Is There a Defect in the European Court's Defect Test? Musings about Acceptable Risk*

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JUDGMENT OF THE COURT (Fourth Chamber) of 5 March 2015 In Joined Cases C-503/13 and C-504/13, preliminary ruling in the proceedings Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse (C-503/13), Betriebskrankenkasse RWE (C-504/13)[1]

On 5 March 2015, the European Court of Justice issued a preliminary ruling on two issues arising under the EU Product Liability Directive,[2] which imposes objective, no-fault or strict liability, but not absolute liability, for defective products. Despite the wide range of issues arising under this directive, the Court has had only a few occasions to construe its ambiguous terms. This case, however, provided an opportunity to the Court to settle key issues relating to the defect test and the scope of damages compensable under the directive. As in other civil law cases, the question arises whether the Court's light treatment will provide a sound basis for the further development of product liability in Europe. The Court did not answer the questions posed by the referring court, but in some respects went beyond these questions and in other respects avoided the difficult issues raised thereby. As discussed in this note, the Court paints with a broad brush, and the test set forth in its judgment to determine whether a product is defective, may itself be defective.

I. The Facts and Legal Proceedings

A company now owned by Boston Scientific Corporation (BSC) manufactures and sells pacemakers and implantable cardioverter defibrillators. It imported and marketed in Germany two models of pacemakers manufactured in the United States and an implantable cardioverter defibrillator manufactured in Europe. By letter of 22 July 2005, addressed to treating physicians, BSC indicated that its quality control system had established that a component utilised to hermetically seal the pacemakers it marketed may experience a gradual degradation which could adversely affect the device's therapeutic efficacy. That defect could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning. On this basis, BSC recommended that physicians consider replacing such pacemakers. Although the warranty for the pacemakers might have expired, BSC offered to provide replacement devices free of charge for pacemaker-dependent patients and those deemed by their physicians to be best served by replacement.

In September and November 2005, two patients received replacement pacemakers. The pacemakers that had been removed were destroyed in the hospitals without further examination. The insurance company that covered the expenses associated with these replacement operations brought proceedings before the local courts in Germany to recover the costs incurred. The court in first instance found the claim justified and awarded damages. After BSC's general appeal was dismissed, it lodged an appeal on a point of law.

* Cf. George W. Conk, Is There A Design Defect In The Restatement (Third) of Torts: Products Liability?, *Yale Law Journal*, Vol. 109, No. 5, 2000, pp. 1087-1133.

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1 Available at http://curia.europa.eu/juris/celex.jsf?celex=62013CJ0503&lang1=en&type=TXT&ancre=

2 Directive 85/374 of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 07/08/1985, pp. 29-33, as amended, OJ L 141 20 (4.6.1999). http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1426872627268&uri=CELEX:01985L0374-19990604

Not only the pacemakers, but also the defibrillators had issues, which were the subject of a second case pending before the German courts. In a letter to physicians in June 2005, BSC announced that an investigation had shown that a magnetic switch in those defibrillators might remain stuck in the closed position. If the "enable magnet use" mode was activated and the magnetic switch became stuck in the closed position, treatment of ventricular or atrial arrhythmias would be inhibited. As a consequence, any cardiac dysrhythmia that could be fatal would not be recognised by the defibrillators and no potentially life-saving shock would be given to the patient. In light of these issues, BSC recommended that treating physicians deactivate the magnetic switch in the defibrillators concerned. If that function is deactivated, the patient monitor feature remains unaffected; it does not result in a health risk, but simply a restriction of the functions which the defibrillator can perform.

In March 2006, however, a patient's defibrillator was replaced prematurely. The patient's insurer sought compensation from BSC and prevailed. BSC appealed also in this case and both appeals were handled by the Bundesgerichtshof. In the ensuing proceedings, two issues arose that the Bundesgerichtshof decided to refer to the Court of Justice for a preliminary ruling:

(1) "Is Article 6(1) of Directive 85/374 to be interpreted as meaning that a product in the form of a medical device implanted in the human body (in this case, a pacemaker [and an implantable cardioverter defibrillator]) is already defective if [pacemakers] in the same product group have a *significantly increased risk of failure* [or where a *malfunction has occurred in a significant number* of defibrillators in the same series], but a defect has *not* been detected in the device which has been implanted in the specific case in point?" (emphasis supplied)

(2) "If the answer to the first question is in the affirmative, do the *costs of the operation to remove the product* and to implant another pacemaker [or another defibrillator] constitute *damage* caused by personal injury for the purposes of Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374?" (emphasis supplied)

In its decision by which it referred these question to the European Court, the Bundesgerichsthof found with respect to the pacemakers that no issues had occurred prior to the 44th month of operation, and that the defect rate in the approximately 28,000 devices in service was around 0.88% as of January 2006.[3] With respect to the defibrillators, it found that 4 cases of malfunctioning had been confirmed out of a total of 46,000 devices. In these 4 cases, the device produced audible squeaky sounds. Apart from device replacement, no patients have suffered injury due to malfunctioning of the devices.[4]

II. The Court's Judgment on the Defect Issue

The Court holds that the pacemakers and the cardioverter defibrillator implanted in the patients, or any products for that matter, may be regarded as defective products under the Product Liability without any defect having been proven in an individual device, if "it is found that products belonging to the same group or forming part of the same production series (...) have a *potential* defect."[5] (emphasis supplied) This judgment is based on the Court's interpretation of the directive's "defect" test, which provides that a product is defective if it does not provide the safety which the "*public at large*" (emphasis supplied) is entitled to expect, taking all the circumstances into account, including "the intended purpose, the objective characteristics and properties of the product in question and the specific requirements of the group of users for whom the product is intended."[6] With regard to medical devices such as the pacemakers and implantable cardioverter defibrillators, the Court reasoned, "it is clear that, in the light of their function and the particularly vulnerable situation of *patients using such devices*, the safety requirements for those devices which *such patients* are entitled to expect are particularly high."[7] (emphasis supplied) Remarkably, for reasons that are not further explained, despite its earlier insistence, here the Court no longer refers to the expectation entitlements of the "public at large," but to those of the "pa-

3 Bundesgerichtshof, Beschluss VI ZR 284/12, 30. Juli 2013.

4 Bundesgerichtshof, Beschluss VI ZR 327/12, 30. Juli 2013.

5 Judgment, paras. 41 and 56(1).

6 Judgment, para. 37-38.

7 Judgment, para. 39.

tients using such devices," and declares that they are entitled to high expectations.

