APIL Joint Product Liability/ Multi-Party Special Interest Group

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An Introduction to Product Liability in Germany

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Comparative perspectives – Why Bother?

General

1 Putting aside the academic arguments on the pros and cons of engaging in comparative (foreign language) law[1], national courts are referring to foreign legal materials with **increasing regularity**[2].

2 In England and Wales, the House of Lords confirmed that judges may have *"regard, where appropriate, to decisions of judges in other jurisdictions"*[3]. This reality is now reflected in the relevant Practice Direction on the citation of authorities[4]. Furthermore, English Courts have shown a willingness and interest in looking beyond authorities found in other Commonwealth legal systems[5].

3 One of the prime examples of the House of Lords engaging with comparative law material is Fairchild v Glenhaven[6], where Lord Bingham remarked on the obvious merit in considering material from other jurisdictions:

"Development of the law in this country cannot of course depend on a head-count of decisions and codes adopted in other countries around the world, often against a

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[1] On which, see, by way of example: C. von Bar, '*Vereinheitlichung und Angleichung von Deliktsrecht in der Europaeischen Union*' (1994) 35 Zeitschrift fuer Rechtsvergleichung, Internationales Privatrecht und Europarecht (ZfRV) 221 at 231, B. Markesinis QC, '*Judicial Mentality: Mental Disposition or Outlook as a Factor Impeding Recourse to Foreign Law*' (2005-2006) 80 Tulane Law Review 1325, J. Stapleton, '*Benefits of Comparative Tort Reasoning: Lost in Translation*' [2007] Journal of Tort Law Volume 1, Issue 3, Article 6

[2] See, generally, G. Canivet, M. Andenas and D. Fairgrieve, *Comparative Law Before the Courts* (British Institute of International and Comparative Law, 2004)

[3] *Kleinwort Benson Limited v Lincoln City Council* [1999] 2 AC 349 (HL)at 378B per Lord Goff.

[4] *Practice Direction (Citation of Authorities)* [2001] 1 WLR 1001 (CA), which at §9.1 states that *"Cases decided in other jurisdictions can, if properly used, be a valuable source of law in this jurisdiction"*

[5] In addition to the *Fairchild* case cited below, see (i) Lord Slynn's reference to foreign legal materials in *McFarlane v Tayside Health Board* [2000] 2 AC 59 (HL) at 73 and 80-1, reaching the view that there was no universal and clear approach but some systems did allow compensation for the consequences of the birth of a healthy child; (ii) Lord Goff's analysis in *Henderson v Merrett Syndicates* [1995] 2 AC 145 (HL) at 184, noting that the fact that the German system allows concurrent remedies in tort and contract had not caused that system "perceptible harm"; and (iii) Lord Goff's recourse to German law in *White v Jones* [1995] 2 AC 207 (HL) at 263: *"Strongly though I support the study of comparative law, I hesitate to embark in an opinion such as this upon a comparison, however brief, with a civil law system; because experience has taught me how very difficult, and indeed potentially misleading, such an exercise can be. Exceptionally however, in the present case, thanks to material published in our language by distinguished comparatists, German as well as English, we have direct access to publications which should sufficiently dispel our ignorance of German law and so by comparison illuminate our understanding of our own."*

[6] *Fairchild v Glenhaven Funeral Services Limited (t/a GH Dovener & Son)* [2003] 1 AC 32 (HL)

background of different rules and traditions. The law must be developed coherently, in accordance with principle, so as to serve, even-handedly, the ends of justice. If, however, a decision is given in this country which offends one's basic sense of justice, and if consideration of international sources suggests that a different and more acceptable decision would be given in most other jurisdictions, whatever their legal tradition, this must prompt anxious review of the decision in question. In a shrinking world (in which the employees of asbestos companies may work for those companies in any one or more of several countries) there must be some virtue in uniformity of outcome whatever the diversity of approach in reaching that outcome."[7]

4 Fairchild does, however, underline the need for real care in the use of foreign law materials. Weir's[8] analysis of that case makes the powerful point that the House of Lords failed to respect a fundamental of comparative law: to see foreign norms in their proper context: *"Omitted is the salient fact that in almost none of the jurisdictions glanced at would the claimants in Fairchild have succeeded: in most places an employee simply cannot sue his employer in tort, since workmen's compensation or social security takes its place".*

5 German Courts similarly refer to foreign legal materials. As Odersky, former President of the Bundesgerichtshof, has said:

"the national judge is not only entitled to engage with the views of other courts and legal systems; he is also entitled, when applying his own law and naturally giving full weight to its proper construction and development, to take note of the fact that a particular solution conduces to the harmonisation of European law. In appropriate cases this argument enables him at the end of the day to adopt the solutions of other legal systems, and it is an argument he should use with increasing frequency as the integration of Europe proceeds."[9]

6 There is, perhaps, obvious application in civil claims for product liability where the courts of member states of the European Union are engaged in a similar task, viz attributing meaning to Directive 85/374/EEC and interpreting domestic implementing measures to give effect to that Directive.

