

Manufacturer responsibility under European Union law - prevention and prophylaxis in ECJ jurisprudence

A product's individual defectiveness does not need to be detected for said product to fall within the meaning of "defective" as defined by the Product Liability Directive 85/374/EEC¹ and, therefore, as defined by Section 3 of the German Product Liability Act (ProdHaftG), if products in the same series have a significantly increased risk of failure. This finding is at the very core of a decision by the European Court of Justice (ECJ)² on a reference for a preliminary ruling submitted by the German Federal Court of Justice (BGH).³

Two cases are at the basis of the ECJ's judgment: The first was about the compensation for operation costs incurred in removing an artificial cardiac pacemaker which belonged to a series in which functional defectiveness had occurred with significant frequency and implanting another pacemaker. In the second case, a magnetic switch of an implantable cardioverter defibrillator (ICD) might have failed (a serial defect, too) without (as the manufacturer claimed) compromising the ICD's overall functionality. In both instances the medical devices were replaced by means of surgery. The BGH asked whether these two cases fell within the definition of "defect" as provided for in the Directive. If this were the case, the BGH's second question went on, would the costs of the operations to remove the devices and implant another pacemaker or defibrillator constitute damage caused *by personal injury* for the purposes of Article 1 and point (a) of the first sentence of Article 9 of Directive 85/374/EEC?

In both cases, the ECJ deemed the Directive's concept of "defect" applicable. In the case of the potentially failing artificial cardiac pacemaker, the ECJ held the costs of the operation to be fully caused by the defect.⁴ As regards the case of the ICD, where the device's use was only partially compromised⁵, the Court indicated a similar position but left the final decision to the BGH.

The first voices in the literature on this decision of the ECJ call for equanimity, which is hardly surprising, and basically argue that the judgment can hardly or not at all be generalized and that it is at best relevant within the specific context of medical devices⁶; a detailed analysis of the decision, however, will render business as usual with respect to the traditional German legal understanding of product liability law and

¹ Official Journal of the European Union 1985 L 210/29

² ECJ Judgement of 05.03.2015 in the joined cases C-503/13 and 504/13

³ BGH Decision of 30.07.2013 VI ZR 327/12 = EuZW 2013, 840

⁴ Proceeding C-503/13

⁵ Proceeding C-504/13

⁶ Moelle/Dockhorn NJW 2015, 1165 Anmerkung zur EuGH-Entscheidung

manufacturer liability law hardly possible. A Union law oriented revision of the legal definition of "defect" and its legal consequences will be necessary.

"Defect":

The concept of "defect" as set forth in Directive 85/374/EEC, the latter establishing strict liability, and in the ProdHaftG is not based on technical defects in a product⁷ but on the question as to whether justified safety expectations are met or not: "The safety which the public at large is entitled to expect, in accordance with that provision, must therefore be assessed by taking into account, inter alia, 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", reads the judgment of the ECJ.⁸ With an explicit reference to the Advocate General's Opinion, the ECJ follows the latter's view holding that the "potential lack of safety" gives rise to the producer's liability which, especially regarding medical devices, stems from "the abnormal potential for damage which those products might cause to the person concerned."⁹ Accordingly, the ECJ concludes that it is possible to classify as defective all the products in a series in which defects have occurred with significant frequency, without any need to proof that the specific product at issue is defective.

Like the Advocate General in his Opinion, the ECJ infers its legal view from the objective pursued by the Directive "of adequately solving the problem of a fair apportionment of the risks inherent in modern technological production."¹⁰ According to the Advocate General, the conclusions to be drawn from this Union law objective are as follows:

- The term "product safety" is solely and exclusively defined according to the safety which the public and users are entitled to expect,
- This view is also dictated by consumer protection, which is given high priority under Union law,
- The preventive function of the Union's product safety law and liability law as well as the prophylactic possibilities of the manufacturer to avoid risks outline the framework of product responsibility: "Making proof of a lack of safety subject to the actual occurrence of damage would disregard the *preventive* function assigned to EU legislation on the safety of products offered on the

⁷ The Advocate General explicitly emphasizes, at point 32 of his Opinion, that a product defect "can exist irrespective of any internal fault in the product concerned". Therefore, in view of the justified safety expectations, a technically flawless product, too, can be defective according to Directive 85/374/EEC because it cannot fulfill what is expected in terms of safety: "Its triggering factor does not reside in the product fault, but in the fact that the product does not provide the safety which a person is entitled to expect," point 33 of the Opinion.

