5 II GPSG).

Manufacturers are also obliged to conduct proper *market surveillance*, including the taking of test-samples, and to implement appropriate measures if product risks emerge post-marketing. This includes *warning* suppliers and the public of product risks, using appropriate means. What type of warning is appropriate depends on the nature of the product and the relationship to suppliers and customers. For example, where suppliers and customers are known, personal letters, email and telephone may be appropriate means of contact. In anonymous customer relationships, manufacturers may have to use the media and the internet to effectively issue warnings. Manufacturers are further under a duty to *withdraw* a product from suppliers, or *recall* a product from customers, where the nature and seriousness of the risk requires such action (§ 5 I no. 1 c GPSG).<sup>14</sup>

---

<sup>10</sup> BGHZ 51, 91 ff (*Chicken Pest*)

<sup>11</sup> BGH NJW 1981, 1606 (*Benomyl*); BGHZ 99, 167 (*Honda*).

<sup>12</sup> BGHZ 80, 199 (*Derosal*).

<sup>13</sup> Geräte- und Produktsicherheitsgesetz of 6 January 2004 (BGBl. 2004 I 2).

<sup>14</sup> See also C. Schieble, *Produktsicherheitsgesetz und europäisches Gemeinschaftsrecht* (Nomos, Baden Baden 2003) 64, 177 and 228 ff; for recalls under the general duty of care see Foerste in Westphalen (ed.) *Produkthaftungshandbuch* § 24/233 ff.

A new duty for manufacturers and suppliers is the duty to instantly *notify the competent authority* if they notice that their products pose any risks to life or health of persons, or if there is reason to believe that such risks exist (§ 5 II GPSG).<sup>15</sup>

Failure to comply with product safety duties can lead to a claim for breach of statutory duty under § 823 II BGB. For example, failure to recall a product will lead to liability where a recall would have been the “appropriate action”. Whether and what action is appropriate is not to be judged with hindsight but in consideration of the circumstances at the time when such action was due. However, this is an objective standard focusing on the danger of the product, not on the capabilities of the individual manufacturer. This invokes the difficult question of whether the element of fault, usually required under German law for breach of statutory duty, is still relevant. There is reason to assume that infringements of European product safety law must be sanctioned in an equal fashion if the *effet utile* of this law is to be enforced, and that therefore fault in those cases can no longer be a requirement under § 823 II BGB. The practical relevance of this question may be diminished by the fact that, in the case of breach of statutory duty in Germany, the manufacturer normally has to prove that it could not have identified the breach of duty, and that in the example of a recall, such action was appropriate.

Note finally that courts in Germany are likely to accept claims for mandatory injunctions of consumers with respect to warnings and even recalls.<sup>16</sup>

#### **4. Subject of the duty**

A duty of care in tort can lie 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 of the individual person. In contrast to the situation under the Product Liability Act (see below), the supplier can be liable in tort, regardless of whether the 'producer' can be identified.<sup>17</sup> A duty of care can also rest on members of management, who thus may be personally liable for product defects and post-marketing failures.<sup>18</sup>

---

<sup>15</sup> See also C. Schieble, note 14, 65.

<sup>16</sup> Compare BGH VersR 1986, 1125; critical Foerste in Westphalen (ed.) *Produkthaftungshandbuch* (Munich CH Beck 1997) § 39/1 ff.

<sup>17</sup> BGHZ 139, 43 (*Fireball I*) and BGHZ 139, 79 (*Fireball II*).

<sup>18</sup> BGH VersR 2001, 381 (*Toddler Tea IV*); BGH NJW 1975, 1827; BGH NJW 1987, 372.

## C. STRICT LIABILITY

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')<sup>19</sup>.

### 1. *Product Liability Act*

The PLA faithfully implements the Product Liability 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; 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),<sup>20</sup> this could change. The PLA applies only to products that have been put on the market after 1 January 1990.