As further support for its ruling, the Court refers to the Advocate General's opinion, which suggested that the concept of safety expectation entitlements (and, thus, the concept of defect) "must be understood to refer to a product that poses risks jeopardising the safety of its user and having an abnormal, unreasonable character exceeding the normal risks inherent in its use." Accordingly, the Advocate General states, "the lack of safety does not stem from the danger that may be posed by the use of the product, as a product may be dangerous even without having a safety defect, but from the abnormal potential for damage that the product could cause to the person or to the property of its user."[8] The Court, however, references only the last part of the Advocate General's statement with respect to "*abnormal potential for damage*."[9] Its interpretation, the Court opines, is consistent with the directive's objectives of "a fair apportionment of the risks inherent in modern technological production between the injured person and the producer."[10]

There are remarkable differences between the question posed by the Bundesgerichtshof and the question answered by the Court. Three inconsistencies are particularly important:

- While the Bundesgerichtshof question referred to a "significantly increased risk of failure" (or a "significant number" of cases of malfunction in the same series), the Court uses the phrase "a potential defect."
- The Bundesgerichtshof wanted to know whether such a product *must be* regarded as defective, but the Court holds only that it "*may be* classified as defective," and leaves open whether it *must be* so regarded. (emphasis supplied)
- While the Bundesgerichtshof's question refers to the fact that "a defect has not been detected in the device which has been implanted" in a specific case, the Court answers that there is not "any need to establish that that product has such a defect." In other words, although the Bundesgerichtshof merely stated a specific fact, the Court enacted a general rule.

These discrepancies are troubling because they raise yet further issues and unnecessarily confuse EU products liability law. Below, each of these discrepancies is discussed in turn.

1. Significantly Increased Risk versus Potential Defect

The Bundesgerichtshof question enquired whether a "significantly increased risk of failure" in a series of products, renders an individual item belonging to that series defective even if it has not been found to pose any such risk. The Court's answer is phrased in terms of "potential defect," not increased risk. Given that the Court defines defect in terms of not meeting safety expectations entitlements, a potential defect would be a "potential of not meeting safety expectations entitlements." Apart from the issue as to whether this is a workable concept, the problem is that the directive requires a "defect," not a "potential defect." In this respect, the Court's approach is disingenuous, because it rewrites, rather than interprets, the directive.

As the Bundesgerichtshof appears to see it, the issue is under which circumstances an increased risk should be regarded as a defect. Not every increased risk is a defect or, in the Court's words a "potential defect." Anticipating this issue, the Bundesgerichtshof asked about "significantly" increased risk. It seems to assume that a device posing such a risk does not meet the public's safety expectations. The concept of "significantly *increased* risk," of course, requires a standard of comparison, a baseline risk against which the risk associated with the product concerned can be measured.

On the other hand, the Court's "potential defect" test does not involve any standard of comparison. Since the concept of defect is defined in terms of not meeting safety expectations, the concept of potential defect should refer to products *potentially* not meeting such expectations. But what does it mean for a product to potentially not meet safety expectations? One way to interpret this test is to find a product defective if it may suffer from a shortcoming (whether frequently or rarely) that would cause it to no longer meet safety expectations. In this sense, any product series or product may have a "potential defect," which

8 Opinion of Advocate General Bot in Joined Cases C-503/13 and C-504/13, Boston Scientific, 21 October 2014, available at http://curia.europa.eu/juris/celex.jsf?celex=62013CC0503&lang1=en&type=TXT&ancre=.

9 Judgment, para. 40.

10 Judgment, para. 42.

would deprive the concept of any meaning, so the Court must have meant something else.

Under the "potential defect" standard, the issue arises when there is such a potential. To shed light on this issue, the Court avoids the "significantly increased risk of failure" language used by the German court, without explaining what it thinks of that concept, and cites the "abnormal potential for damage." Does the Court equate significantly increased risk with abnormal potential for damage? The reader is left in the dark. Like the concept of "significantly increased risk," the concept of "abnormal" damage potential requires a standard of comparison. In other words, what is a "normal" damage potential, which does not cause a product to be regarded as defective? The Court does not make any attempt to try to define this standard of comparison. In the *Boston Scientific* case, this lack of a comparison is problematic, because the limited data available suggests only that some of the devices concerned did not meet the manufacturer's own specifications and quality standards. Is the legal standard a subjective or an objective standard? Can a device be defective solely because it fails to meet the manufacturer's own specifications, or must it also flunk some average, or otherwise objective standard? It, of course, is entirely conceivable that a product that does not meet all of a manufacturer's specifications, still poses lesser risk (i.e. offers superior safety) than a competing product that meets all of its manufacturer's specifications. Unfortunately, the Court's judgment fails to provide guidance on these critical issues.

In addition, the case raises the question under which conditions a problem detected in only a few products may be imputed to each and every product that belongs to the same series. The Court's ruling assumes that a "potential defect" has been found in some "group" or "production series." Put differently, it does not specify the conditions that must be met to conclude that products belonging to the same group or production series have a "potential effect." One such condition could be that all products belonging to the group pose an equal, unacceptably high risk of suffering from a defect, or, if there are differences in risk level among individual products, there is no way to differentiate items posing "low" or "acceptable risk" from items posing "high" or "unacceptable risk." In the *Boston Scientific* case, the Advocate General's Opinion, but not the Court's judgment, finds that the producer's July 2005 letter regarding the pacemakers stated that "while interrogation of the device 'may' identify devices that have already experienced the failure mode, it has not been possible to identify any test that will predict if a device will exhibit this failure mode in the future."[11] This, of course, is relevant information that should have played a role in the Court's reasoning.

Further, these substantive law problems correspond to issues of evidence. These evidentiary issues are discussed under 3, below.

2. "Must" or "May Be" Deemed Defective?

Since the Court's answer states explicitly that the products concerned "may be" classified as defective, the issue arises whether the Court intends to suggest that, as a matter of EU law, the national court is free to treat such products as defective, but it not required to do so. Or do the words "may be" really mean "must be?"