7 A v National Blood Authority[10] is the prime example. The case is remarkable both for the scope and depth of the comparative law endeavour which took place before the national judge[11]. The material before the Court included material from the USA and

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[7] Ibid.at §32; see also Lord Rodger at §165.
[8] T. Weir, '*Making it more likely v. making it happen*' (2002) 61 Cambridge Law Journal 519 at 521
[9] W. Odersky, '*Harmonisierende Auslegung und europäische Rechtskultur* ' (1994) 1 Zeitschrift fuer Europaeisches Privatrecht (ZEuP) 1
[10] *A and others v National Blood Authority and another* [2001] 3 All ER 289 (QBD)
[11] The work of the Claimants is set out in M. Brooke QC and I. Forrester QC, 'The use of comparative law in A & Others v National Blood Authority' in D. Fairgrieve (ed) *Product Liability in Comparative Perspective* (Cambridge University Press, 2005), see in particular at 21-22. For the Defendants' view, see N. Underhill QC,

Commonwealth countries as well as from other Member States of the EU. In respect of the latter, the litigants unsurprisingly came up against barriers imposed by language. It appears that not all of these materials were formally translated for the Court, the Claimants' lawyers referring to the abilities of the Judge and Counsel to "comfortably" deal with at least French, and in some cases other languages[12]. A cautionary note is rightly sounded by the Defendants' leading counsel, both in respect of this foreign language material, and more generally in relation to comparative materials more generally. He records his feeling that *"we were skating...on very thin ice. At any point we might fall through the surface and discover ourselves seriously out of our depth. Comparative law materials are not easy to use properly. If they are not in English they have to be translated: even when translated, unfamiliar terminology, concepts and procedures have to be explained if basic misunderstandings are to be avoided. There is no expert available to the Court which is accordingly dependent upon counsel...Without a sure and impartial guide it is very easy to go astray".*[13]

8 For his part, the Judge, Burton J, writing extra-judicially, remarked that *"[t]here has been a considerable jurisprudence developed in the United States which, on analysis, did not appear to be of great assistance in the interpretation of the somewhat differently drafted European Directive..."*[14] Rather he relied much more heavily on European solutions. He said this:

"...so far as relevant, I would of course pay particular attention to any European decisions, not because they are binding upon me, but because not only does respect have to be paid, on the usual principles of comity, to reasoned decisions of competent foreign courts considering the same or similar issues, whatever the nature of the legislation, but particularly so where Community courts are applying the directive. In such a case, even though Community courts are entitled to come to different views, particularly on the facts, by reference to national and local conditions, and even though the Court of Justice can resolve and give final opinion upon issues where different views have been taken in different Community countries on the same legislation, nevertheless harmony is desirable, particularly where it can be said that an autonomous or Community approach or meaning is required..."[15].

9 This view was reached by that Judge having *"the benefit of detailed submissions in writing and some ten days of exegesis and argument orally in opening and closing by leading counsel, just on the law, including authorities and academic writings from*

'Postscript to 'The use of comparative law in A & Others v National Blood Authority" in D. Fairgrieve (ed) *Product Liability in Comparative Perspective* (Cambridge University Press, 2005)

[12] M. Brooke QC and I. Forrester QC, 'The use of comparative law in A & Others v National Blood Authority'ibid. at 22

[13] N. Underhill QC, 'Postscript to 'The use of comparative law in A & Others v National Blood Authority"ibid. at 36-7

[14] M. Burton, 'Afterword to 'The use of comparative law in A & Others v National Blood Authority"ibid., p39.

[15] *A and others v National Blood Authority and another* §44

France, Germany, Spain, Portugal, Sweden, Denmark, Belgium, Italy, Holland, Australia and the United States, as well as the United Kingdom and the Court of Justice"[16].

10 At the ECJ comparative law reasoning informs the Court's approach: a former president of the ECJ has remarked that for the Court, recourse to comparative law is essentially a method of interpretation of Community law itself[17].

The Directive in Context: the Legal Landscape

11 The *Produkthaftungsgesetz* (ProdHaftG) is the German implementing measure of the Product Liability Directive. It applies to all products put onto the market after 1 January 1990.