§ 1 I PLA sets up the basic rule by which producers are liable for personal injury or property damage caused by defective products.

#### a. *Product*

The term 'product', as defined in § 2 PLA, refers to moveable goods and electricity.<sup>21</sup> Implementing Directive 1999/34/EC, the PLA with effect from 1 December 2000 no longer excludes primary agricultural products and game from its scope.

#### b. *Producer*

The term 'producer' (§ 4 PLA) includes the manufacturer of the product or a component, the producer of raw material, the 'own-brander' and the person importing into the EU (or the European Economic Area). The supplier of the product is only liable if the producer cannot be identified unless the supplier fails to inform the injured person within one month of the identity of the producer (in the EU/EEA) or the supplier. The same applies if the importer cannot be identified, even if the producer is indicated.

#### c. *Defect*

According to § 3 PLA, "a product is defective if it does not provide the safety one is entitled to expect, taking all circumstances into account, including:

---

<sup>19</sup> Respectively, Produkthaftungsgesetz, Arzneimittelgesetz, Gentechnikgesetz.

<sup>20</sup> Second Act to change the rules relating to damages (Zweites Gesetz zur Änderung schadensersatzrechtlicher Vorschriften BGBl. 2002 I, 2634 ff.)

<sup>21</sup> An interruption of electricity supply does not trigger product liability, for in such a case no defective product has been supplied.

- (a) the presentation of the product;
- (b) the use to which it could reasonably be expected that the product would be put;
- (c) the time when the product was put into circulation.

A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.”

Although neither the PLA nor the Product Liability Directive distinguish between different types of defects, German courts, through case law, have (re-)established the three known categories of defects: manufacturing defects, design defects and instruction (warning) defects.<sup>22</sup> [LINK] This has far-reaching consequences for the application of the concept of defect. In this trifurcated scheme, certain provisions only apply to certain categories of defects.<sup>23</sup> The most important effect of the disentangling of the concept of defect is that strict liability only really remains for *manufacturing defects*.<sup>24</sup> [LINK]

The issues underlying the question whether a product is defectively designed, or whether the manufacturer has failed to warn consumers of product dangers, largely echo the questions arising in negligence.<sup>25</sup> [LINK] Where the safety of product *design* is in question, courts particularly take into account any existing regulations or (non-binding) standards.<sup>26</sup> [LINK] A frequent but clearly mistaken view, particularly amongst (lower) courts, is that compliance with common industry customs (or standards) will prevent a product from being defective. This erroneous idea usually carries the label “state of the art defence”. However, state of the art is not what everybody else does; it is what could be done.<sup>27</sup> A more recent and also more consistent interpretation of the concept of design defect makes use of the notion of risk-utility analysis. The decisive criterion for design defects is thus normally whether or not a *reasonable alternative design* existed for the product in question.<sup>28</sup>

In many cases it is not possible to design a product in a way that makes it completely safe. Yet its marketing may still be appropriate, considering the product's utility, its

---

<sup>22</sup> BGH NJW 1995. 2162 (Sparkling Water Bottle II) [LINK]; OLG Düsseldorf, 20.12.2002, 14 U 99/02 (Chocolate Bar) [LINK]; OLG Hamm NJW-RR 2001, 1248 (Log Flume) [LINK].

<sup>23</sup> For example, Art 6 I c, 6 II only to design and warning defects, Art 7 b only to manufacturing defects, Art 7 d only to design defects, Art 7 e only to design defects, Art 7 f only to design and warning defects.

<sup>24</sup> BGH NJW 1995. 2162 (Sparkling Water Bottle II) [LINK].

<sup>25</sup> OLG Düsseldorf, 20.12.2002, 14 U 99/02 (Chocolate Bar) [LINK]; OLG Hamm NJW-RR 2001, 1248 (Log Flume) [LINK]; OLG Cologne, 27.8.2002, 3 U 116/00 (Mountain Bike) [LINK].