The difference is significant, of course, because the first interpretation implies that the national laws of the EU Member States may start to diverge on this issue, while the Product Liability Directive is intended to approximate national laws. Having been adopted in 1985, the directive is based on what then was Article 100 of the Treaty, which gave the EU the power to adopt directives "for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market." As the directive acknowledges, however, the "harmonization (...) cannot be total at the present stage, but opens the way towards greater harmonization."[12]

In accordance with their ordinary meaning, the words "may be" should be construed as permitting, not commanding a specific result. Thus, the German court now is to decide whether it will regards the devices concerned as defective.

3. Substantive versus Evidentiary Issues

Although the German court did not ask this question, the Court answers that there is not "any need to es-

11 Opinion, para. 71.

12 Recital 18, Product Liability Directive.

tablish that [the product concerned] has such a defect." The Bundesgerichtshof had merely stated, as a matter of fact, that "a defect has not been detected in the device which has been implanted" in a specific case. Recall that in the case that gave rise to the Court's ruling, the pacemakers that had been removed were destroyed before they could be examined.

By ruling that there is no need to prove a defect in a specific device, the Court apparently suggests that the destruction of the devices is not a bar to recovery. Apart from the question of liability, however, this is a questionable practice; the manufacturer should be offered the opportunity to investigate removed devices, since such investigations may provide useful information. Specifically, they may help the manufacturer to distinguish "defective" products from "non-defective" products, so that any further recalls or remedial action can be targeted only at defective products.

If the Court's ruling is intended to address issues of evidence, it is too cryptic. Apparently, the Court wants to say that even if the manufacturer can prove that a specific device was not defective, the court may still find the device defective based on the sole ground that it belonged to a group or production series that has been found to "have" a "potential defect." As noted above, the Court's ruling does not specify the conditions that must be met to conclude that products belonging to the same group or production series have a "potential effect." But whatever those conditions are, a claimant is required to prove the existence of a defect[13] and thus that these conditions are met; if the claimant has provided some, non-conclusory evidence, and the burden of proof shifts, basic principles of procedural fairness require that a producer be given an opportunity to demonstrate that one or more of the relevant conditions are not met.

It may make sense not to allow a producer to prove that an individual item was not defective if it has been ascertained that each item in the group or series poses an equal unacceptable risk of suffering from the defect concerned, and it can be ascertained only "after the fact" (i.e. after remedial action had to be taken to reduce the unacceptable risk) whether an individual item was defective. If these conditions are not met, however, it should be left to the national courts to decide whether the producer should be allowed to provide evidence. If the Court wants to disallow this possibility in any and all cases, its ruling is a questionable contribution to civil procedure and the law of evidence. (For a discussion of the doctrine of *res ipsa loquitur*, see under III, below.)

III. The Defect Test Under the Product Liability Directive

It is generally accepted that a defect in the meaning of the EU Product Liability Directive can be a harmful effect that a product should not have, or the absence of a beneficial effect that a product should have. Under the directive, the test for defect does not distinguish, as US product liability law does, between manufacturing, design, and warning (or instruction or other informational) defects. That does not mean, however, that the directive rejected these distinctions. Rather, the directive intended to provide an over-arching standard that encompasses all three types of defects.[14] If this is true, the directive's defect standard may still have to be interpreted in light of the type of defect at issue.

Under US product liability law, two main tests have been used to determine whether a product is defective: the risk/utility test and the consumer expectations test.[15] Unlike the Second Restatement of Torts, the Third Restatement favors the risk/utility test, which provides that "[a] product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by

13 Article 4, Product Liability Directive.

14 See, for instance, the monograph by Taschner, the draftsman of the Product Liability Directive. Hans Claudius Taschner. Produkthaftung: Richtlinie des Rates vom 25. Juli 1985 zur Angleichung der Rechts- under Verwaltungsvorschriften der Mitgliedstaaten ueber die Haftung fuer fehlerhafte Produkte (85/374/EWG) mit Erlaeuterungen. Muenchen: Beck, 1986. For the three categories of defects, Taschner refers to Lorenz (1966). See also the leading treatise by Taschner and Frietsch. Hans Claudius Taschner, Edwin Frietsch. Produkthaftunggesetz under EG-Produkthaftungsrichtlinie: Kommentar. Second Edition. Muenchen: Beck, 1990.

15 Cf. Restatement (Third) of Torts, Product Liability (1997). § 2(b), and Restatement (Second) of Torts (1977), § 402(a). See also D.A. Kysar. The Expectations of Consumers. Columbia law Review, Vol. 103, 2003, pp. 1700-1790. D.T. Ramsey. Consumer Expectations test for Design Defect in California: From an Independent test of Limited Use to a Dangerous Substitute for Risk-Benefit Analysis. Tort & Insurance law Journal, Vol. 24, 1989, pp. 650-670. J.A. Henderson and A.D. Twerski. Achieving Consensus on Defective Product Design. 83 Cornell Law Review, 1998, pp. 867-920. J.A. Henderson and A.D. Twerski. Intuition and Technology in Product Design Litigation: An Essay on Proximate Causation. Georgetown Law Journal, Vol. 88, 2000, pp. 659-689. J.A. Henderson and A.D. Twerski. Drug Designs Are Different. Yale law Journal, Vol. 111, 2001, pp. 151-181.

the adoption of a reasonable alternative design (...), and the omission of the alternative design renders the product not reasonably safe."[16] In the US, the risk-utility test is generally applied for design defects, except in cases in which "an inference of defect can be drawn from the happening of a product-related accident." Under these circumstances, there is no need to prove a "reasonable alternative design," because "a product fails to perform its manifestly intended function" and the doctrine of *res ipsa loquitur* applies, and therefore the theory of consumer expectations can serve as an efficient "short cut."[17] Thus, US law does not apply a "one-fits-all" test to determine safety expectations. This raises the question whether also under EU law public safety expectations entitlements in design defect cases should be based on a risk/utility test. As noted above, however, the EU Product Liability Directive did not endorse these distinctions, but did not explicitly reject them either.