12 However, to focus upon that measure alone would be to fail to take account of the parallel (or concurrent) bases of liability which can found product liability claims in Germany. These are founded on the German Civil Code (BGB[18]) and, as we shall see, have significantly influenced the application of the Directive in Germany.

13 It is perhaps the strength of these alternatives (particularly that founded in tort) which at least partly explains the relative lack of impact of the ProdHaftG.

The Chicken Pest Case

14 The various strands of liability are well illustrated by the classic and leading Chicken Pest[19] case of 1968. Commentators have described this case as being *"basically preoccupied with finding a legal basis for this essentially new heading of [product] liability"*[20].

15 The **outline facts** present as a standard product liability scenario: C ran a chicken farm. She had her chickens inoculated against fowl pest by a vet. The vaccine used was manufactured by D and had been purchased by the vet. A few days after the inoculation, fowl pest broke out and 4,000 chickens died and over 100 needed to be slaughtered.

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[16] Ibid.§17

[17] J. Mertens de Wilmars, '*Le driot comparé dans la jurisprudence de la Cour de justice des Communautés européennes*' [1991] Journal des Tribunaux 37: *"le recours au droit compare est, pour la Cour de justice, essentiellement une method d'interprétation du droit communautaire"*. This vision is supported by another judge of the ECJ: K. Lenaerts, '*Interlocking Legal Orders in the European Union and Comparative Law*' (2003) 52 International and Comparative Law Quarterly 873

[18] Extracts which follow in English are taken from http://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html#p1462

[19] 26 November 1968, NJW 1969, 269

[20] See, e.g. Markesenis and Unberath, *The German Law of Torts* (Hart, 2002), p94

16 C claimed compensation from D on the basis that the vaccine was defective. She alleged that the bottles filled with vaccine were not sterile and were contaminated by bacteria and that the outbreak of fowl pest could be traced to that.

17 Claims were brought in contract and tort.

Contractual Claims Generally

18 In order to found a claim for damages in contract, the Claimant must establish a breach of contractual duty (§280 BGB[21]). Various duties are set out by the BGB. Perhaps the most relevant are:

a. Under §433(1) BGB, the seller must "procure the thing for the buyer free from material and legal defects"

b. Material defects are explained further in §434 BGB:

(1)The thing is free from material defects if, upon the passing of the risk, the thing has the ***agreed quality****. To the extent that the* ***quality has not been agreed****, the thing is free of material defects*

1. if it is ***suitable for the use intended under the contract****,*

2. if it is ***suitable for the customary use*** *and its* ***quality is usual*** *in things of the same kind and the buyer may expect this quality in view of the type of the thing.*

Quality under sentence 2 no. 2 above includes characteristics which the buyer can expect from the public statements on specific characteristics of the thing that are made by the seller, the producer (section 4 (1) and (2) of the Product Liability Act [Produkthaftungsgesetz]) or his assistant, including without limitation in advertising or in identification, unless the seller was not aware of the statement and also had no duty to be aware of it, or at the time when the contract was entered into it had been corrected in a manner of equal value, or it did not influence the decision to purchase the thing.

(2)It is also a material defect if the agreed assembly by the seller or persons whom he used to perform his obligation has been carried out improperly. In

[21] Section 280 Damages for breach of duty; *"(1)If the obligor breaches a duty arising from the obligation, the obligee may demand damages for the damage caused thereby. This does not apply if the obligor is not responsible for the breach of duty."*

addition, there is a material defect in a thing intended for assembly if the assembly instructions are defective, unless the thing has been assembled without any error.

(3)Supply by the seller of a different thing or of a lesser amount of the thing is equivalent to a material defect.

c. A buyer also has the rights set out in §437 BGB:

If the thing is defective, the buyer may, provided the requirements of the following provisions are met and unless otherwise specified,

1. under section 439, demand cure,

2. revoke the agreement under sections 440, 323 and 326 (5) or reduce the purchase price under section 441, and

3. under sections 440, 280, 281, 283 and 311a, demand damages, or under section 284, demand reimbursement of futile expenditure.

The Chicken Pest Contractual Claim

19 Various contractual arguments were deployed in the Chicken Pest case in order to overcome the fact that C was not in a direct contractual relationship with D. All were rejected by the Court:

a. **Transferred loss theory**: There were no exceptional circumstances (such as a union of interests between vet and C) so as to justify the shifting of the protected interest to C as non-contractual party. The case could not be seen as one which justified claiming damage as suffered by a third party: *Drittschadenliquidation*.

b. **Contract with Protective Effects for Third Parties**: Nor could a claim in contract be allowed on the basis that the contract had protective effects for third parties (*Vertrag mit Schutzwirkung fuer Dritte*).

c. **Quasi Contract Actions**: Arguments that the de facto reliance of the consumer on the manufacturer as being capable of founding a separate action, akin to contract (e.g. on the basis of a social contract) were also rejected: such liability is not to be found in the code.