⁸ C-504/13, point 38

⁹ C-504/13, point 40

¹⁰ Opinion, point 30

market and to the specific liability regime established by Directive 85/374, which manifestly pursues a *preventive* function by imputing liability to the person who, having created the risk most directly by manufacturing a defective product, is in the best position to minimise it and to prevent damage at the lowest cost."¹¹

- The EU's objective of human health protection, enshrined in Articles 169 and 168 TFEU as well as in Article 35 of the Charter of Fundamental Rights of the European Union, forms part of the objectives of the liability regime laid down in Directive 85/374/EEC.

Deriving the European liability regime from Union law *objectives* is alien to German tort law (delict law), which is shaped by legal doctrines on concepts and definitions. In light of the Union law's primacy over domestic legal orders, German delict law will have to adapt.¹² This applies in particular to the product responsibility of the manufacturers, as appositely emphasized by the Advocate General, who are in the best position to foresee a product's risks and avoid these, for instance, in accordance with the requirements of Section 6 (1) ProdHaftG. By referring to the Advocate General's viewpoint¹³ the ECJ follows his path of reasoning.

If the general objectives of European legislation on product safety and product liability are the decisive factors, it is not possible to deny the importance of the ECJ judgment by reducing its applicability to sensitive products such as pacemakers or other medical devices. The major premise that a product is to be deemed defective without the need for individual proof if it belongs to a series with a significant defect rate applies in a general manner where a product is concerned "that poses risks jeopardising the safety of its user and having an abnormal, unreasonable character exceeding the normal risks inherent in its use."¹⁴

If the Union law objectives regarding product safety, consumer protection and human health protection are the most decisive factors, the fact that the risk may reside in a medical device or a vehicle or a wood preservative will, at the most, make a slight difference in the degree to which users are personally concerned or affected: In the absence of information on the risks, the users in any case expect a risk-free product. They generally only learn of the risk-triggering defectiveness – for instance within the context of recalls – when the potential risk has already materialized and led to casualties. Thus, the decisive factors stressed by the Advocate General and the ECJ are preventing risk materialization and damage prevention on the part of

¹¹ Opinion, point 38

¹² For further detail see Helmig: "Relevance of the European Union Law - Product Liability Law and Product Safety Law Put to the Test", Gen Re October 2014, p. 1 ff.

¹³ C-504/13, point 40

¹⁴ Opinion, point 30

the producer. The pacemaker cases present clear evidence as to this understanding: According to the circumstances of the cases found by the courts, the measures taken by the manufacturers, i.e. recommending to replace the artificial pacemaker and to deactivate the defibrillator's magnetic switch, were caused by *post-production* findings of the manufacturers' quality control systems. By argumentum e contrario, this absolutely has to be construed as meaning that the manufacturers' quality management systems as risk organization tools as well as the product-related quality assurance system laid down in Annex II of Directive 93/42/EEC have failed; because their most honorable task is that of preventing risks during the design process (in the terminology of the ProdHaftG the "construction process") and the manufacturing process ("fabrication process") and not of detecting defects afterwards which have already caused an abnormal hazard potential.¹⁵ According to the ECJ decision, it is this lack of reliability, for which the manufacturer is responsible, that gives rise to his liability.

Therefore, the Advocate General accurately states at point 37 of his Opinion: "In actual fact, all EU legislation on product safety would be called into question if, in that situation, it was necessary to wait for the risk of failure in connection with a lack of safety shown to exist in certain products to materialise in other products through damage occurring."¹⁶

"Damage":

The two cases referred to the ECJ by the BGH were different from each other:

The reimbursement of the operation costs incurred in replacing the defective pacemaker upon recommendation of the manufacturer was at the center of proceeding C-503/13. If a product defect in the legal sense were established in this case, the defendant would be held liable to compensate these costs under German delict law, which also corresponds to the BGH's opinion.