1. The Constituent Elements of the Test

As Taschner explains, the directive's defect standard of safety expectations raise three distinct sets of issues:

- Who are the subjects whose safety expectations count?
- To which of their safety expectations are they *entitled*?
- What is the relevant *point in time* at which these decision should be made?[18]

Thus, the directive does not intend to turn the defect test into a purely legal test that can be applied without regard to the relevant facts and the actual expectations based on those facts. In other words, it does not suggest that a product can be defective even if no one expected it to be completely safe. Rather, it requires that a court examine the relevant circumstances to determine what safety expectations a person could reasonably have under those circumstances. Those reasonable or legitimate safety expectations may accord with actual expectations, but they may also deviate therefrom; they may exceed the public's actual expectation, thus imposing a higher standard of safety, or they may be less than public expectations, thus reducing the safety standard from actual.[19] The test's objective, of course, is to divide harmful characteristics in products that have led to injury or damage, into two categories: those that constitute defects and those that are not defects.

As discussed above, the Court's judgment is confusing on the first issue. It first suggests, based on the wording of one of the directive's recitals,[20] that the relevant group is the public at large, but, without explanation, it then switches to the group of users of the product concerned. These are different groups, of course, but the Court does not seem to feel that this matters much. Under the directive, however, neither the subjective expectations of the injured person in a specific case, nor those of the consumers of the specific product,[21] are useful or relevant. Instead, the objective safety expectations of the general public are the relevant yardstick. As Taschner observes, the consumer safety expectations must be shared by the general public, which does not share the user interests in the specific products concerned to the same degree.[22] In other words, the relevant safety expectations are those of members of the general public that are not necessarily consumers of the product concerned. In this regard, the Court's ruling misconstrues the directive's safety expectations test.

On the second point, the general public must also be *entitled* to its safety expectations. To express this idea, the French text of the Product Liability Directive employs the word "légitimement,"[23] while the Court in Boston Scientific refers to "reasonable" expectations.[24] Whether the public is *entitled* to specific safety expectations is a legal issue that must be determined by a court in a specific case. Although the directive does not explicitly require that the court conduct an empirical assessment of safety expectations,[25] the court must take into account the criteria

16 Restatement (Third) of Torts, Product Liability (1997 ed.). § 2(b).

17 Aaron Twerski, and James A. Henderson Jr. Manufacturer's Liability for Defective Product Designs: The Triumph of Risk-Utility. Cornell Law Faculty Publications. Paper 794, 2009, 74 Brook. L. Rev. 1061 2008-2009.

18 Taschner, Produkthaftung, pp. 65-72.

19 A and Others v. The National Blood Authority and Others, Queen's Bench Division, 26 March 2001, EWHC QB 446, 65 BMLR 1, (2001) 65 BMLR 1, [2001] 3 All ER 289, para. 31.vii.

20 Recital 6, Product Liability Directive.

21 C. Hodges, *Product Liability – European Laws and Practice*, Sweet & Maxwell, 1993, 52.

22 Taschner, Produkthaftung, p. 68.

23 Article 6.1, Product Liability Directive (French version).

24 Judgment, para. 37.

25 Taschner, Produkthaftung, p. 69.

of Article 6 of the directive and the facts relevant to these criteria. These criteria include (i) the presentation of the product; (ii) the use to which it could reasonably be expected that the product would be put;[26] and (iii) the time when the product was put into circulation.[27] With respect to the application of these criteria in a specific case, the court can act as "an informed representative of the public at large."[28] In the case of a medical device, the product's presentation includes information that is generally known, as well as information that was made available with the device or by any "learned intermediary," such as a physician, who may have recommended the device to the patient.[29] As a general rule, the public is entitled to expect that products are designed and manufactured in accordance with the state-of-the-science-and-technology, including best industrial practices, presented with due regard to users informational needs, and do not pose unreasonable risks, except to the extent that any hazardous properties are generally known or they are specifically informed of risks. There, of course, cannot be a safety expectation entitlement with respect to unavoidably unsafe products, and risks that are voluntarily assumed.[30]

Further, in relation to the third point above, the legally relevant safety expectations are limited to those that were legitimate at the time when the device was put into circulation, and they should not be inflated based on better products subsequently becoming available. As the Product Liability Directive provides, "[a] product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."[31]

2. Court Cases in which The Directive's Defect Test Has Been Applied and the Relation to the "State-of-the-Art Defence"

The *Boston Scientific* cases raise issues in relation to not only the defect test, but also the "state of the art" defence. Even if the pacemakers and defribrillators are defective, the manufacturer may still escape liability if it can demonstrate that these products met the "state of the art" and the defects could not be discovered given the state of scientific and technical knowledge at the time when the products were put into circulation.

Under the Product Liability Directive, the safety expectation entitlement test is intended to distinguish between situations where products cause damage but are not defective, and situations where products cause damage and are defective, since there can be no entitlement that all products are entirely safe. Moreover, it has to do so in a predictable and balanced way, so that one can determine in advance under which conditions liability may arise and plan accordingly. The relation between the safety expectations entitlements test and the so-called "state-of-the-art" or "development risk" defence[32] should therefore be thought through. This defence is described in the directive as the case in which "the state of scientific and technical knowledge at the time when (...) the product [was] into circulation was not such as to enable the existence of the defect to be discovered."[33] The EU legislature probably had chiefly design and informational defects in mind, but it is conceivable that the defence could apply also in cases involving manufacturing defects.

Some product liability cases decided by national courts provide insight into the choices that courts have to make. A Dutch case decided in 1999 involved blood contaminated with HIV, the Amsterdam court agreed with the plaintiff that,

> "taking into account the vital importance of blood products and that in principle there is no alternative, the general public expects and is entitled to expect that blood products in the Netherlands have

26 Misuse of a product generally precludes recovery, except, possibly, if the misuse was foreseeable. A. Geddes, *Product and Service Liability in the EEC*, Sweet & Maxwell, 1992, 22.

27 On this point, Article 6(2) adds that "[a] product shall not be considered defective for the sole reason that a better product is subsequently put into circulation." Article 6(2), Product Liability Directive.