Tort: §823 BGB

20 §823 BGB contains two separate obligations, both central to product liability claims:

(1)A person who, intentionally or negligently, unlawfully injures the life, body, health, freedom, property or another right of another person is liable to make compensation to the other party for the damage arising from this.

(2)The same duty is held by a person who commits a breach of a statute that is intended to protect another person. If, according to the contents of the statute, it may also be breached without fault, then liability to compensation only exists in the case of fault.

21 To use English terminology, the duty at (1) might be compared to the general duty of care in negligence, whereas (2) might be compared to the tort of breach of statutory duty.

22 Both were deployed successfully in the Chicken Pest case.

Tort and the Chicken Pest

23 The BGH found that the conditions for liability in tort under §823 (1) were made out. Importantly for the development of this cause of action for other product liability cases was the way the Court dealt with the issue of fault and the burden of proof. The Court held:

If anyone when using an industrial product for its declared purpose suffers injury in one of the legal interests protected by §823 I BGB through the defective manufacture of the product, it is for the manufacturer to explain the antecedents that caused the defect and thereby to show that he was not to blame for it.

...when damage has arisen within the range of the manufacturer's business risks, he cannot be regarded as exonerated merely because he points out that the defect in the product might have arisen without any organisation fault of his. On the contrary, he must supply positive and complete evidence that the defect in the product is not due to his fault.

24 In the Chicken Pest case, the manufacturer could not discharge the reversed burden.

25 In addition, the Court found the claim under §823(2) BGB was also sound. Delivering dangerous bottles of vaccine infringed a protective enactment (the Medicines Act), and this is presumed to be the result of fault unless the infringer could produce facts sufficient to disprove his fault. This the D could not do.

The Basic Scene Post Chicken Pest

26 Following the Chicken Pest ruling, the basic approach for civil actions for product liability absent a contractual relationship rely on §823(1) and, where other enactments are applicable, (2) BGB with the reversed burden of proof expounded by the BGH.

27 To English eyes, the practical effect of that reversed burden is to substantially dilute the "fault" element of the cause of action. It might be seen as a particularly strong version of the *res ipsa loquitur* doctrine.

28 This approach has been extended by the case law into various categories of defect. Here, German law has adopted the American model of identifying different types of defect. It should be noted, however, that even without proof of the type of defect, where C can show damage caused by an objective safety deficit existing at the time the product was put into circulation, this will be sufficient to make out a prima facie case which will shift the burden to the Defendant. Relevant defect types are:

(1) **Manufacturing defects**: where products depart from the intended design and are defective at the time of marketing. The Chicken Pest case is an example of such a defect. Manufacturers have duty to undertake every safety precaution that is technically possible, practical and economically reasonable: e.g. Lemonade Bottle case[22]. A manufacturer of an isolated defective product (*Ausreisser* (runaway)) might escape liability, but only where the manufacturer can prove that the defect did not occur due to the fault of any of his employees. It is a heavy burden indeed, which some have likened to the strict tort liability imposed by American Courts[23].

(2) **Design defects**: here C must persuade the court that the design was defective in a way that created an unreasonably great risk of danger. Standards play a significant (although not determinative) role here. The *Geraetesicherheitsgesetz* (GSG) requires a wide range of equipment to meet certain technical standards when sold in Germany. A cost/benefit type analysis is regularly undertaken (see further below).

(3) **Warning defects**: the duty to provide appropriate warnings and instructions arises when the product is put into circulation[24]. The warnings should cover foreseeable misuse as well as dangers in the ordinary use. C must prove the

[22] BGHZ 104,323: Lemonade Bottle; "It as the task of the defendants to deal with this risk within the limits of what was technically possible and financially reasonable..."
[23] Markesenis and Unberath, *The German Law of Torts* (Hart, 2002), p99
[24] See review of BGH in Apple Scab Case, NJW 1981, 1603

warning was reasonable with hindsight in order to trigger the reversal of the burden, with the manufacturer then having to show it could not have known of the need to warn at the time of marketing[25].

The Directive and its Implementation

29 The ProdHaftG applies to products put into circulation after 1 January 1990.

30 As is well known, the central organising concept is that of "defect" set out in §3 ProdHaftG. This follows the wording of the Directive.

31 Whilst the Directive and ProdHaftG do not distinguish between types of defect, the BGH has continued to do so after the implementation of the directive. This can be seen, by way of example, in one well known German case, a case considered by Burton J in A v National Blood.