In Case 504/13, the manufacturer did not recommend to replace the defibrillator by means of surgery but merely to deactivate the magnetic switch from the outside (without surgery). According to traditional BGH jurisprudence, the operation costs of an actually performed replacement surgery would have been deemed a so called equivalent damage not covered by delict law and thus not reimbursable.

As with the definition of "defect", the ECJ infers the Union law concept of "damage"¹⁷, the meaning of which is not final, from the Union law objective of protecting

¹⁵ Different opinion without careful judgment in Handorn, „EuGH bestätigt Haftung für den bloßen Fehlerverdacht bei Medizinprodukten“, VDE MedTech, Spezial April 2015

¹⁶ Consenting in this respect Reich, "Anmerkung zur Entscheidung des EuGH" EuZW 2015, 320, yet differing on the applicability to other products, *ibid*, 321

¹⁷ Case Veedfald, C-203/99

consumer health and safety.¹⁸ Where causality between defect and materialized damage is established, damages extend to everything that is necessary in order to eliminate the consequences of the damage and to restore the level of safety which one is entitled to expect pursuant to Article 6 (1) of the Directive.¹⁹ This also covers operation costs.

Yet, the ECJ leaves it to the BGH to decide whether the costs relating to the surgical replacement of the ICD that was still functional, though only limitedly so, have to be compensated; according to BGH case-law, these costs have to be treated as equivalent damage. According to the ECJ, compensation is in order "if such an operation is *necessary* to overcome the defect in the product in question"²⁰. Thus, the "necessity" of the operation for eliminating the defect is the decisive factor.

It is hard to image that a responsible court could possibly negate the necessity of the operation. The patient's implanted defibrillator was undisputedly defective due to the faulty magnetic switch, and its abnormal risk potential as electronic device – there is no such thing as defect-free software – could not be ruled out. A court could only justify an affirmation of the operation's lacking necessity with the patient's consent or with the argument that a life with a defective ICD could be reasonably expected of the patient and that, therefore, the operation would be a disproportionate measure. A decision of this kind would have to include the idea that from the patient's point of view, too, no abnormal risk resided in the defective ICD. Such a decision would not conform to the objectives of Union law, notably so with respect to consumer and health protection and the protection of the integrity of the human body, and would also not eliminate the defect in the defibrillator. The consent of a patient who is under the worrying impression of the risks posed by surgery cannot possibly be the decisive factor under German tort law for exonerating the manufacturer. Therefore, the costs of the surgical replacement of a defective, yet functional, ICD as preventive measure²¹ are also damage "caused by death or by personal injuries" pursuant to Article 1 and Article 9 (1) point a) of Directive 85/374/EEC, and not equivalent damage.²²

This corresponds to the ECJ's finding at point 46 of the judgment: According to the Court's case-law, "full and proper compensation for persons injured by a defective product must be available" – cumulatively – for the damage. "Proper" means any expenses made in order to eliminate the potential source of the damage, i.e. the surgical removal of the defective defibrillator. "Compensation" does not mean a mere payment of money, but necessarily also includes the physical removal of the

¹⁸ Judgment of the ECJ, point 47

¹⁹ c.f. Reich, „Fehlerhaftigkeit von Medizinprodukten“, EuZW 2014, 898, 899

²⁰ Judgment of the ECJ, point 55

²¹ Opinion, point 75

²² Reich, EuZW 2015, 321

source of the damage. Thus, in addition to compensation in the form of money for necessary expenses, ECJ jurisprudence also requires the actual elimination of the root cause as preventive measure so as to avert future damage; because only then will the "abnormal potential for damage" be eliminated beyond the scope of individual cases, as is envisaged by the objectives of Union law.