28 H. Bartl. Produkthaftung nach neuem EG-Recht. Landberg am Lech: Verlag Moderne Industrie, 1989.

29 The learned intermediary doctrine serves as a defense to product liability suits in Canada and the US, but there is an exception for direct-to-consumer advertising. See http://www.thefederation.org/documents/pratt.htm#_edn1

30 Cf. Question and Answer by Mrs Flesch MEP to the European Commission, answered by Viscount Davignon on behalf of the Commission in June 1980. "The Commission agreed with the Honourable Member that nobody can expect from a product a degree of safety from risks which are, because of its particular nature, inherent in that product and generally known, e.g., the risk of damage to health caused by alcoholic beverages. Such a product is not defective."

31 Article 6.2, Product Liability Directive.

32 On this defense, see the European Court's judgment in Commission v United Kingdom, C-300/95, [1997] ECR I-2649.

33 Article 7(e), Product Liability Directive.

> been 100% HIV free for some time. The fact that there is a small chance that HIV could be transmitted via a blood transfusion, which the Foundation estimates at one in a million, is in the opinion of the Court not general knowledge. It cannot therefore be said that the public does not or cannot be expected to have this expectation. The fact that the Foundation acted in accordance with the relevant Guidance, and that the use of an HIV-1 RNA test at the time could not have detected the HIV virus does not have any bearing on this."[34]

The defendant, a foundation for blood supply, however, was not found liable because the Court accepted the state-of-the-science defence invoked by the defendant, who argued that a new test (the PCR test) was technically not yet fully developed. The Court held that "[g]iven the state of scientific and technical knowledge at the time of the blood donation and the transfusion to Scholten, (...) it was, practically speaking, not possible to use the [PCR] test as a screening test in order to detect HIV contamination in blood products. This could therefore not have been expected of the Foundation."[35] Thus, the Court found that "the Foundation carefully carried out investigations of the blood and followed the correct and relevant Guidance, so that one is not able to expect a greater safety of the blood product than that which can be offered by the proper compliance with the relevant regulations." Likewise, in the *Boston Scientific* case, the manufacturer could still escape liability if it proves that the particular problem with the pacemakers and defribillators could not be discovered given the state of the art at the relevant time.[36]

A case in the UK also involved blood, this time contaminated with Hepatitis C virus. Although no test existed to detect Hepatitis C virus, the UK court found that blood contaminated with Hepatitis C virus was defective, because users of blood products are entitled to expect that blood be *not* contaminated with Hepatitis C virus, as the risk of such contamination is not general knowledge and they had *not* been informed of this risk.[37] Interestingly, the Court described the steps that it deemed necessary to determine whether a product is defective as follows:

> "The first step must be to identify the harmful characteristic which caused the injury (Article 4). 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."[38]

For standard products, the Court then articulated the following test:

> "If a standard product is unsafe, it is likely to be so as a result of alleged error in design, or at any rate as a result of an allegedly flawed system. The harmful characteristic must be identified, if necessary with the assistance of experts. The question of presentation/time/circumstances of supply/social acceptability etc. will arise (...). The sole question will be safety for the foreseeable use. If there are any comparable products on the market, then it will obviously be relevant to compare the offending product with those other products, so as to identify, compare and contrast the relevant features. (...) Price is obviously a significant factor in legitimate expectation, and may well be material in the comparative process."[39]

Avoidability of the risk played no role in the Court's defect analysis, but it did play a major role in the assessment of the state-of-the-science defence set forth in Article 7(e) of the Directive. Based on the Euro-

34 Scholten v Sanquin, Rb. Amsterdam 3 February 1999, NJ 1999, 621.

35 Scholten v Sanquin, Rb. Amsterdam 3 February 1999, NJ 1999, 621.

36 Germany allows the manufacturer to invoke the state-of-the-art defense; only three Member States, Finland, Luxembourg and Spain, have used the option to exclude this defense. C. Hodges, *Product Liability – European Laws and Practice*, Sweet & Maxwell, 1993, 160.

37 A and Others v. The National Blood Authority and Others, Queen's Bench Division, 26 March 2001, EWHC QB 446, 65 BMLR 1, (2001) 65 BMLR 1, [2001] 3 All ER 289.

38 A and Others v. The National Blood Authority and Others, Queen's Bench Division, 26 March 2001, EWHC QB 446, 65 BMLR 1, (2001) 65 BMLR 1, [2001] 3 All ER 289, para. 67.

39 A and Others v. The National Blood Authority and Others, Queen's Bench Division, 26 March 2001, EWHC QB 446, 65 BMLR 1, (2001) 65 BMLR 1, [2001] 3 All ER 289, para. 71.

pean Court's ruling in *Commission v UK* that the defence refers to the "objective state of scientific and technical knowledge of which the producer is presumed to have been informed" insofar as such knowledge is "accessible at the time when the product in question was put into circulation,"[40] however, the Court found that "non-standard products are incapable of coming within Article 7(e)." It summarized the rules on risks as follows:

> "Unknown risks are unlikely to qualify by way of defence within Article 6 [defect test]. They may however qualify for Article 7(e) [state-of-the-science defence]. Known risks do not qualify within Article 7(e), even if unavoidable in the particular product. They may qualify within Article 6 if fully known and socially acceptable."[41]

Importantly, both the UK and Dutch contaminated blood cases differ from the *Boston Scientific* case in two respects: in the contaminated blood cases, the defect was a harmful effect the product should not have had (rather than the absence of a beneficial effect the product should have had, as in the *Boston Scientific* case), and only the patients that were actually infected have asserted claims, not those that are merely exposed to the potential risk of harmful effects, as in the *Boston Scientific* case.

In *Boston Scientific*, the key question is whether a risk of malfunction, not actual malfunction, constitutes a defect. Under an Australian consumer protection law which, like the Directive, applies a safety expectation test, a case similar to *Boston Scientific* arose: due to the use of "yellow spool solder," supplied by a Belgian business, in the manufacture of certain pacemakers in California they had an "appreciably higher risk of premature failure than the ordinary risk to be expected in pacemakers."[42] The issue was "whether a product which, at the time of trial, can be demonstrated to have performed, and to be continuing to perform, satisfactorily can nonetheless be found to be 'not of merchantable quality' within the meaning of s 74D(1) of the Trade Practices Act 1974," which is to be determined with reference to reasonable consumer expectations. According to the Court, this higher risk due to the use of yellow spool solder failed to meet "reasonable consumer expectations" and thus rendered the product "not of merchantable quality." Apparently, testing could not "conclusively establish" whether or not there would be premature failure.[43] Although the standards of "reasonable consumer expectations" and "*conclusively establish*" require further elaboration, the Australian court's judgment provides more sophisticated analysis than the European Court's judgment in *Boston Scientific*.