<sup>26</sup> OLG Düsseldorf, 20.12.2002, 14 U 99/02 (Chocolate Bar) [LINK]; OLG Hamm NJW-RR 2001, 1248 (Log Flume) [LINK]; OLG Frankfurt, 1.2.2001, 1 W 11/00 (Tobacco Claim) [LINK].

<sup>27</sup> The contrary view is wrong with respect to design defects and negligence. The common standard of care is not always the required and reasonable standard of care as the *Bundesgerichtshof* has made clear (BGHZ 8, 141; 23, 290; see also BGH NJW 1965, 1075).

<sup>28</sup> Compare § 2 US Restatement (Third) of Torts: Products Liability. Assenting MünchKomm/Wagner ProdHaftG § 3/31.

general benefits for society, and the fact that there is simply no safer alternative design. Manufacturers are then under a duty to reduce such unavoidable product risks by means of adequate product information and warnings.<sup>29</sup> The producer thereby not only needs to warn of dangers present in the ordinary use of the product but also of dangers related to any foreseeable misuse.<sup>30</sup> The extent of the duty to warn generally depends on the level and nature of the risk, and the probability of its manifestation.<sup>31</sup> The extent of the duty to warn is limited by general consumer knowledge. That is, there is no need to warn of risks which are generally known to its possible users.<sup>32</sup> The courts have thus denied a duty to warn of the dangers of tobacco,<sup>33</sup> alcohol<sup>34</sup> and chocolate bars<sup>35</sup>.

*d. Proof of defect, damage and causation*

According to § 1 IV PLA, it is for the claimant to prove the damage, the defect and the causal relationship between defect and damage. On the issues of defect and causation German courts have on several occasions allowed the claimant to rely on *prima facie* evidence. For example, a guest who contracted Hepatitis-A after having eaten in the restaurant of the defendant could rely on evidence that the chef of the restaurant had been infected with Hepatitis-A.<sup>36</sup> [LINK] However, the courts are often strict about the conditions under which the rule of *prima facie* applies.<sup>37</sup> As far as defect is concerned, referring to the rule of *prima facie* is unnecessary: all the claimant has to do is to show that the product “did not provide the safety that one is entitled to expect” (§ 3 PLA). Safety is a complex concept. There may not always be an exact technical explanation as to why a product is considered unsafe. If a product fails in circumstances where one is entitled to expect that it does not fail, this in itself is proof of a defect. Generally speaking, the higher the expectations of safety to which the typical consumer

---

<sup>29</sup> BGH VersR 1972, 1161 (*Estil*).

<sup>30</sup> BGH VersR 1987, 102, 103 (*Zinc Spray*); BGH NJW 1989, 1542 (*Asthma Spray*); BGHZ 116, 60, 65 (*Toddler Tea I*); BGH ZIP 1995, 747 (*Toddler Tea III*); BGH VersR 1999, 892 (*Paper Shredder*); OLG Hamm NJW-RR 2001, 1248 (*Log Flume*) [LINK]; OLG Düsseldorf, 20/12/2002, 14 U 99/02 (*Chocolate Bar*) [LINK].

<sup>31</sup> BGHZ 80, 186, 192 (*Apple Scab, Derosal*).

<sup>32</sup> BGH NJW 1986, 1863, 1864; BGH NJW 1996, 2224 (*Lubricating Gel*); OLG Hamm NJW-RR 2001, 1248 (*Log Flume*) [LINK]; OLG Düsseldorf, 20/12/2002, 14 U 99/02 (*Chocolate Bar*) [LINK].

<sup>33</sup> OLG Frankfurt NJW-RR 2001, 1471 [LINK].

<sup>34</sup> OLG Hamm NJW 2001, 1654 [LINK].

<sup>35</sup> OLG Düsseldorf 20/12/2002, 14 U 99/02 [Link].

