A Comparison of Civil Liability for Defective Products in the United Kingdom and Germany

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Introduction*

[1] The Product Liability Directive of 1985 (85/374/EEC) ("the Directive"), which sought to harmonise a strict liability regime for defective products across the European Union, has now been implemented into domestic law by all EU member states.(1) In some countries the implementing legislation has been in force for more than 10 years. Nevertheless, until recently, there were few decided cases, both in the United Kingdom and across Europe generally, considering in detail the often critical provisions of articles 6 (definition of defectiveness) and 7(e) (the development risks defence).

[2] However, in March 2001, the case of *A & Others v The National Blood Authority* ("the *Blood Transfusion* case") was decided in the UK.(2) The UK now has a detailed exposition of principle as to how these provisions of the Directive, and their counterparts in the UK's implementing legislation, the Consumer Protection Act 1987 ("CPA"), are to be applied in practice.(3) Questions remain as to whether distinctions ought to be drawn, or at least refinements made, for issues within specific product sectors not before the Court; and at least some of those issues are likely to be aired this year in two English cases involving oral contraceptives and vaccines. But those issues aside, the *Blood Transfusion* case is likely to be of general application to most product liability cases in the UK under the CPA. Although the case concerned non-standard, or "rogue", blood products, the Court considered both non-standard and standard products and dealt at length with contested issues of interpretation.

[3] Just as the Court in the *Blood Transfusion* case had regard to the judicial decisions of other EU member states in interpreting the key provisions of the Directive, so too may the courts of other EU member states be expected to have regard to the *Blood Transfusion* case in future product liability cases before them.

[4] The purpose of this article is to provide German and international companies producing and/or marketing products in England and/or Germany with an outline of the *Blood Transfusion* case and other important aspects of UK litigation procedures and to comment on the similarities and differences one may encounter when such litigation is brought before the courts of Germany. The differences may be significant when the product in question is a medicinal product for which a marketing authorisation is required because, unlike in the UK where the implementing legislation applies equally to pharmaceutical products, Germany has a separate strict liability regime for licensed pharmaceutical products with no development risks defence. Other aspects of German litigation procedures may make life more difficult for claimants in Germany than for claimants in the UK although in certain areas proposed German reforms are likely to improve their position.

The United Kingdom's Blood Transfusion Case

[5] The case concerned a group action brought by 114 individuals who had all contracted the hepatitis C virus as a result of blood transfusions prior to the introduction of screening tests in the UK in September 1991. The risk of infection with non-A, non-B hepatitis ("NANBH") had been known to hepatologists, epidemiologists and blood specialists since at least the 1970s, but the hepatitis C virus was not identified until Spring 1988, when a prototype immunoassay that was thought to lead to a screening test for NANBH was developed. Thereafter an anti-hepatitis C assay was developed, a US export licence was granted in November 1989, the FDA approved the assay use as a screening test within the US in May 1990 and, after more trials in the UK, the tests were introduced in England and Wales on 1 September 1991. The CPA came into effect on 1 March 1988.

[6] The claimants argued, successfully, that the blood and blood products that had infected the claimants were "defective" under the CPA and that the "development risks" defence was not available to the National Blood Authority. The Court considered both issues in detail and, in doing so, focussed on the wording of the Directive itself.

The Question of Product Defectiveness

[7] The first key provision in the Directive and CPA is the definition of "defective product" (article 6 of the Directive; section 3 of the CPA). A product is defective if it does not have the level of safety that persons generally are entitled to expect, taking into account all the circumstances and, in particular, certain specific circumstances which are set out in the Act. These include the presentation of the product, including warnings, the use to which the product can

reasonably be expected to be put and the time when the product is circulated.

[8] The Court in the *Blood Transfusion* case emphasised that safety and intended or foreseeable use are the lynchpins and, leading on from these, what legitimate expectations there are of safety in relation to the product's foreseeable use. It set out the following approach to determining whether a product is defective:

(a) The first step, the Court said, is to identify the harmful characteristic which caused the injury (Article 4; section 2 [1]).