In the *Boston Scientific* case, the German court has to determine (1) what level of safety the general public was entitled to expect in light of (a) the information made available with the device, (b) general knowledge about pacemakers and defribillators, and (c) other relevant circumstances at the time at which the devices were put into circulation, and (2) whether the issues with the devices ("significantly increased risk" or "potential defect") resulted in any or all of these devices not meeting these safety expectations, and thus being defective. There can be no reasonable or legitimate expectation of 100% efficacy and safety. Note that in the *Boston Scientific* case, no actual patient injuries had occurred due to device malfunctioning, and the statistical chance that a device functioned properly was over 99%. The key issue therefore is at which point an increased risk of malfunctioning in the future, without any indication of current malfunctioning in a specific device, becomes a defect. Once that decision is made, the court may have to decide whether the state of the art defence applies. These two issues are for the German court to decide.

3. An Attempt to Give the European Court's Judgment a Place

As discussed, the European Court's "conclusory" preliminary ruling does not consider public knowledge about medical devices or specific information made available with the devices concerned, nor the time at which the devices were put into circulation, employs the ambiguous term "potential defect," and is phrased in permissive terms. Is this ruling helpful to the German court? If it is interpreted to mean that the German court does *not misconstrue* the EU Product Lia-

40 Commission v UK, Case C-300-95, Judgment of 29.5.1997, [1997] ECR I-2663, para. 27-28.

41 A and Others v. The National Blood Authority and Others, Queen's Bench Division, 26 March 2001, EWHC QB 446, 65 BMLR 1, (2001) 65 BMLR 1, [2001] 3 All ER 289, para. 78.

42 Meditel Pty Ltd v Courtney, 2003, 130 FCR 182, para. 78.

43 Meditel Pty Ltd v Courtney, 2003, 130 FCR 182, para. 49.

bility Directive should it find the pacemakers and defibrillators defective on the ground that they present an increased risk of malfunctioning, it might be perceived as somewhat responsive.

Unfortunately, the Court's defect ruling is phrased in broad language suggesting that it has application to all products, rather than only to implanted potentially life-saving medical devices. While the judgment does not consider a range of cases, by its terms, it could apply to any product. It is easy to see how this could result in unacceptable outcomes. For instance, if a line of thermostats for home use, suffers from a deficiency in design as a result of which there is a 1% chance of it not measuring the temperature accurately, would it be fine to treat all such thermostats as defective? The concept of a "potential defect" does not work well in this situation. To make sense of the Court's approach, should we assume that it was simply construing the defect test in this specific case? General knowledge and the information provided with the product concerned will often have a bearing on the defect issue. In the *Boston Scientific* case, the European Court may have assumed that no such knowledge or information could have any bearing on the application of the defect test, as the Court seems to treat the case as one in which the manufacturer already admitted to the existence of a defect in the products concerned (although that was exactly what the manufacturer contested!). But that does not justify the assumption that knowledge and information should not play a role in any case.

To give the Court's rudimentary ruling a place in European product liability law, attention should be paid to what the Court leaves out of its reasoning and "assumes away." If the ruling does *not* mean that in all cases in which products pose increased risk, they are defective and producers are exposed to liability for the costs of replacement, a standard has to be applied that is able to distinguish cases in which products are defective from those in which products are not defective. Such a standard could be based on the concept of *acceptable risk*,[44] and thus on the answer to the question "*should the public expect the individuals concerned to accept (continued) exposure to an increased risk of malfunctioning or adverse effects arising the products they use?*" The answer to this question is strongly influenced by general knowledge possessed by the public and specific product-related information provided by the producer. In a specific case, the nature and magnitude of the risk arising from the product is likely to also play a role, with lower tolerance for personal injury and death and higher risk. If the answer to the question "is the risk acceptable" is yes, no liability attaches; if it is no, however, the product is defective and the producer may be liable. For what damages the producer is liable, is the subject of the second question posed to the European Court.

IV. Damage Caused by Death or Personal Injuries

The patients who received the pacemakers that posed the increased risk of malfunctioning, underwent surgery to replace these pacemakers. In the case of defibrillators, the manufacturer did not recommend replacement, but merely deactivation of the magnetic switch; despite this recommendation, some of the defibrillators were replaced.

1. The Court's Ruling on Compensable Damage

Under the Product Liability Directive, the producer is liable for "damage caused by death or personal injuries" caused by a defect.[45] This suggests that the directive imposes liability only for damage resulting from actual injury or death, not for damage resulting from the prevention of injury or death. Such preventive costs would be covered by the directive if the implantation of a device posing an increased risk constitutes a "personal injury." The Court does not explore this option, however, but turns straight to the blunt and subjective instrument of teleological interpretation. According to the Court, in light of the objective of protecting consumer health and safety pursued by the directive, the phrase "damage caused by personal injuries" must be given a broad interpretation. This would imply that "[c]ompensation for damage (...) relates to all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect."[46]

44 B. Fischoff, S. Lichtenstein , P.Slovic. Acceptable Risk. Cambridge: Cambridge University Press, 1981.

45 Article 1 juncto 9, Product Liability Directive.

46 Judgment, para. 47-49.

Thus, the Court concludes, in the case of defective medical devices, such as pacemakers and implantable cardioverter defibrillators, "compensation for damage must cover, inter alia, the costs relating to the replacement of the defective product." Given that the manufacturer in the *Boston Scientific* case recommended to surgeons that they consider replacing the pacemakers in question, the Court finds that the replacement costs, including the costs of the surgical operations, constitute damage for which the producer is liable. With respect to the defibrillators, given that the manufacturer recommended merely that the magnetic switch be deactivated, the Court ruled that "it is for the national court to determine whether, having regard to the particularly vulnerable situation of patients using an implantable cardioverter defibrillator, the deactivation of the magnetic switch is sufficient for the purpose of overcoming the defect in that product, bearing in mind the abnormal risk of damage to which it subjects the patients concerned, or whether it is necessary to replace that product in order to overcome the defect."