<sup>36</sup> OLG Frankfurt NJW 1995, 2498 (*Hepatitis-A*) [LINK].

<sup>37</sup> OLG Hamm 4.10.2001 – 6 U 6/01 (*Ski Accident*); OLG Frankfurt NJW-RR 1994, 801 (*Bicycle*); LG Kiel NJOZ 2001, 935 (*Salmonella Infection*).

is entitled, the lower the extent to which the claimant has to investigate the exact nature of events leading to the product's failure - and vice versa.<sup>38</sup>

Special problems arise where it cannot be ascertained which of several generic products did in fact cause the damage. According to § 830 I 2 BGB, participants of a tort<sup>39</sup> are jointly and severally liable "where it cannot be ascertained which of several participants caused the damage through his conduct". It is controversial whether several individual producers can be seen as "participants". On a sound reading of § 830 I 2 BGB, several manufacturers should be seen as participants if they all contributed to the risk of injury, provided that other causes for the injury can be excluded. The rule may therefore apply in cases where the claimant cannot prove which of the products *he had actually used* in fact caused the damage.<sup>40</sup> However, it will not apply where he cannot even say *which* products he had used, which is the typical situation where some courts in the US in certain circumstances (especially in asbestos cases) have applied the concept of *market share liability*.

*e. Damage*

The PLA only covers damage flowing from personal injury or damage to property other than the defective good. It does not cover:

- damage to property not ordinarily intended for private use;
- damage to the product itself;
- (other) pure economic loss;
- property damage of less than €500.

As of 1 August 2002, compensation for pain and suffering is included within the range of recoverable damages (§ 8 sentence 2 PLA).

In the case of personal injury caused by one product, or by generic products with the same defect, the maximum liability is €85 million (§ 10 PLA). This provision was originally included in the Product Liability Directive in order to guarantee insurability for development risks. The implementation of both the development risks defence and damage caps is incoherent as liability for design and instruction defects - this is where

---

<sup>38</sup> S. Lenze, *Proof of Defect*, 9 (2002) European Product Liability Review 40 ff; Lenze, *Zum Beweis des Produktfehlers, Produkthaftpflicht International* (6) 2003, 242; Lenze, *Strict Liability for Manufacturing Defects – What proof is needed*, 11 (2003) European Product Liability Review. See also L Nottage, *Product Liability in Japan* (forthcoming). S. also the case law of the Austrian Supreme Court [LINK].

<sup>39</sup> Albeit seeded in tort law, this provision also applies to the law of contract as well as to strict liability (BGH NJW 1999, 3633)

<sup>40</sup> BGH NJW 1994, 932 (*Toddler Tea II*) [LINK]

development risks can occur - essentially parallels the issues underlying a negligence standard. It is nevertheless applicable law in Germany.

*f. Defences*

§ 1 II - IV stipulate a number of defences:

- The producer is not liable if it did not put the product into circulation. A product is put into circulation when it is passed on to the next person in the chain of supply (another manufacturer, supplier, or consumer) or made available for collection. That means, for example, a product which is stolen from the premises of the manufacturer is not put into circulation by the manufacturer. On the other hand, a component-product is put into circulation with delivery to the manufacturer of the final product. According to the European Court of Justice, a product is also put into circulation when it is used during the provision of a service even if the final consumer never comes into contact with that product.<sup>41</sup>
- The producer is not liable if “it is to be assumed” that the product was free from defect at the time of circulation. The producer is therefore not liable for damage caused by inappropriate storage by the supplier, and for post-marketing contamination or sabotage. Although the German rules on standard of proof generally require establishing a very high probability of the relevant facts, an autonomous interpretation of the Product Liability Directive suggests that the manufacturer is not liable if, on a balance of probabilities, it is more likely than not that the defect came into being post-circulation.<sup>42</sup>
- The producer is not liable if the product was not manufactured for sale or for any other form of distribution with economic purpose. This defence excludes private non-profit activities from product liability.
- The producer is exempted from liability if the defect is due to compliance with mandatory regulations issued by the public authorities. Contrary to what the wording of this defence seems to suggest, its scope is very narrow. Most of the relevant provisions (e.g. those in the Product Safety Act) only set minimum standards, which do not release the manufacturer from its responsibility to observe stricter obligations imposed by product liability law.
- The producer is not liable if the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the exis-

---

<sup>41</sup> Case C-203/99, *Henning Veedfald v Arhus Amtskommune*, [2001] ECR-I 3569.