(b) In order to establish that there is a defect in Article 6, the next step will be to conclude whether the product is standard or non-standard. This will be done (in the absence of admission by the producer) most easily by comparing the offending product with other products of the same type or series produced by that producer. If the respect in which it differs from the series includes the harmful characteristic, then it is, for the purpose of Article 6, non-standard. If it does not differ, or if the respect in which it differs does not include the harmful characteristic, but all the other products, albeit different, share the harmful characteristic, then it is to be treated as a standard product.

(c) For non-standard products, whilst the *circumstances* specified in Article 6 (section 3) may be relevant (e.g., the product may be a second) as may be the circumstances of the supply, the primary issue is likely to be whether the public at large accepted the non-standard nature of the product (i.e., they accepted that a proportion of the products was defective). That is not the end of it because the question is one of *legitimate* expectation and the Court may conclude that the expectation of the public is too high or too low. But manifestly, said the Court, questions such as warnings and presentations will be in the forefront. At the same time, the following were held to be irrelevant:

• the avoidability of the harmful characteristic, that is, the impossibility or unavoidability in relation to precautionary measures;

• the impracticality, cost or difficulty of taking such measures; and

• the benefit to society or utility of the product, except in the context of whether – with full information and proper knowledge – the public does and ought to accept the risk.

(d) The Court added that, whether or not there could have been some other way of manufacturing or designing the product, the social acceptability of the actual product, as it in fact was, must be tested against the background of the warnings that were in fact given.

(e) For standard products, the Court said that the questions of presentation, time, circumstances of supply, and social acceptability will arise as for non-standard products and the sole question will be safety of the product for its foreseeable use. If there are any comparable products on the market, then it will be relevant to compare the offending product with those other products, so as to identify, compare and contrast the relevant features and there will obviously need to be a full understanding of how the product works, particularly if it is a new product, so as to assess its safety for such use. Price can be a significant factor in legitimate expectation and may be material in the comparative process. But again, the questions of avoidability and whether the producer could or could not have done the same as the others did are irrelevant. The Court stated later: "Even in the case of standard products such as drugs, side-effects are to my mind only capable of being 'socially acceptable' if they are made known." (Unlike Germany, England does not have a separate liability regime for defective pharmaceutical products.)

[9] Under Article 6, as implemented in the UK, the burden of proof, on the balance of probabilities, is on the claimant.

The Development Risks Defence

[10] If a product is defective, the "development risks" defence (Article 7(e) of the Directive; section 4[1](e) of the CPA) will shield the producer from liability if the producer can demonstrate that the state of scientific and technical knowledge at the time the product was supplied was not such as to enable the defect to be discovered. It is to this defence that producers will most usually wish to be able to resort. The burden of proof lies with the producer.

[11] The Court's restrictive approach in the *Blood Transfusion* case to the availability of the development risks defence is set out below:

(a) If there is a known risk, i.e., the existence of the defect is known or should have been known in the light of reasonably accessible information, then the producer continues to produce and supply at its own risk. It is inconsistent with the purpose of the Directive if a producer, in the case of a known risk, continues to supply products simply because, and despite the fact that, he is unable to identify in which if any of his products that defect will occur

or recur or, where the producer is obliged to supply, continues to supply without accepting the responsibility for any injuries resulting, by insurance or otherwise.

(b) The "existence of the defect" is generic. Once the *existence* of the defect is known, there is then the risk of that defect materialising in any particular product.

(c) The purpose of the Directive, from which Article 7(e) should not derogate more than is necessary, is to prevent injury, and facilitate compensation for injury. This is achieved by imposing obligation in respect of a known risk irrespective of the chances of finding the defect in the particular product. A risk ceases to be a development risk and becomes a known risk not if and when the producer in question has the requisite knowledge, but if and when such knowledge is reasonably accessible anywhere in the world. Hence the defence protects the producer in respect of the unknown.

[12] This restrictive interpretation of the development risks defence requires producers to look beyond their own knowledge base and testing to the wider pool of global information to the extent that that information is reasonably accessible.

Other Relevant Aspects of the Litigation Environment in the UK

[13] The *Blood Transfusion* case provides a measure of pro-consumer guidance to some of the key issues under the strict liability regime, particularly the ingredients necessary to establish a product's defectiveness and the scope of the development risks defence.