The European Court extends the scope of compensable damages under the Product Liability Directive on the basis of its understanding of the objectives pursued by the EU legislature. Article 9, which carefully defines the types of damages covered by the directive, is replaced by a formula that simply refers to "*all that is necessary* to eliminate harmful consequences," including *potential* harmful consequences, and "to restore the level of safety which a person is entitled to expect." Can all of that reasonably be read into Article 9? If so, it would have to be an interpretation of damage caused by "personal injuries," which would imply that a risk of injury is equated with actual injury. As a practical matter, it may cause non-activist courts to be more stringent in applying the defect test, since, once a defect is found, the scope of damages to which the producer is exposed is large.

2. The Consequences of the Court's Formula for Damage Awards

Under the "*all that is necessary*" formula,[47] all of the "material" costs[48] incurred in the following scenarios involving defective implantable devices appear to be compensable under the directive and thus be for the account of the producer of a defective product:

- A patient needs surgery to replace a defective device with a non-defective device made by the same producer. This is the *Boston Scientific* case, and the producer is liable for the cost of the replacement device as well as the cost of surgery, follow-up monitoring, and treatment of any complications or side effects.
- A patient needs surgery to replace a defective device with a non-defective device made by a competing producer. Of course, the price of the replacement device may be much higher than the price of the device provided by the liable producer; if the replacement is deemed medically necessary, the producer would have to pay for its competitor's device. It would therefore be risky to supply low cost, high risk devices, because, if they are found not to meet safety expectation entitlements, the producer would have to compensate the cost associated with purchasing and implanting competing high price, low risk devices. Monitoring and related treatment cost, including treatment of complications, would also be compensable.
- A patient cannot undergo replacement surgery due to contra-indications or his refusal to consent (e.g. in the case of serious heart disease). In this case, the producer may not be liable if there is no compensable damage (note that the Product Liability Directive does not impose liability for pain and suffering or moral damage). If, however, the increased risk of injury is deemed to constitute compensable damage, or if, due to defect, intensive monitoring or expensive medication is required, the producer would still be exposed to liability and substantial cost. In addition, if a patient suffers injury or dies as a result of the defective device, the producer would be required to compensate the harm.

In light of the "particularly high" safety expectation entitlements for medical devices proclaimed by the Court,[49] the ruling, by disfavoring all but the lowest

47 Note that the Court's answer to the question posed by the German court does not include the "all that is necessary" formula. It provides that "the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question." Opinion, para. 56. But the Court's reasoning is broader than this answer suggests.

48 The Product Liability Directive is "without prejudice to national provisions relating to non-material damage." Article 9, Product Liability Directive.

49 Opinion, para. 39.

risk devices, will likely cause device design and production to gravitate towards the high end of the spectrum, and thus exercise an inflationary effect on the cost of medical devices and limit the availability of cheap devices. Only if (and insofar as) information about risks is able to reduce safety expectation entitlements, producers may decide to insert additional disclaimers in their labels and augment their disclosure of other risk-related information.[50]

The new formula also improves the prospects for claims for compensation of consequential damage, including loss of income and lost profits. In the *Boston Scientific* case, such claims were not asserted and the Court did not explicitly address the issue. Compensation for loss of income and lost profits, however, could be viewed as "necessary to eliminate harmful consequences." This does not mean that national courts are now likely to begin to award such claims, not until a further Court ruling clarifies this point.

3. The Role of Causation in Moderating the Scope of Compensable Damages

But maybe these conclusions are premature, since the Court ruled on damages, but not, at least not explicitly, on causation. The EU Product Liability Directive holds the producer liable only for damages "caused by a defect in [its] product,"[51] and the claimant has to establish the "causal relationship between defect and damage."[52] Since the Directive does not specify causation requirements, the Member State courts may apply the causal requirements imposed by their national law.

In the *Boston Scientific* case, the Court found implicitly that there was a causal relation between the defective device and the surgical operation for its replacement. Whether it would also find a causal relation between the defective device and anything else that is "necessary to eliminate harmful consequences" is an open question. The Court clearly suggested that "all that is necessary" would qualify as compensable "injury," but national law doctrines of proximate cause and remoteness, and similar causal doctrines that limit the scope of compensable damages, may prevent recovery in specific cases.[53] Thus, it remains to be seen to what extent national causal requirements will moderate the scope of compensable damages under the Product Liability Directive.

V. The Broader Regulatory Context and Policy Considerations

In the *Boston Scientific* case, the product liability claims were triggered by product notices or alerts issued by the manufacturer. In the case of the pacemakers, these alerts were accompanied by a recommendation that pacemakers of particular series be replaced. This recommendation probably has a substantial impact on the outcome of the product liability claims. The Advocate General observes that the action taken by the manufacturer might be regarded as a "recall" by the United States Food and Drug Administration,[54] but this issue is not further developed and the Court ignores it. Nevertheless, the case raises some interesting regulatory issues that might affect the liability analysis.

First, was the producer required under EU law to recall the medical devices concerned? Surprisingly, the answer to this question is not clear. No "Rapex" notification has been submitted for these devices. Pursuant to Article 10 of the Medical Device Directive, Member States are required to ensure that information on incidents involving medical devices is recorded, centrally evaluated, and, in some cases, reported to other authorities or the manufacturer concerned. The incidents covered by this provision include "(a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;" and "(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer."[55] Note, however, that the Medical Device Direc-

50 Producers will have no incentive to increase post-marketing monitoring beyond the regulatory minimum, however, unless the information it generates will effectively reduce their liability exposure.

51 Article 1, Product Liability Directive.

52 Article 4, Product Liability Directive.

53 Cf. J. Spier (Editor). Unification of Tort Law: Causation. Principles of European Tort Law. The Hague: Kluwer Law International, 2000.