<sup>42</sup> See S Lenze, *Defective but not at time of circulation*, 11 (2003) *European Product Liability Review* 35, 36.

tence of the defect to be discovered (the so-called development risks defence). According to the European Court of Justice, this requires proof that it was objectively impossible to discover the harmful characteristics of the product, 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).<sup>43</sup> However, such knowledge must be accessible.<sup>44</sup> The *Bundesgerichtshof* has maintained that this defence does not apply to manufacturing defects.<sup>45</sup> The consequence of this jurisprudence is that liability for manufacturing defects is strict, whereas design defects and warnings are judged by a depersonalized high standard of negligence.

- A producer of a component is further not liable if 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.

*g. Limitation period*

A claim under the PLA must be brought within three years of the time when the injured consumer became aware of the damage, the defect and the potential defendant (§ 12 PLA). The limitation period is suspended by pending negotiations between the parties (§ 203 BGB), and interrupted only by the filing of a formal action (§ 204 BGB). Correspondence before any action is taken does not prevent claims from becoming statute-barred.

The Act also states that claims expire 10 years after the product has been put in circulation (§ 13 PLA). The “product” is put into circulation when the producer supplies the actual defective product to the next person in the chain of supply, i.e. not already at the launch of the product line.

## **2. Drug Act**

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 and renders insurance compulsory. Together with new rules on causation and a special - and in German law unusual - claim for disclosure, both of which were introduced in

---

<sup>43</sup> Case C-300/95, *Commission v UK*, at para. 26; see also H.-J.Kullmann, *Produkthaftungsgesetz* (3<sup>rd</sup> ed. 200) § 1/5 b.

<sup>44</sup> *Commission v UK*, note 29, 29.

<sup>45</sup> BGH NJW 1995, 2162.

2002,<sup>46</sup> the German Drug Act is one of the strictest (statutory) product liability regime in the EU.

*a. Background*

The Drug Act of 1976 was enacted against the background of the Thalidomide crisis of the late 1950s, which had struck Germany particularly badly. This incident highlighted the necessity of reviewing the quality, efficacy and safety of medicinal products prior to their marketing, authorization and sale.

*b. Conditions for liability*

A claim under § 84 of the Drug Act requires:

- that as a result of a defective medicinal product, or of incorrect or insufficient product information;
- a person has suffered personal injury or death;
- that the medicinal product holds a marketing authorization, or is deemed to hold such authorization; and
- that the use of the product was appropriate, that is, in accordance with the product information included in and on the packaging.

*c. Defendant company*

Under § 84 of the Drug Act, the entity named on the packaging which placed the product on the German market is a potentially liable 'pharmaceutical enterprise'. Importing companies are also responsible if the product is sold under their name. Even if the product is re-imported to Germany, it is the re-importer that holds the marketing authorization, and that is named on the outer packaging of the product, which is liable, not the German producer as the German producer did not place the product on the German market.

Where a foreign subsidiary of a German-based company imports a product into Germany, the German parent-company is liable, provided that the product is placed on the market under its name. Conversely, in the case of a parallel import, the liable party is the importer and not the German subsidiary of the original producer. Where there is more than one responsible party, each party is jointly and severally liable, and is entitled to seek recourse from co-debtors (§ 93 of the Drug Act).