Sparkling Mineral Water

32 In the Sparkling Mineral Water Bottle case[26], the BGH found liability where C was injured because of an exploding mineral water bottle. There was a very detailed system of inspection, both by eye and by machine which was found to be in accordance with the latest state of technology. Nonetheless, the BGH found that the bottle was defective when manufactured with a hairline crack which was not discovered by that process.

...a consumer expects a mineral water bottle to have no obvious or even microscopic damage which might lead it to explode. The fact that it is not technically possible to detect and repair such defects in the bottle does not alter the consumer's expectations.

33 In so finding, the BGH expressly used the terminology of "manufacturing faults" when describing the hairline crack. Further, in its assessment of Art 7(e) of the Directive – the development risk defence, provided for by §1(2)S.5 ProdHaftG – the BGH held that this defence cannot apply to manufacturing defects.

34 This latter point was considered by Burton J in the A v National Blood case:

there is no need nor call for differentiation between manufacturing and design defects in the construction of the directive, and the BGH appears to have been working on the assumption, not an uncommon one, as discussed, that rogue or non-standard products are always manufacturing defects. It is not perhaps surprising that

[25] Kindertee/Child Tea case: BGHZ 116, 60
[26] NJW 1995, 2162

Professor Stapleton in her recent article in the Washburn Law Journal ([2000] Wash LJ 3R/BL) at 381 described as extraordinary that 'the [BGH] merely asserted that the development risk defence in the ... Directive does not apply to manufacturing errors'. But I do not consider either that the question of 'boxing' was central to the decision of the BGH, or that that is all that the BGH decided, on a careful reading of the judgment. I have already set out, in [44](ii) above, that, in relation to the claim in respect of the exploding mineral water bottle, the court rejected the defence under art 6. It is right to say that the BGH categorised the undiscoverable crack in the bottle as a rare and inevitable production defect, but they did so, with reference to the word 'Ausreisser', as a rogue product or non-standard product, as it seems to me, irrespective of the categorisation as a production defect; and the relevant conclusion, as I see it, was that set out at II(bb) in the judgment (as translated from the German) namely—

> *'such rare and inevitable [production] defects ("Ausreisser") are not defects for the purposes of Article 7(e) of the ... Directive ... simply because they are inevitable despite all reasonable precautions. The purpose of the [Directive] is merely to exclude liability for so called development risks.' (My emphasis.)*

This proposition plainly supports the claimants. The BGH continues (again in translation) 'Liability should only be excluded when the potential danger of the product could not be detected because the possibility to detect it did not (yet) exist at the time of marketing'. As 'the potential danger of re-usable bottles filled with carbonated drinks has been known for a long time' the art 7(e) defence was not available. In those circumstances the perhaps unnecessary repetition by the BGH of the words 'unavoidable production risks do not constitute development risks' seems to me to be set into context. What the BGH was primarily saying is that if the risks are known, unavoidability of the defect in the particular product is no answer.

Defect

35 The notion of defect under the ProdHaftG is that found in the Directive. German Courts have, however, resorted to considerations of liability under §823(1) BGB, particularly where it is difficult to ascertain what might be a consumer's entitled expectations in a particular case.

36 As noted above in the discussion on claims under §823(1) BGB, account has traditionally been made of a risk-benefits approach in the notion of defect in German law particularly in respect of pharmaceuticals (on which, see further below)[27]. In a 2009 decision, the BGH referred to that American approach, although

[27] See OLG Hamm, NJW-RR 2003, 1382 (Hepatitis B Vaccination).

without explicitly adopting it[28]. Similar considerations can be seen in another recent case in which the Bundesgerichtshof decided that it would be disproportionate to expect a producer of cherry cakes to do everything possible to ensure that no cherry stone or bits of it remain in the cherry cake, given how small the risk to health connected to the issue was[29].

Defences

37 The ProdHaftG provides for a number of defences as set out in the Directive. Of particular importance are:

a. That the product has not yet been put into circulation
b. That the product was not defective when put into circulation
c. The Development risks defence (although, as mentioned above, the BGH does not consider that this applies to manufacturing defects)

Losses

38 Under the ProdHaftG, claimants can claim for personal injury damage (including pain and suffering[30]), damage to property other than the defective product itself (provided it is ordinarily indented for private use). Pure economic loss is excluded, as is property damage of less than EUR 500. There is a maximum liability in cases of personal injury caused by one product, or generic products with the same defect: EUR 85 million.

Special Regime for Pharmaceuticals

39 The *Arzneimittelgesetz* (AMG) – the Medicinal Products Act of 1976 – was a (in fact the only) special product liability regime which existed prior to the Product Liability Directive. It is therefore unaffected by the Directive by virtue of Art 13, which provides:

This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.