[14] There are other aspects of UK litigation procedures which, in conjunction with the *Blood Transfusion* case, are now, in theory, making for a comparatively favourable legal environment for consumers who suffer injury from defective products:

(a) There are detailed disclosure rules pursuant to which personal injury claimants (among others) are entitled to inspect and copy all non-privileged documents in the possession or control of the producer upon which the producer relies, or which may be harmful to the producer's case or upon which the claimant may otherwise wish to rely.

(b) Victims of personal injury can claim both general damages and special damages, both in proceedings under the strict liability regime of the CPA and in negligence at common law. General damages compensate for pain, suffering and loss of amenity ("PSLA"), that is, non-pecuniary loss. Indicative damages awards for PSLA for particular injuries and conditions are set out in the Judicial Studies Board's *Guidelines for the Assessment of General Damages in Personal Injury Cases* (5th Edition, 2000) (the "JSB Guidelines") based on pre-existing case law. The JSB Guidelines give defendants a measure of certainty as to their potential exposure for non-pecuniary loss. Special damages represent the costs incurred in treating the condition and losses resulting from unemployment, nursing and other medical expenses, in other words, pecuniary loss. The additional sums that may be awarded by way of special damages depend very much on claimants' individual circumstances. In certain cases, provisional damages may be awarded. Provisional damages are awarded in cases where the claimant, having established liability, satisfies the Court that there is a real danger of further injury arising. Such awards enable the claimant to apply to the court for further substantial damages should that further injury arise. A fairly common example is where a claimant establishes liability for asbestos-related pleural plaques or asbestosis and wishes to be able to apply to the court for further damages should he or she contract mesothelioma.

(c) Conditional fee agreements (loosely speaking, the "no win, no fee" agreement) are permissible in the UK.

(d) The UK has new group litigation procedures by which, where there are or are likely to be a number of claims which give rise to common or related issues of fact or law, a Court may make a Group Litigation Order ("GLO") pursuant to which all those claims can be managed. GLOs have been made in personal injury cases, including cases of asbestos-related diseases and damages arising from an air crash. A Multi-Party Information Service has been set up to assist parties to ascertain whether their claims involve GLO issues. Courts may require claimants on the "group register" to serve "group particulars of claim" and they have the power to appoint a lead solicitor from the claimants' different sets of solicitors. Judgments or orders given or made in a claim being managed under a GLO are binding on the parties to all other claims that are on the group register.

(e) Although, in general, personal injury claimants are not able to receive state funding for their claims, on the basis that such claims are more appropriately funded using conditional fee agreements, state funding may be granted for those personal injury claims which have a "wider public interest". For example, the UK body which makes funding decisions concluded that the appeal to the House of Lords in the asbestos-related disease claims brought in *Lubbe v Cape Plc* [2000] 4 All ER 268 on behalf of South African miners merited a high to exceptional wider public interest

rating.

[15] Given that it is easier to establish liability under the CPA than it is in negligence (where the claimant must establish on the balance of probabilities not only that the producer's defective product or other failure caused the damage in suit, but also that the producer was negligent), claimants in the UK who have suffered injury from defective products are likely to rely primarily on causes of action under the CPA. Whilst causes of action in negligence may be pleaded, following the *Blood Transfusion* case they may prove to be redundant.

[16] Equally, however, where the actions or omissions giving rise to liability occurred before enactment of the CPA, negligence will be the main cause of action available to affected parties. Cases of asbestos-related diseases, caused through exposure to asbestos in the 1950s and 1960s, are a good example of cases in which causes of action under the CPA are not available.

The Product Liability Environment in Germany

[17] German law has two principal bases of "product liability": strict liability as circumscribed by the Product Liability Law ("PLA") and sector specific statutes such as the Drug Law (the separate strict liability regime for licensed medicinal products), and negligence as set out in the German Civil Code (*Bürgerliches Gesetzbuch*; "BGB").

The Product Liability Law

[18] The PLA (*Produkthaftungsgesetz*), which implemented the Directive, came into force on 1 January 1990. Under the PLA, claims for damages may be brought for personal injury and for property damage (provided the damaged property was intended and primarily used for private purposes) (section 1[1]).