---

<sup>46</sup> See also I. Brock, *German parliament passes the Second Act to change the rules relating to damages*, Lovells, European Product Liability Review, June 2002 at 16 f.; <http://www.lovells.com> (Publications - Newsletters).

*d. Products*

Strict liability under § 84 of the Drug Act only applies to medicinal products produced for human use that have a marketing authorization and that have been placed on the German market. § 84 of the Drug Act is *not* applicable to:

- veterinary medicines, even though an animal for human consumption that is treated with a hazardous medicinal product may indirectly cause personal injury to consumers;
- bulk material that is not designated for sale to consumers;
- most homeopathic preparations;
- specialty products produced by pharmacies without a marketing authorization;
- medicinal products imported on a 'named patient' basis without a marketing authorization;
- non-approved medicinal products used in clinical trials; and
- medicinal products manufactured in Germany but exclusively earmarked for export.

Injuries suffered from these medicinal products may be covered by the Product Liability Act and liability based on tort.

*e. Defectiveness*

According to § 84 II no. 1 of the Drug Act, the 'pharmaceutical enterprise' is liable if "a drug, at correct use, has harmful effects which, taking into account the state of medical knowledge, exceed a tolerable level", i.e. if the risks of the drug outweigh its benefits.

Alternatively, the distributor is liable "if the injury is caused by an instruction which does not adequately represent the state of medical knowledge" (§ 84 II no. 2 Drug Act). The product information must, in a clear and appropriate way, point to any product risks and side effects known at the time of circulation, and point out any serious possibility of such risks and side-effects, even if scientific evidence on that issue is not fully clear. The product information must also include instructions relating to the correct use of the drug and it must in certain circumstances also highlight the possible consequences of foreseeable misuse.<sup>47</sup>

---

<sup>47</sup> BGHZ 106, 273, 284 (Asthma Spray).

The pharmaceutical enterprise must also monitor the product post-marketing and if it finds out about risks previously unknown, including a frequent misuse of the drug, update product information accordingly.

*f. Causation*

The claimant, in principle, needs to prove a causal link between the defective drug and the damage. Yet there are exceptions to this rule. The *Bundesgerichtshof* decided that in the case of inadequate product information, it is for the defendant to prove that the patient would have used the drug even if he or she had been correctly and fully informed.<sup>48</sup> However, this “actual assumption” is not as difficult to rebut as it may seem.

Additionally, in 2002 the German legislator, in an unprecedented fashion, changed the rules on causation. According to the new rules, *actual* causation between the application of the drug and the damage is presumed if the drug in question is, in the actual circumstances, *generally* capable of causing such damage (§ 84 II 1 Drug Act). This rule does not, however, apply “if, in the actual circumstances, a different instance could have caused the damage” (§ 84 II 3 Drug Act). However, another drug which also may have caused the injury is *not* regarded as a “different instance”. This is different if this drug is not considered defective (e.g. because its harmful effects are acceptable in the light of the benefit-risk assessment).

Whether the new causation rules are in compliance with EC law remains to be seen. There are sound reasons why the new rules may contravene Article 13 of the Product Liability Directive. Article 13 allows special product liability systems to remain applicable if they existed at the time when the Directive was adopted by the Council, i.e. on 25 July 1985. The German Drug dates back to 1976, yet the changes happened in 2002. The question thus is whether Article 13 allows changes to existing systems. The European Court of Justice recently made clear that the Product Liability Directive seeks to achieve maximum harmonisation within its scope.<sup>49</sup> That suggests a narrow reading of Article 13, one that does not allow the German legislator to go it alone in the EU and change the only (national) co-existing product liability regime in a way that would, after 18 years of practical symmetry with the Directive, make a real difference.

*g. Damage caps*

Under § 84 of the Drug Act, only compensation for personal injuries caused by defective medicinal products is recoverable. § 88 of the Drug Act limits individual claims under § 84 to €600,000. If the claimant is awarded an annuity, the annuity must not ex-

---

<sup>48</sup> BGH NJW 1992, 560, 562 (Toddler Tea); see also OLG Frankfurt NJW-RR 1999, 27, 30.