The breast implant case:

A second case revolving around medical devices now depends on the ECJ's evaluation of liability law: With its decision of 9 April 2015²³ the BGH has referred to the ECJ the question of whether it falls within the scope of purposes and intentions of the Medical Devices Directive 93/42/EEC that the notified body carrying out the audits of the quality assurance systems, the examination of the design of the product and the required surveillance acts to protect all potential patients in cases regarding medical devices of Class III and, therefore, can be held liable directly and unlimitedly in the event of culpable breach of duty. Furthermore, the BGH asks whether the quoted points of Annex II of Directive 93/42/EEC have to be interpreted as meaning that the notified body carrying out the audits of the quality assurance systems, the examination of the design of the product and the required surveillance has a general duty, or at least one that is warranted in specific cases, to inspect products. The BGH's third question aims at clarifying whether the notified body has a general duty, or at least one that is warranted in specific cases, to inspect business documents of the manufacturer and/or carry out unannounced audits.

The plaintiff is a woman who had been implanted breast implants of poor quality produced by a French manufacturer which she had to have removed for fear of health damage. She sued the notified body TÜV Rheinland whom she, in essence, accuses of having breached its duties in its capacity as notified body.

The lower courts²⁴ dismissed the action. What is remarkable about their judgments in this context is that a consideration of Union law played no role at all despite references having been made to Directive 93/42/EEC.

From the point of view of liability law, the principles established by the ECJ in Cases C-503/13 and C-504/13 would have to be applied to the same extent.²⁵ However, this was of no advantage to the plaintiff in the German proceedings due to the manufacturer's bankruptcy. It appears that her action now, for the first time, raises the question of certified quality assurance and quality management systems' legal relevance, their significance within the European product safety regime and, in particu-

²³ VII ZR 36/14

²⁴ Regional Court Frankenthal (Palatinate region), judgment of 14.03.2013, 6 O 304/12; Higher Regional Court (OLG) Zweibrücken, judgment of 30.01.2014, 4 U 66/13

²⁵ The Advocate General explicitly refers to the breast implant case at point 73

lar, whether the applicable regulatory acts have protective effects to the benefit of third parties.

A Recommendation by the European Commission of 24 September 2013²⁶, presumably a reaction to the French breast implant case, "on the audits and assessments performed by notified bodies in the field of medical devices" does not generally rule out such third-party effects. The notified bodies' rights and obligations specified therein are of a recommending nature. The Recommendation's purpose is that "by providing general guidelines for such assessments and unannounced audits, this Recommendation should facilitate the work of the notified bodies as well as the Member States' evaluation thereof." But it is explicitly emphasized that "*[t]his Recommendation does not create any new rights and obligations. The legal requirements applicable to all types of devices and conformity assessments are set out in the Union legislation on medical devices.*" However, this also means that with respect to the questions referred to the ECJ by the BGH, the role of the notified bodies regarding the accuracy of the breast implant manufacturer's EC declaration of conformity set out in Annex II of Directive 93/42/EEC has to be determined in correspondence to the Recommendation.

European product safety law:

The ECJ's pacemaker decision already has and the breast implant case will contribute substantially to consolidating the legal understanding and the legal application of the comprehensive, albeit very complex, European product safety law as these decisions undermine national obduracy of domestic courts. This jurisprudence will also affect the manufacturers' market behavior as well as their attitude towards their product responsibility to the consumer, be it against the threatening backdrop of expanding sanctioning due to the relevant Union legislation's objectives.²⁷

The legal framework is in essence determined by the Product Liability Directive 85/374/EEC²⁸, the General Product Safety Directive 2001/95/EC²⁹, Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008³⁰ and complementary thereto Decision Regulation (EC) No 765/2008 of 9 July 2008³¹ as well as Regulation (EU) No 1025/2012 of 25 October 2012 on European standardi-

²⁶ Official Journal of European Union of 25.09.2013 L 253/27

²⁷ In this respect, the Advocate General is quite optimistic at point 74 of his Opinion on the proceedings C-503/504/13: "Recognising that compensation may be awarded in respect of damage caused by action intended to avert a risk of much more serious damage is likely to prompt producers to improve the safety of their products and to create a better balance between the need for compensation for injured persons and the objective of preventing damage."

²⁸ Official Journal of the European Union of 07.08.1985 L 210/08

²⁹ Official Journal of the European Union of 15.01.2002 L 11/4

³⁰ Official Journal of the European Union of 13.08.2008 L 218/82

³¹ Official Journal of the European Union of 13.08.2008 L 218/30

zation³², all of which are summed up and outlined in the European Commission's 2014 "Blue Guide on the implementation of EU product rules"³³.