40 Key features:

[28] See BGH, NJW 2009, 2952 (Airbags).
[29] BGH, NJW 2009, 1669 (Cherry Stone), against the lower instance court.
[30] §8 S2 ProdHaftG, importing in §253BGB to the cause of action.

- AMG applies to drugs and medicinal products holding a marketing authorisation

- Test of liability:

  1. the pharmaceutical enterprise is liable if the drug, used correctly, "has harmful effects which, taking into account the state of medical knowledge, exceed a tolerable level" (§84(2)S1 AMG[31]).

  or

  2. the injury is caused by an instruction "which does not adequately represent the state of medical knowledge" (§84(2)S2 AMG).

- No separate development risks defence (but is this built into the test of liability?)

- In general, C must prove causation[32] between drug defect and damage being caused. This is presumed where the drug in question is capable of causing such damage in the pertaining circumstances

[31] §84 provides: (1) If, as a result of the administration of a medicinal product intended for human use, which was distributed to the consumer within the purview of the present Act and which is subject to compulsory marketing authorisation or is exempted by ordinance from the need for a marketing authorisation, a person is killed, or the body or the health of a person is substantially damaged, the pharmaceutical entrepreneur who placed the medicinal product on the market within the purview of the present Act shall be obliged to compensate the injured party for the damage caused. The liability to compensate shall only exist if:

1. when used in accordance with its intended purpose, the medicinal product has harmful effects which exceed the limits considered tolerable in the light of current medical knowledge, or
2. the damage has occurred as a result of labelling, expert information or instructions for use which do not comply with current medical knowledge.

(2) If the medicinal product administered is capable of causing the damage, in the circumstances pertaining to the individual case, the damage will be presumed to have been caused by the medicinal product in question. The capability in the individual case will be determined according to the composition and the dosage of the administered medicinal product, the manner and duration of its administration when used as intended, the temporal relationship to the occurrence of the damage, the damage symptoms and the person's state of health at the time of the administration as well as all other circumstances which, in the individual case, speak for or against the causation of damage. The presumption shall not apply if, in the light of the circumstances pertaining to the individual case, another fact is capable of causing the damage. However, the administration of additional medicinal products which, in the circumstances pertaining to the individual case, are capable of causing the damage shall not be considered as another fact unless, owing to the administration of these medicinal products, claims for reasons other than the lack of causality for the damage, do not exist under this provision.

(3) The pharmaceutical entrepreneur shall be exempted from liability to pay damages pursuant to sub-section 1 sentence 2 number 1, if the facts indicate that the damaging effect of the medicinal product is not attributable to its development and manufacturing process.

[32] Note there are issues about whether the causation amendments to the AMG, enacted in 2002, are compatible with the Directive: see generally Lenze, op cit, p121

(§84(2)S1 AMG). An exception applies where another cause could have caused the damage (§84(2)S3 AMG).

- Insurance is compulsory for those placing medicinal products onto the German market.

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Product Liability Actions and International Law

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Introduction

1. There is a global market in products which cause injury. English people suffer injury when they take prescription drugs made in Belgium by companies registered in Germany. They are injured when in Hemel Hempstead their Italian brand named dishwashers (assembled in China and purchased online from a Dutch retailer) develop electrical resistance faults and catch fire overnight. And when the defective steering mechanisms of their cars, marketed in England by a French manufacturer but assembled in Poland and containing a Danish computer enabling system, causes a collision on an Austrian road during a holiday, they suffer injury.

2. When weighing the merit of a cause of action for a personal injury caused by a defective product, it is necessary to separate three different concepts: jurisdiction, substantive law and procedure. This talk affords a gentle introduction into the issues relative to each of those concepts which are particular to the law of defective products, particularly since the implementation of the Rome II Regulations.

Jurisdiction

3. Jurisdiction is the entitlement of the English Court to hear an action. The first question that needs to be answered about any intimated action is whether it is possible to initiate proceedings in England and Wales. Whereas within the European Union the Product Liability Directive (Council Directive 85/374/EEC) aims towards a harmonisation of substantive law within member states, the Directive does not contain any rules with regard to jurisdiction.

4. The law on jurisdiction is to be found, broadly, in the Civil Procedure Rules from CPR 6.30 to 6.47. The CPR incorporates the law on jurisdiction which have been harmonised primarily by the Brussels Regulation 44/2001 and the Lugano Convention. There are no special rules for product liability cases. The rules of jurisdiction to be applied are the general rules for civil actions.