<sup>49</sup> Case C-52/00, *Commission v France* [2002] ECR I-2553; Case C-154/00, *Commission v Greece* [2002] ECR I-3879; Case C-183/00, *González Sánchez v Medicina Asturiana* [2002] ECR I-3901.

ceed €36,000 per year. If the same medicinal product has caused injury to several persons, these amounts cannot exceed €20 million in total, or €7.2 million annually. The new § 87 sentence 2 extends liability to immaterial damages such as pain and suffering.

*h. Compulsory insurance*

A party placing a medicinal product on the German market must be insured against all liability under § 84 of the Drug Act, either through a German insurance company or by obtaining a confirmation of cover from a credit institution in Germany or within the EU. The German insurance industry has created a 'pharma pool' through which all major insurance companies pool the statutory strict liability risk, thus facilitating affordable insurance premiums.

**3. Genetic Engineering Act**

The Genetic Engineering Act came into force on 1 July 1990 and aims at protecting human beings and the environment against dangers which may arise from genetic engineering. It also establishes a legal framework for relevant research and development and the exploitation and promotion of this technology. Activities conducted in genetic laboratories are classified into four containment levels according to the degree of risk they involve.

§§ 32 ff of the Genetic Engineering Act provide for the operator's absolute liability if damage is caused to third parties as a result of properties of a genetically modified organism. Liability is limited to a maximum amount of €85 million. The Act also includes liability for development risks (i.e. there is *no* development risks defence).<sup>50</sup> Liability based on the Genetic Engineering Act covers material as well as immaterial damages (the latter as of August 2002). In so far as the Genetic Engineering Act derogates from the Product Liability Directive,<sup>51</sup> one could query its compliance with Article 13 of the Directive (see above).

**D. STATE COMPENSATION SCHEMES**

State compensation schemes play a significant role in German product liability law. Thalidomide victims have a right to benefits provided by a public foundation established in 1971.<sup>52</sup> Another public foundation has been set up to help patients who were infected with HIV through contaminated blood products before 1 January 1988.<sup>53</sup> In

---

<sup>50</sup> § 37 II GentechnikG.

<sup>51</sup> That is, particularly with regard to products without marketing approval (compare § 37 II GentechnikG).

<sup>52</sup> Gesetz über die Errichtung einer Stiftung 'Hilfswerk für behinderte Kinder', BGBl. I 1971, 2018 ff.

<sup>53</sup> Gesetz über die humanitäre Hilfe für durch Blutprodukte HIV-infizierte Personen, BGBl. I 1995, 972 ff.

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.<sup>54</sup>

Most notably, however, there is special compensation scheme for accidents at the work place and occupational diseases.<sup>55</sup> A large part of asbestos litigation, for example, is for this reason redirected to social security system.

### **III. PRACTICE AND PROCEDURE**

#### **A. PRE-TRIAL OR PRE-ACTION DISCOVERY**

German law has traditionally been fairly restrictive regarding pre-trial discovery and document disclosure in particular. There is no pre-trial discovery procedure and no general claim for disclosure that would help the claimant establish liability. Recent reforms of the Code of Civil Procedure (CCP)<sup>56</sup> and the Drug Act, however, have introduced tighter rules for the disclosure of documents.

Under § 84a of the Drug Act, the injured person can now request that the manufacturer (and the relevant authority) provide information on known effects, side effects and interactions of a drug. 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 substantiated reference 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.<sup>57</sup>

#### **B. EXPERT OPINIONS**

Many product liability cases deal with issues which are highly technical in nature. These cases always require the opinion of experts. According to German procedural law, it is the duty of the judge to instruct experts for the purpose of giving expert evidence in court. Counsel for the claimant and the defendant file their briefs prior to the trial, presenting the facts and legal issues relevant to the case. The judge then - usually after a preparatory hearing - formally orders the hearing of evidence and instructs the experts. The parties have a right to obtain their own expert opinions (in addition to the

---

<sup>54</sup> See I. Brock, *State Compensation for HCV Infections in the Federal Republic of Germany*, Lovells, European Product Liability Review Dec 2000 at 16 f., also at <http://www.lovells.com> (Publications - Newsletters).