[19] The definition of defective product in the PLA is more or less the same as that in the CPA and to the extent that there has been any case law on its terms, it appears to have been construed in a manner similar to that of the English High Court's later decision in the *Blood Transfusion* case. In the so-called *German Bottle* ("*Mineralwasser*") case,(4) the Bundesgerichtshof (Federal Court of Justice) allowed an appeal by a claimant injured as a result of an exploding mineral water bottle, resulting from either a chip or a very fine hairline crack, not discovered notwithstanding what was found to be a technical and supervisory procedure in the defendant's factory in accordance with the very latest state of technology. The Court concluded that the harmful characteristic was a defect within section 3 of the PLA (modelled on Article 6 of the Directive) and noted (5)

"The Court of Appeal … [assumed] correctly that 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." [Translated from German.]

[20] Under section 1[4][1.] of the PLA, the claimant has the burden of proof in establishing that the defendant's product was defective and caused the damage in suit. The burden of proof for the defences available to the producer rests with the producer (section 1[4][2.] PLA).

[21] The development risks defence is available under the PLA (section 1[2]5.) However, in the *German Bottle* case, the Court held that the defence applies exclusively to defects at the design level and is not available for defects on other levels such as production, instruction and product monitoring. The judge in the English *Blood Transfusion* case considered the Bundesgerichtshof's judgment and questioned whether it was a correct interpretation of the Directive. In his view, "there is no need nor call for differentiation between manufacturing and design defects in the construction of the Directive" and "[w]hat the [Bundesgerichtshof] was primarily saying is that if the risks are known, unavoidability of the defect in the particular product is no answer". This issue may still be a live one in German courts. (Lower courts are not bound to follow the *German Bottle* case although they are likely to at least take it into account.)

[22] As to the standard under the development risks defence in Germany, one commentator opines that, in practice, producers and designers of new products must take into account the newest, accessible technical and scientific know-how and that adherence to industrial standards is not sufficient.(6) That view is consistent with the judge's approach in the English *Blood Transfusion* case.

[23] Notably, however, on the question of damages, currently no claim may be brought under the PLA for pain and suffering and loss of amenity. Rather, only pecuniary damages are recoverable.

[24] The unavailability of PSLA damages under the PLA is a significant point of comparison with the UK regime. It means that claimants in Germany still need to establish liability in negligence to recover damages for pain and suffering. Accordingly, currently claimants in product liability cases in Germany are more likely than claimants in

England to plead and rely upon causes of action under both the Directive (as implemented) and in negligence.

[25] Another significant difference is that, unlike the position under the UK's CPA, Germany's PLA contains a financial ceiling for cases of personal injury in respect of the producer's overall liability across cases arising from the same defect. In the days of the Deutsch Mark, that overall cap was set at DM 160 million (section 10[1]), which is approximately Euro 81.75 million. Where total damages exceed this amount, the DM 160 / Euro 81.75 million is apportioned between claimants (section 10[2]).

[26] However, both the lack of PSLA damages and the cap are of less practical significance than an English practitioner might think, given the reversal in Germany of the burden of proof in product liability negligence claims (discussed below) which, in some cases, may make it easier to establish negligence in Germany than in the UK. There is no liability cap for claims in negligence.

[27] In any event, legislative reforms are before the German Parliament pursuant to which damages for pain and suffering would be recoverable under strict liability regimes, such as the PLA and Drug Law, where the claimant can establish a violation of body, health or freedom or sexual integrity which is substantial in either duration or gravity or which was caused with malicious intent.(7) This would bring the German strict liability regimes closer to that of England on the issue of recoverable damages. Moreover, the liability caps would be amended, increasing the overall cap, albeit only moderately, to Euro 85 million. These reforms are expected to be enacted before the next German election this September.

The Drug Act

[28] As noted above, Germany also has a separate liability regime for medicinal products, in the form of the Drug Act (*Arzneimittelgesetz*) (as well as other sector specific regimes which are not addressed in this article). That Act, which came into force in 1978, applies, to the exclusion of the PLA, to claims against pharmaceutical entrepreneurs (any person placing drugs on the market under its own name) for damages arising from defective drugs.