54 Opinion, para. 19.

55 Although Article 10(4) contemplates implementing measures, no such measures have been adopted.

tive does not impose a clear recall obligation on manufacturers. Rather, it imposes an undefined "undertaking" on the manufacturer to "implement appropriate means to apply any necessary corrective action,"[56] and requires that the manufacturer notify the authorities if it issues a systematic recall.[57] Non-binding guidelines issued by the European Commission describe a system for the notification and evaluation of "incidents" and "field safety corrective action" involving medical devices, also called the "Medical Device Vigilance System," but does not recommend that manufacturers conduct device recalls.[58] The General Product Safety Directive[59] establishes a system for product recall, but this directive does not apply to non-consumer medical devices.[60]

Second, given that there was no clear affirmative obligation for Boston Scientific to recall the pacemakers and defibrillators, the Court's judgment is likely to have an effect on medical device manufacturers' incentives to issue a replacement recommendation. Under the Court's judgment, the cost of replacement recommendations includes not only the cost of replacement devices but also the cost of any necessary medical procedures, and, possibly, the expenses and loss of income due to any necessary medical procedures, hospitalization, etc.[61] Moreover, liability for these costs extends to entire product lines, unless the producer can demonstrate that certain specific products do not pose an increased risk. Where an issue with a medical device presents only a small risk of malfunction or adverse effect, the expanded liability imposed by the Court may cause producers not to issue a recall or recommend replacement. As an alternative to a recall or recommendation, a manufacturer could merely provide updated information on the medical device and the related risks and let the patient and his physician decide whether replacement is necessary. In light of the Court's "potential defect" approach, however, even a "field safety notice" that does not recommend replacement, might result in liability for replacement cost. If the risk of malfunction or adverse effects is sufficiently small, and there are also risks associated with replacement, a manufacturer could also decide not to take any field safety corrective action, and, in the large grey area, the Court's ruling has made that decision more likely. Consequently, the Court's ruling may adversely affect patient safety and choice.

Third, given that the ECJ's judgment does not attempt to limit the applicability of the potential defect concept to specific product categories or types of users, producers and importers will have stronger incentives to attempt to limit its effect by providing extensive risk-related information, including information about potential risks and defects. Under the *Boston Scientific* ruling, products from computers and televisions, smoke detectors and sprinklers, thermostats and video cameras, wires, conduits, and pipes incorporated into office buildings and homes, to parts of cars, trains, and airplanes, could expose the producer to extensive liabilities for replacement costs without any product actually having failed or caused damage. Potential defects include both lack of performance and positive safety risks. The supply of additional information about such risks may reduce the liability exposure by defining the public's expectations, if the presentation of the product is allowed to play a role in a specific case. If a product recall is appropriate, the producer will attempt to narrow the recall through root cause analysis and/or testing to those products that pose the most significant risk, to the exclusion of products posing low, acceptable risk. Of course, inasmuch as the cost of possible product issues has increased across the board, producers may invest more in preventing any risks, which would result in increased prices.

In the case of medicinal products and medical devices, producers will also take great care in drafting alerts and communications addressed to health care

56 Cf. Annex II, section 3.1, seventh indent; Annex IV, section 3; Annex V, section 3.1., 8th indent; Annex VI, section 3.1., 8th indent; Annex VII, section 4; Annex VIII, section 5, Medical Device Directive.

57 Guidelines issued by the European Commission state that "The Medical Device Directives require the manufacturer to report to the National Competent Authority any technical or medical reason leading to a systematic recall of devices of the same type by the manufacturer." European Commission. Guidelines on a Medical Devices Vigilance System. MEDDEV 2.12-1 rev, 8 January 2013.

58 European Commission. Guidelines on a Medical Devices Vigilance System. MEDDEV 2.12-1 rev, 8 January 2013.

59 Directive 85/374 of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 07/08/1985, pp. 29-33, as amended, OJ L 141 20 (4.6.1999). http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1426872627268&uri=CELEX:01985L0374-19990604

60 Cf. European Commission. Guidance Document on the Relationship between the General Product Safety Directive (GPSD) and certain Sector Directives with Provisions on Product Safety, http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/general_product_safety_directive/index_en.htm

61 Compensation for pain and suffering is not covered by the Product Liability Directive, but subject to the applicable national law.

professionals about possible product-related issues; a key question is whether the producer will merely inform about such issues or recommend specific remedial steps. In any event, the producer will have reason to anticipate the possible actions that physicians or patients might take, and to consider ways to limit their exposure to the costs associated with such actions, including through prevention, monitoring, supply of risk-related information, and insurance.[62]

VI. Conclusions

The Product Liability Directive is an undeveloped civil liability regime that leaves many questions unanswered. In the same vein, the Court's ruling answers a few questions, and in doing so, raises many other questions. With this judgment, the defect test and the scope of compensable damages under the directive are far from settled. The beneficiaries of the Court's pontifications are health care insurers, not patients. Rather than helping patients, the Court's ruling may adversely affect patient safety and choice.

It is hard for national courts to ensure adequate administration of justice if they are confronted with weak legal reasoning from Europe's highest court. The defect test set forth in the Court's *Boston Scientific* judgment is phrased in broad and ambiguous terms. Apparently, the Court believes that medical devices do not meet safety expectation entitlements where no actual patient injuries have occurred due to device malfunctioning, and the statistical chance that a device functions properly is over 99%. Outside of the specific *Boston Scientific* context, the concept of "potential defect" does not allow courts to make the fine distinctions necessary to distinguish between "unavoidably unsafe products," "products posing generally known risks," "products posing disclosed risks," "obviously dangerous products," "unreasonably dangerous products," etc. By creating liability for "potentially" defective products and for cost associated with product replacement, the Court has rewritten the Product Liability Directive.

It has been said that hard cases make bad law.[63] But it is also possible that bad law makes cases hard. The Product Liability Directive does not give the courts much to go by in all but the obvious cases. By clinging onto the directive's general objectives of consumer protection and fair apportionment of technological risks, the Court uses unsophisticated teleological interpretation to justify its judgment. As discussed in this case note, the Court's rudimentary ruling may have serious counter-productive effects, including product withdrawal, more limited choice, and diminished patient safety. One way to mitigate the potential consequences of the Court's judgment is to ignore its broad wording, and give it narrow application to only the specific facts of the *Boston Scientific* case. Another way, as I suggested in this note, is to focus on what the Court left out, and ask what risks should be acceptable.

62 If a product liability insurance policy covers all damage to which liability attaches, the cost of surgical procedures to replace defective products will be covered. In that case, given that the scope of coverage has increased under the *Boston Scientific* ruling, insurance premiums will likely be subject to upward pressures.

63 Winterbottom v Wright (1842) 10 M&W 109.