<sup>55</sup> The competent institutions are the *Bundesberufsgenossenschaften*.

<sup>56</sup> Gesetz zur Reform des Zivilprozesses vom 27.7.2001, BGBl I, 1887 ff.

<sup>57</sup> See further I. Brock, *Does discovery find its way into the German rules on civil procedure?*, Lovells, European Product Liability Review, December 2002 at 28 f., also at <http://www.lovells.com> (Publications - Newsletters)

reports delivered by court-appointed experts) on the questions at issue. However, such private expert opinions are normally not of equal value to reports by court-appointed experts.

### **C. TRIAL ON PRELIMINARY ISSUES**

There is no trial on preliminary issues in the German law of civil procedure. For example, at no time does the court decide on the *admissibility* of scientific evidence, for it appoints the experts itself. Furthermore, the court cannot split the trial to decide on certain *preliminary issues* (e.g. causation) first. What the court can do, however, is focus on certain issues (e.g. causation) first, take evidence on them - and then 'discuss' the outcome with the parties. Courts may also initially take a decision on the merits, while reserving the assessment of damages until later (§ 304 CCP).

Each party may in certain circumstances *prior to the trial* request that the court appoint an expert to give an opinion on the cause of injury or defect<sup>58</sup> (§ 485 II CCP). This may, depending on the opinion, prompt the claimant to withdraw the claim or it may lead to a settlement. The claim for disclosure under the Drug Act can be litigated separately, prior to the damage action.

### **D. FEE ARRANGEMENTS AND LEGAL COSTS**

Lawyers in Germany are not allowed to work on a 'no win - no fee' basis or to agree on contingency fees.

The losing party must generally reimburse the winner's legal fees and court costs. Fees and costs are calculated on the basis of the amount of damages claimed. To cover the costs of litigation, legal insurance is available. An uninsured claimant sues at his own risk, which increases proportionally to the amount claimed. This may prevent some claimants from claiming unrealistically high compensation amounts simply to improve their position in settlement negotiations. However, with legal insurance becoming increasingly common in Germany, this effect loses significance.

More recently companies which offer financing of claims have been emerging in Germany. This effectively operates similarly to contingency fee arrangements. The company guarantees coverage of the costs of litigation in return for a 20% to 30% share of the amount of compensation realized. These companies will consider the amount of money in dispute and the claimant's prospects of success.

---

<sup>58</sup> Defect here, in the strict sense, refers to contract law, but there seems to be no reason why it should not apply to 'product liability defects' as well.

**E. CLASS OR REPRESENTATIVE ACTIONS**

Class actions or similar means of bundling mass tort actions are not available under German law. In cases of serial damages, however, it is possible for one particular lawyer or firm to coordinate litigation. Mass tort actions are thus often settled out of court. Companies financing litigation have recently tried to set up a fund for group or mass tort cases to pursue the claims assigned to it.

Representative actions too are not available in the areas of product liability and product safety. Although the Injunction Act 2002 (*Unterlassungsklagegesetz*) gives certain bodies the right of representative action where (any) 'consumer protection laws' are being infringed, this Act does not apply to provisions related to product risks such as, for example, the Product Safety Act. 'Consumer protection' in this context refers to business-to-consumer practices only.<sup>59</sup>

---

<sup>59</sup> See the legislative intention to the Act, BT-Drucks. 14/2658 at 52 - 53 and Directive 98/27/EC on injunctions for the protection of consumers' interests.