Regulation and Product Liability
The European Approach
Overview

- Changing environment for product liability litigation
- The European product liability directive and regulatory compliance
- Case law on compliance and non-compliance
- Regulatory compliance and pharmaceuticals
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Changing Environment for Product Liability Litigation in Europe
Hunderte Tote in Deutschland?
Comment participer à un procès collectif ?

Qu'est-ce qu'une "Class Action"?
"class action" est le vocable d'origine anglo-saxonne désignant les recours entrepris pour le compte de personnes identifiées ("class" ou catégorie) ayant subi des préjudices individuels qui ont été causés par le fait d'un même auteur et dont l'origine est commune.

"Class Action" en cours ou à venir
Vous avez une idée de Class Action !!! Cliquez ici

Le procès en réparation du préjudice causé par l'entente illicite entre les 3 opérateurs mobiles est imminent.

Pour en savoir plus sur cette action(Cliquez ici)

Procès pour les actionnaires de VIVENDI UNIVERSAL

Pour en savoir plus sur cette action(Cliquez ici)

Vos témoignages...
Jean-Michel H. (68)
Je possède plus de 250 DVD!
En savoir +

Claire B. (22)
J'ai un fils de 9 ans qui est fou de dessins animés
En savoir +

Roger et Michelle (84)
Impossible de faire une copie privée
En savoir +

Dernières nouvelles :
Dans les médias : Presse / TV / Radio / Internet

- Lawsuits fuel debate in France
  - ABC News Business
    (04-10-05)

- L'introduction des class actions en France
  - La Gazette du Palais

FAIRE CONNAITRE CE SITE À UN AMI
Cliquez-ici

Le site classaction.fr donne au public la nécessaire information sur ses droits et lui permet de les faire valoir grâce à des procès collectifs.

EN SAVOIR +

- Déontologie
- Vos droits
- Informations utiles
- Conditions générales
- Conditions générales applicables à compter du 23-06-05
- Déclaration à la Cnil
- Informations sur la CARPA

Quelques exemples d'actions collectives de ce type :
- Philip Morris le procès du tabac
“Bring me your CLASS ACTIONS”
March 2007: German Federal Constitutional Court: Ban of contingency fees not in line with constitution
The European product liability directive and regulatory compliance

- Regulatory compliance defence rejected in the legislative process of Directive 85/374/EEC

  - Regulatory compliance defence is an area the Commission wants to “monitor”
  - “Some stakeholders, and in particular representatives of the pharmaceutical industry, have argued strongly for the introduction of a defence of regulatory compliance, which would apply to a product whose safety was closely regulated, provided that the product complied fully with the applicable regulations.”
The relevant provisions

Article 7
The producer shall not be liable (...) if he proves (...) that the defect is *due to compliance* of the product with mandatory regulations issued by the public authorities.

Section 4 Consumer Protection Act
(...) in respect of a defect in a product it shall be a defence for him to show that the defect is *attributable* to compliance with any requirement imposed by or under any enactment or with any Community obligation.

Article 6
A product is defective when it does not provide the safety which a person is *entitled* to expect, taking all circumstances into account (...).
A producer may be liable for a defect although the product was manufactured in accordance with the rules of the trade or of existing standards or although it was the subject of an administrative authorization."
European Case law on regulations and product liability
Non-compliance

- **Pollard v Tesco Stores Ltd** [2006] EWCA Civ 393
  - Violation of non-binding British Standard is not conclusive proof of defect
  - Actual consumer expectations ≠ product standard

- **District Court of Düsseldorf 24 EPLR 2006, 20**
  - Violation of binding regulations is conclusive proof of defect
  - Legitimate expectations
  - In line with § 4 (a) Restatement Third of Torts: Products Liability
Compliance

*Cologne Court of Appeal (Haribo) 21 EPLR 2005, 34*

- Compliance is no automatic defence
- Compliance is strong evidence that product is not defective
- Compliance in this case conclusive evidence because the relevant regulations were
  - exhaustive
  - up-to date
  - outcome of expert analysis
- In line with § 4 (b) of Restatement Third of Torts: Products Liability
Regulatory compliance and pharmaceuticals
European Medicines Agency - EMEA

- Authorisation of medicinal products centralized procedure (EC 2309/93) and responsibilities in mutual recognition procedure (Art. 27 ff Dir 2001/83 EC)

- Centralized expert evaluation of risks v benefits
  Scientific resources of over 40 national competent authorities in 30 EU and EEA-EFTA countries in a network of over 4,000 European experts
EMEA - Authorisation of labelling

- Urgent safety restriction
  - agency has 24 h to review and approve
  - subsequent variation procedure requiring approval

→ EMEA rules stricter than FDA rules
EMEA - Maximum harmonisation

- Harmonisation of pharmaceutical product throughout EU
  “uniform decisions throughout the Community” (EC 2309/93)

- Optimum level of safety
  “(...) a single scientific evaluation of the highest possible standard of the quality, safety and efficacy” (EC 2309/93)
Conclusion

- Executive and judiciary
- Effect on regulatory process - damages liability of regulator
- Article 6 ECHR review
- Satellite litigation
- Divide b/w civil liability & regulatory default