[29] Under section 84 of the Drug Act, a pharmaceutical entrepreneur who places a drug subject to the Act (i.e., one which requires marketing authorisation) on the market is liable for death or injury caused by the administration of that drug if:

(a) when used in accordance with its intended purpose, the drug has harmful effects which exceed the limits considered tolerable in the light of current medical knowledge and which have their origin in the development or manufacturing process, or

(b) the harm has occurred as a result of labelling, expert information or instructions for use which do not comply with current medical knowledge.

[30] There is no requirement to establish negligence. The liability regime is one of strict liability and there is no separate development risks defence. However, as one can see, and in contrast to the position which, in the light of the *Blood Transfusion* case, might (on one view) prevail for pharmaceutical product liability in the UK, a medicine's risk-benefit ratio can be taken into account under the first limb of liability.

[31] In the case of death, compensation is payable for the costs of an attempted cure as well as the costs incurred by the pecuniary prejudice sustained by the deceased party as a result of the suspension or reduction of his or her earning capacity or the resultant increase in needs during the disease. The defendant is also liable for funeral costs. Further, if, at the time of injury, the deceased party maintained a relationship with a third party by virtue of which he was or could come under the legal obligation to support this third party and if the third party was deprived of the right to maintenance as a result of the death, the defendant shall indemnify the third party, guaranteeing maintenance to the extent to which the deceased party would have been liable for the length of lifespan he would probably have had. Liability for damages shall also arise if, at the time of injury, the third party had been conceived but not yet born (section 86).

[32] In the case of injury to a person's body or damage to health, compensation takes the form of reimbursement of the costs of treatment as well as the costs incurred by the pecuniary prejudice sustained as a result of the temporary or permanent suspension of or reduction in earning capacity or the resultant increase in the person's needs (section 87).

[33] Like the PLA, however, the Drug Act contains liability caps (section 88), although the caps are different. In the case of death of injury of one person, the defendant may be liable to a maximum of DM 1 million (approximately Euro 511,000) or an annuity of up to DM 60,000 (Euro 30,677) per year. Where several people suffer death or injury from

the same drug, the defendant may be liable up to a maximum of DM 200 million (Euro 102.26 million) or an annuity of up to DM 12 million (Euro 6.136 million) per year.

[34] If the reforms referred to in paragraph 27 above are enacted, these caps will be amended as follows: (a) in the case of death of injury of one person, the defendant may be liable to a maximum of Euro 600,000 or an annuity of up to Euro 36,000 per year; and (b) where several people suffer death or injury from the same drug, the defendant may be liable up to a maximum of Euro 120 million or an annuity of up to Euro 7.2 million per year.

[35] Pharmaceutical entrepreneurs are obliged to ensure that they can meet their legal commitments in respect of compensation under the Drug Act to the extent of the maximum liability exposure as set out in section 88 of the Act (section 94). They can do so by means of third party insurance taken out with an insurance company authorised to conduct business within the purview of the Drug Act; or an exemption or warranty obligation issued by a domestic credit institution, or a credit institution of another EC Member State or a State party to the Agreement on the European Economic Area.

[36] Currently, and as with the PLA, damages for pain and suffering are not available under the Drug Act. Negligence must be established to recover such damages and as such currently pharmaceutical product liability cases can be expected to be brought in negligence as well as under the Act. However, as mentioned above, legislative reforms are in the pipeline in Germany pursuant to which damages for pain and suffering would be recoverable under strict liability regimes including the Drug Act.