5. The CPR provides for two regimes – a European regime and a non-European regime. There is no overlap between the two. It is therefore important to identify where the defendant is domiciled before starting proceedings.

6. The basic rule is provided by Article 2 of the Brussels Regulation – the domicile of the defendant is the principal basis of jurisdiction. Where the defendants are domiciled in more than one member state of the EU, the claimant is given a choice as to the jurisdiction in which to bring the action.

7. Article 5(3) of the Brussels Regulation provides for special rules of jurisdiction. It provides that a person domiciled in one member state may be sued in another "in matters relating to tort, delict or quasi delict, in the courts for the place where the harmful event occurred or may occur". This expression of the rule gives rise to two main issues: (1) is there a matter relating to a tort (or delict)? (2) in which place did the harmful event occur?

8. A claim based on liability under the Product Liability Directive is likely to be accounted a matter related to a tort. The Explanatory Memorandum to the draft Directive indicated that liability was tortious and that the Directive was drafted on the understanding that it fell within the scope of Article 5(3). This position was supported by the view of Advocate General Jacobs in *Societe Jakob Handte et Cie GmbH v Societe Traitements Mecano-Chimiques des Surfaces* (C-26/91).

9. Article 5(3) allows a wide definition of the "the place where the harmful event occurred". It can mean either the place of the event giving rise to the damage or the place where the damage (to the product) occurred (see *Handelskwekerij GJ Bier BV v Mines de Potasse d'Alsace SA* C-68/93). In personal injury actions which do not involve defective products the place where the accident which caused injury occurred is understood to be the relevant place for Article 5(3). There is however no authority which confirms this interpretation for claims brought under the Product Liability Directive and there is a body of academic argument which prefers the view that the place in which the defective product was manufactured should be regarded as the place of the event giving rise to the damage.

10. Article 6(1) of the Brussels Regulation permits proceedings brought against a co-defendant in the Court where one defendant is domiciled. The possibility of joining a co-defendant arises where there is a risk that separate actions in different jurisdictions will give rise to irreconcilable outcomes. Where there are a number of defendants, each being a producer for the purposes of the Product Liability Directive, proceedings can be brought against each in the state in which one defendant is domiciled.

11. The Brussels Regulation also regulates allocation of jurisdiction in relation to contractual claims. The general rule is set out in Article 5(1) to the effect that claims may be brought in the Courts of the place of performance of the relevant contractual obligation. This may not provide much help for the English party which has purchased a product abroad and been injured whilst using the product abroad because the place of performance will generally not be England and Wales. Although if the person is a consumer he may rely on Article 15 of the Brussels Regulation.

Proper law

12. Once it is established that the English Court has jurisdiction to hear a claim, the next step it to identify the applicable law. Where it is decided that foreign law applies, the

relevant rules of that law must be pleaded. The Court will not decide the case as if it were a foreign court but will determine how foreign law applies.

13. The question of the proper law to be applied can be critical in defective product claims because although the Product Liability Directive has achieved some harmonisation of laws in EU member states, there is a considerable amount of substantive law which has not been harmonised. First, whilst the Directive established a principle of strict liability for personal injury caused by defective products, it has not affected national rules of law on fault based or warranty based liability. Second, the rules for the quantification of damages remain distinct to each jurisdiction (including entitlement to compensation for pain and suffering). Third, the Directive left the member states significant freedom in implementation of its provisions, including the fixation of an upper limit on compensation.

14. The Rome II Regulation governs the identification of proper law for non-contractual actions. It replaces the previous regime contained in the Private International Law (Miscellaneous Provisions) Act 1995. Rome II applies to a choice of law irrespective of the location of an accident caused by a defective product. Therefore accidents in the USA, in relation to which a claimant wishes to pursue a claim in England, will as a matter of substantive law be governed by the conflicts of law regime contained in the Rome II Regulation (Regulation 864/2007).

15. Rome II contains a special and specific provision for product liability actions. It is Article 5 and I set it out in full:

Product Liability

1. Without prejudice to Article 4(2), the law applicable to a non-contractual obligation arising out of damage caused by a product shall be:

(a) the law of the country in which the person sustaining the damage had his or her habitual residence when the damage occurred, if the product was marketed in that country; or failing that,

(b) the law of the country in which the product was acquired, if the product was marketed in that country; or failing that,

(c) the law of the country in which the damage occurred, if the product was marketed in that country.

However, the law applicable shall be the law of the country in which the person claimed to be liable is habitually resident if he or she could not reasonably foresee the marketing of the product, or a product of the same type, in the country the law of which is applicable under (a), (b) or (c).