Article 1 (1) of Decision 768/2008 requires that products placed on the Community market shall comply with all applicable legislation and, which has to be added for purposes of clarity, with its objectives, the latter being open to interpretation. The second paragraph unmistakably stipulates that "[w]hen placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation." They "shall be responsible for ensuring that all information they provide with regard to their products is accurate, complete and in compliance with Community rules applicable" (third paragraph). The latter means nothing less than the manufacturer's personal responsibility for contributing to meeting the conditions of "defect" pursuant to Article 9 of the Product Liability Directive (Section 3 Prod-HaftG) by means of, for instance, praising and advertising the product.

Products enjoy the freedom of movement of goods in the Community if they carry the CE marking. This is conditional on the manufacturer's compliance with the applicable module for the conformity assessment procedures laid down in Decision No 768/2008, which the manufacturer, as a general rule, may choose himself, but which is prescribed by legislation regarding medical devices. The EC declaration of conformity at the manufacturer's sole responsibility (Article 5 of Decision 786/2008) is at the very core of the Decision, requiring that an effective quality management system on the basis of EN ISO 9001 be in place³⁴ and that the declaration, for instance in the case of medical devices, be certified by an independent conformity assessment (notified) body, its competence being the result of a special system of accreditation set out in Regulation (EC) No 765/2008. The manufacturer needs certification by the body's auditors for his declaration of conformity. This suggests that the auditors, who are aware of how important their approval certificate is for the authorization to place a product on the market, are (in part) responsible for the accuracy of the contents of the manufacturer's declaration.

Certification is a business which results from the separation between legislation competence and the technical expertise of economic actors: The legislator needs this technical expertise in order to pass regulations and harmonized standards on product safety; as regards the "how" of this endeavor, the legislator draws from standardization organizations, as is provided for in Regulation (EU) No 1025/2012.³⁵ Although most industrial companies are certified according to EN ISO 9001 or oth-

³² Official Journal of the European Union of 14.11.2012 L 316/12

³³ http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm#h2-3

³⁴ „Blue Guide“ footnote 33, p. 59 f

³⁵ „Blue Guide“ footnote 33, p. 33 ff

erwise, i.e. the existence of effective quality management systems is confirmed, increasing numbers of recalls in the automotive industry, for example, seem to present prima facie evidence that the quality management systems do not work properly in many instances and for various reasons. At this point, no proposition can be made as to whether it is "only" the companies who have failed or whether auditors have not met their assessment responsibility in a sufficient way. The auditors' tasks and obligations in the public interest regarding the level of protection of consumers, health and the integrity of the human body will, however, be one key issue in the ECJ's decision on the breast implant case. Not only does the declaration of conformity, as precondition for placing a product on the market, create confidence on the part of market surveillance bodies in the declaration's accuracy, which is supposed to reflect the quality assurance behind it, but also on the part of those who use the products manufactured therewith as they (should) have confidence in the overall statutory control system and its objectives.

Conclusion:

The pacemaker decision of the ECJ determines that a product is also defective within the meaning of the Product Liability Directive 85/374/EEC if it forms part of a series in which defects have occurred with significant frequency, even if the product's individual defectiveness has not been established. The decisive factor is the product's abnormal potential for damage, irrespective of its defects.

The liability regime of the European Union has a preventive and prophylactic function that goes beyond merely reacting to damage materialization.

The resulting concept of "damage" is of a tortious nature under German law, too, and must lead to full compensation, including the elimination of the source of the risk, for any damage incurred.

The breast implant case, which has now been referred to the ECJ by the German Federal Court of Justice, has to be judged with the same reasoning as the pacemaker case in terms of liability. What makes this case special is that it revolves around the sphere of obligations held by the notified bodies' auditors who check quality assurance and quality management systems and share responsibility for the manufacturer's declaration of conformity.

European product safety law is a closed, safety-objective-oriented system and is built on conclusive formal safety mechanisms which, in light of prima facie evidence as presented by increasing numbers of recalls, can be deemed not fully effective at the least.