[37] There are three further proposed reforms which may have a significant impact on claims for damages under the Drug Act:

(a) a reversal of the burden of proof by which the defendant will have to establish or be able to point to circumstances suggesting that the source of the side-effect in question was not in the drug's development or manufacturing process;

(b) a presumption as to causation: where the pharmaceutical product used is, in the circumstances of an individual case, of such a nature as to be capable of causing the harm, it will be presumed that the harm in question is attributable to that pharmaceutical product; however, the presumption may be displaced where another circumstance suggestive of causal responsibility exists (although pointing to consumption of another pharmaceutical product capable of causing the harm will not be sufficient to displace the presumption);

(c) a new disclosure rule by which a claimant under the Drug Act will be able to obtain information (as to side effects, interactions, adverse event reports etc) in cases where it appears that the injury in question was caused by a particular pharmaceutical product. The power to request disclosure may be exercised against the pharmaceutical manufacturer and the German regulatory authorities, unless either of them can establish that non-disclosure is justified by an overriding interest of the company or a third party or if there is a legal prohibition on disclosure. One can, therefore, see significant confidentiality disputes on the horizon.

Negligence

[38] Section 823(1) of the German Civil Code provides:

"A person, who intentionally, or negligently [i.e., recklessly or carelessly], unlawfully injures the life, body, health, freedom, property or other right of another is bound to compensate him for any damage arising therefrom."

[39] Negligent breach of a statute designed for the protection of others is also actionable (section 823[2]).

[40] The case law in this area of negligence (developed by the Bundesgerichtshof) is not affected by the PLA, which provides in section 15[2] that it does not affect liability for defective products based on other legal principles and statutory provisions.

[41] As foreshadowed above, there is a notable difference of approach in German negligence case law (which, unusually for a civil law country, provides the most guidance in this area) compared to that of most common law jurisdictions. The Bundesgerichtshof has, through a series of decisions, shifted the burden of proof from plaintiff to defendant on the issue of whether the defendant breached its duty of care. For example, in the *German Bottle* case referred to above, the Court said:(8)

"The court below correctly held that on the question whether a particular defect, such as the chip or hairline crack in this case, arose or even remained undiscovered while it was in the producer's sphere of responsibility, the burden of proof can be reversed if the producer was in breach of his Befundsicherungspflicht, his duty to ascertain the condition

of his product and correct it if defective (BGHZ 104, 323 [330]; BGH NJW 1993, 528)." [Translated from German.]

[42] And in a judgment of 2 February 1999, the Court held that if, following the proper use of a product, damage is caused because the product is defective, then the producer must show that it did not breach its duty of care and that it did not therefore act negligently.(9) This is a significant point of comparison to the law of England where the claimant must establish a breach of the defendant's relevant duty of care.

[43] As noted above, in Germany PSLA damages are available in negligence claims. The courts exercise their discretion pursuant to section 287 of the Rules on Civil Procedure (*Zivilprozeßordnung*), taking into account, among other things, the nature and duration of the injury and its consequences for the individual. Although there is not an equivalent to the Judicial Studies Board and its Guidelines setting out indicative damages awards for PSLA for particular injuries and conditions, commentaries do exist that list in some detail awards of PSLA damages and courts are known to consult these commentaries for guidance. German courts are said, traditionally at least, to have granted fairly modest awards for pain and suffering, although in one case, for example, the Düsseldorf Court of Appeal awarded DM 450,000 (approximately Euro 230,000) for paraplegia resulting from a car accident.(10)

Other Relevant Aspects of the German Litigation Environment

[44] Procedural and costs rules always have a bearing on the viability of bringing or defending product liability claims and it is fair to say that, in certain respects, litigation procedures in Germany are more restrictive for personal injury claimants than those in England. Some relevant aspects of the German scene are these: there is no formal group litigation procedure of the sort recently introduced in England; there are limited disclosure obligations; the courts are more interventionist and more willing to suggest settlement proposals than their English counterparts (this, of course, can be good and bad, depending on your point of view); both contingency and conditional fee arrangements with lawyers are prohibited; the judge decides which witnesses to hear and which experts to call; and costs recovery is limited to low statutory fees.