2. Where it is clear from all the circumstances of the case that the tort/delict is manifestly more closely connected with a country other than that indicated in paragraph 1, the law of that other country shall apply. A manifestly closer connection with another country might be based in particular on a pre-existing relationship between the parties, such as a contract, that is closely connected with the tort/delict in question

16. Recitals 18 and 19 to Rome II gives a helpful indication of the tenor and purpose of Article 5 stating that: "specific rules should be laid down for special torts ... where the general rules does not allow a reasonable balance to be struck between the interests at stake ... The conflict of law rule in matters of product liability should meet the objectives of fairly spreading the risks inherent in a modern high-technology society, protecting consumers' health, stimulating innovation, securing undistorted competition and facilitating trade. Creation of a cascade system of connecting factors, together with a foreseeability clause, is a balanced solution in regard to these objectives".

17. Like the Directive, Art. 5 is not restricted to claims by consumers or "end users" it is however confined to circumstances in which damage is caused by a product. The

definition of product is taken from the Directive, this is made clear in the Explanatory Memorandum which expressly states: "for the definition of product ... Directive 85/374 will apply". As implemented in the Consumer Protection Act 1987, the product is likely to be required by English Courts to be tangible in order to fall within the scope of Art. 5.

18. Art. 5 does not give a precise definition of "damage caused by a product" but Art. 2(1) gives a very broad definition to mean "any consequence arising out of tort/delict". "personal injury" is included in the list of examples of damage given in the Explanatory Memorandum.

19. Article 5 does not exclude party autonomy to choose the law applicable to a product liability claim. If both or all parties have their domicile in the same jurisdiction, the law of that state applies. The source of this provision is Article 14(1) and (2).

20. Only if neither of the above applies does the Regulation set out a hierarchical order for the state law to be applied. To determine the appropriate proper law it is necessary to work through the categories in sub-paragraph 1 in order. Subparagraph 2 of Art. 5 then provides a defendant with some protection against circumstances where the product was marketed in a location which was not reasonably foreseeable. This is the foreseeability clause to which the recital quoted above refers. The foreseeability clause allows escape from each category of sub-paragraph 1 and, in the final eventuality, from all the categories.

21. It is not yet clear whether there is a significant overlap between the provisions of Art. 5 and Art. 7 which deals with environmental damage but for personal injury actions this may not be a material consideration.

22. There are several significant effects of the Rome II Regulation:

- The less rigid imposition of applicable law may well allow for "forum shopping", helpful to claimants even if contrary to the intention of the Regulation.
- Although it specific instances fixing the applicable law as that of the claimant's residence may disadvantage a claimant, there is likely to be a general benefit to claimants in that it will be easier to obtain legal advice and damages will reflect the prevailing needs of the location.
- The provisions allow the producer to take into account the safety standards prevalent to the market place and the costs of compliance with relevant safety standards.

23. Where the cause of action in a product liability action is tortious (or under the Directive), Rome I (Regulation 593/2008) remains the relevant starting point. Article 3 gives the parties a free choice of regime; Article 6 governs consumer contracts. Article 12 of Rome I governs the proper law for performance and interpretation of contracts together with assessment of damages.

24. Example:

A German all terrain vehicle manufacturer produces bikes fitted with a braking system which ensures that the vehicle remains stable even when braking on severe inclines or when taking sharp corners. The braking system is operated by an internal computer system enabled by software produced in France. The vehicle is marketed in Sweden, Denmark and Germany. A driver from the UK buys the vehicle in Germany and drives it to Finland to use on an elk shooting holiday. Whilst on holiday, a defect in the braking system causes the vehicle to overturn causing him catastrophic injury.

Limitation

25. Under the Private International Law (Miscellaneous Provisions) Act 1995, the limitation period of the relevant foreign law applied. English law determined how limitation was

interrupted but the substantive law of limitation was the foreign law. Under Rome II foreign law governs the issue of limitation but it is now necessary to understand how to suspend or interrupt the limitation clock in accordance with the relevant proper law. It will not be possible to rely on the issue or proceedings to avoid the effects of limitation if the foreign law does not recognise this step. Contrariwise, it may not be necessary to issue in order to interrupt the limitation period. Several European jurisdictions allow formal letters of claim to interrupt time and to initiate a new limitation period.

Service

26. Where jurisdiction is established over a European domiciled party, under CPR 6.33 there is no need for permission to serve proceedings out of the jurisdiction. CPR 63.4 requires notice of the grounds to be identified where permission is not required, to safeguard against other proceedings being continued concerning the same action in another member state.

27. Where it is intended to sue a non-European domiciled defendant, then it is necessary to obtain permission to serve proceedings outside the jurisdiction in accordance with CPR 3.36.

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