Conclusions

[45] The UK's *Blood Transfusion* case provides an interpretation of the Directive and its implementation in the UK through the CPA which is more favourable to consumers than to producers. In some respects it requires practitioners and risk managers to wipe clean their earlier slates of interpretation. The court has construed the concept of defectiveness in an all-embracing way, excluding questions of avoidability, impracticality and social utility; an otherwise defective product is saved only, at least in some cases, by adequate warnings of the risks. Similarly, the development risks defence has been narrowly construed, creating a tight interplay between the loss of that defence upon reasonably accessible knowledge of the relevant risk and the need to either withdraw the product or warn consumers of the newly discovered risks of use or consumption. The Court's interpretation of the Directive, coupled with other aspects of UK litigation procedures which enable prospective claimants to access adverse documents, pool resources, strike conditional fee agreements with their lawyers and possibly obtain state funding, may lead to claims being brought under the CPA both more than previously and more than one currently finds in Germany and, unlike in Germany, the availability under the CPA of PSLA damages will usually render negligence actions redundant. Equally, distinctions from, or at least refinements to, the *Blood Transfusion* case may emerge from the oral contraceptive and vaccine cases currently before the English courts.

[46] The position in Germany under its PLA appears to be the same on the question of defectiveness whilst debate still surrounds the Bundesgerichtshof's interpretation of the development risks defence. PSLA damages are not available under either that regime or the sector-specific Drug Act (or other strict liability regimes), and liability caps are found in both, leading to greater reliance by German claimants on causes of action in negligence. Unlike in England, however, the burden of proof for the producer's breach of its duty of care is reversed. At the same time, claimants may still be disadvantaged through Germany's absence of a general disclosure obligation, limited group action procedures and funding mechanisms and low level costs recovery. Nevertheless, reforms currently before the German Parliament, expected to be enacted before the next election, will go some way to helping claimants, by allowing claims for PSLA damages under strict liability regimes such as the PLA and Drug Act and by increasing the existing liability caps. Further, under the Drug Act, there would be a reversal of the burden of proof, a legislative presumption as to causation and a new disclosure rule. If these reforms go ahead, one can imagine a greater number of claims being brought in Germany under both the PLA and Drug Act and without reliance on supplemental causes of action in negligence.

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who commented on earlier drafts of or issues addressed in this article. Equally, responsibility for errors lies with the author alone. Views expressed in this article are not necessarily those of the firm. Reliance should not be placed on this article without seeking advice relating to one's individual circumstances. Further information on the firm's product liability practice is available on request or via the firm's website: www.ashurst.com/practice/product/index.htm

(1) Austria in July 1988, Belgium in November 1991, Denmark in June 1989, Finland in September 1991, France in May 1998, Germany in January 1990, Greece in July 1988, Ireland in December 1991, Italy in June 1988, Luxembourg in May 1989, The Netherlands in November 1990, Portugal in November 1989, Sweden in February 1992, Spain in July 1994 and the United Kingdom in March 1988.

(2) [2001] 3 All ER 289; available in full text on-line via: http://www.bailii.org.

(3) Previously there was limited case law in the UK on the civil liability provisions of the CPA and in none of those cases did the courts undertake the kind of jurisprudential analysis one sees in the *Blood Transfusion* case: *Abouzaid v Mothercare (UK) Ltd* (unreported, 21 December 2000, Court of Appeal) (successful claim for damage to eye following flicking back of elasticated buckle/strap used to attach a fleece-lined sleeping bag to a pushchair); *Richardson v LRC Products Ltd* (2001) 59 BMLR 185 (unsuccessful claim for alleged injury following the splitting of a condom in use after which the claimant became pregnant); *Worsley v Tambrands Ltd* (unreported, 3 December 1999, High Court) (unsuccessful claim arising from alleged toxic shock syndrome following the use of a tampon).

(4) BGH judgment of 9 May 1995, ZIP 1995, p. 1094; an English translation can be found at www.iuscomp.org/gla/judgments/tgcm/z950509.htm.

(5) Translation per paragraph 44(ii) of the Blood Transfusion judgment: above n 2.

(6) *Business Transactions in Germany*, 2000, vol. 4, §38.03[3][ii].

(7) Entwurf eines Zweiten Gesetzes zur Änderung schadensersatzrechtlicher Vorschriften, Drucksache 14/7752, available via www.bundestag.de.

(8) Translation cited at n 4 above, p. 3, para 2(a).

(9) BGH judgment of 2 February 1999; NJW 1999 p. 1028.

(10) Business Transactions in Germany, above n 6, §38.03[1][C], citing OLG Düsseldorf judgment of 10 February 1992, 1U 218/90.