

Relevance of the European Union Law Product Liability Law and Product Safety Law Put to Test

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1 BGH Calls upon ECJ:

The relevance of European Union law will be the yardstick to examine German case law on liability of manufacturers according to Section 823 (1) of the German Civil Code (BGB) and on product liability provided for in the German Product Liability Act (ProdHaftG) as well as the relationship between these two: The BGH has requested the Court of Justice of the European Union (ECJ) in two orders for reference to provide a ruling on whether a product – in this case a cardiac pacemaker – is defective as defined by Section 3 (1) ProdhaftG and Article 6 of Council Directive 85/374/EEC, if its individual defectiveness has not been established, the product, however, is part of a series which has shown a significant defect rate for other products of the same type. Should the ECJ confirm this notion, the Court is to further answer the question of whether the costs of the operation to remove the product and implant a different pacemaker constitute damage caused by personal injuries according to Article 1 and Article 9 (1)(a) of Council Directive 85/374/EEC? The BGH as well as the lower courts held the defectiveness to be given.¹

These decisions basically follow a judgment of the Higher Regional Court (OLG) Hamm which also deemed a defect to be given if a product belongs to a defective series.² According to the OLG, already an abstract potential for this device's defectiveness, and not the device's past or possible future failure, constitutes a defect. The BGH, in its judgment of 13 July 2010, had referred a similar case back to the OLG Munich, mostly due to procedural reasons.³ The OLG Frankfurt dismissed a similar case with hardly tolerable reasoning: It is not the functional capabilities of single components that are essential to the patient, but those of the device as a whole (the component in question was a leaking sealing component, which could

¹ BGH, decision of 30 July 2013, VI ZR 284/12, VersR 2013, 1450; lower courts: Local Court Stendal, decision of 25 May 2011, 3 C 408/09; Regional Court Stendal, decision of 10 May 2012, 22 S 71/11. BGH decision of 30 July 2013, VI ZR 284/12, VersR 2013, 1451. For a summary see PHi 2013, 181. Lower courts: Regional Court Düsseldorf, decision of 3 February 2011, 3 O 182/10; Higher Regional Court (OLG) Düsseldorf, decision of 20 June 2012, I-15 U 25/11: Without providing further reasons, the OLG Düsseldorf denied a motion by the defendant to submit an order for reference to the ECJ, stating that a potential reduction in quality does not cause the suspicion of a defect, but constitutes the defect.

² VersR 2011, 637, incl. concurring note by Schultze-Zeu.

³ BGH, decision of 13 July 2010, VI ZR 254/09, VersR 2010, 1666; lower courts: Regional Court Munich I, decision of 1 December 2008, 3 O 9161/08; Higher Regional Court Munich, decision of 21 July 2009, 18 U 1549/09.

at any rate compromise the pacemaker's functional capabilities). If a product series in its entirety complied with the safety standards of the control group the market's justified safety expectations would be met and not neglected. The market could not expect a one hundred percent safety, i.e. a complete freedom from defects, during a device's average service life, not even with respect to such important products. A revision of the ruling was dismissed.⁴

The above cited preceding decisions dealt with the Product Liability Directive 85/374/EEC⁵ but left the Product Safety Directive 2001/95/EC⁶ completely unconsidered. Article 3 (1) of the Product Safety Directive provides that manufacturers shall place only safe products on the market. This principle is also enshrined in the German Product Safety Act (ProdSG)⁷ which transposes the Directive into national law.

2 Product Liability and Product Safety under European Union Law

It would come as no surprise if the ECJ were to confirm the BGH's and lower courts' interpretation of 'defect' as laid down in Section 3 ProdHaftG.⁸ Predicting whether the ECJ will follow the BGH's path as to the definition of 'damage' is more difficult. Moreover, it is just as unclear, whether the ECJ will endorse the German courts' view regarding the consequences caused by the damage.

It is interesting, however, that neither the lower courts nor the BGH have so much as indicated as to which EU law principles underpin their decisions and why the BGH has actually submitted the orders. They simply refer to the Product Liability Directive. They do not refer to the Product Safety Directive, which is just as relevant, or to the also pertinent Directive 93/42/EEC on medical devices and the amendments thereto.⁹

The Union law implications of the BGH's questions, though, are obvious, which the order for reference itself also states, and there is apparently no relevant ECJ jurisprudence. In the following this issue is discussed in detail, the article's focus lies with European Union law. Some questions of legal dogmatics can only be briefly addressed in this article.

⁴ OLG Frankfurt am Main, decision of 20 May 2010, 1 U 99/09, BeckRS 2010, 14952; Backmann agrees, Beck-online MPR 2012, 37, 40.

⁵ Official Journal of the European Economic Community, L 210/29 of 31.8.1985.

⁶ Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety (Official Journal, L 11 of 15.1.2002).

⁷ Equipment and Product Safety Act (Gesetz über die Neuordnung des Geräte- und Produktsicherheitsrechts) of 8 November 2011, Federal Official Gazette I 2178.

⁸ Brock/Lack dissent, PharmR 2013, 480 - beck-online, suggesting that if the ECJ were to follow the BGH's interpretation, severe consequences would ensue for the entire liability law, and progress in medical technology as well as the manufacturers' will to provide innovative products could be compromised.

⁹ Official Journal of the European Economic Community, L 169/1 of 12.7.1993.

2.1 German Law vs. European Union Law

The German law governing liability of manufacturers under Section 823 BGB has seen its development mainly propelled by BGH judgments. Product liability law and, always complementary, product safety law are anchored as one in the European legal order. Despite the transposition of the Product Liability Directive 85/374/EEC and the General Product Safety Directive 2001/95/EC into German national law, the Union law context is scarcely reflected in domestic product liability and product safety law, although the European law is incorporated into German law.¹⁰ As a general rule, the German Product Liability Act is subordinated to the primacy of the traditional manufacturer's liability law according to Section 823 BGB.¹¹ Not seldom does the relevant literature on this aspect tend to trivialize fundamental BGH decisions that may give momentum to a broad-based rethinking of this practice, warn against generalizing the decisions, and reduce them at best to the level of somewhat interesting new ideas.¹² This domestic conservative approach of preventively overturning or trivializing forward-looking BGH rulings, such as its airbag decision¹³, is not tenable at European level and is probably not going to be supported by the ECJ.

European Union law is not shaped by national legal dogmatics, but is purpose and goal-oriented, economically and politically motivated.¹⁴ Product liability and product safety law under the EU legal system are goal-oriented and devoted to comprehensive consumer protection and general safety.¹⁵

The European legal basis for this derives in particular from Article 169 TFEU (ex Article 153 TEC)¹⁶, which provides:

“(1) In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.”

¹⁰ Bamberger/Roth, BGB, 3rd ed. 2012, § 823, note 0.13.

¹¹ Günes rightly speaks of the Product Liability Act's 'shadowy existence' in the face of the manufacturer's liability under Section 823 BGB, c.f. PHi 2013, 229, 233.

¹² Cit. op. footnote 8.

¹³ See, for instance, Burckhardt's comment on the airbag decision (VI ZR 107/07 of 16 June 2009) in: Betriebs-Berater 2009, 1888.

¹⁴ Oexle, EuZW 2004, 628.

¹⁵ Schucht in NJW 2013, 967, on trade with used work equipment and conflicts between product safety law and occupational safety law (Der Handel mit gebrauchten Arbeitsmitteln im Spannungsfeld von Produktsicherheits- und Betriebssicherheitsrecht).

¹⁶ Consolidated Version of the Treaty on the Functioning of the European Union, Official Journal of the European Union, C 115/47 of 9.5.2008.

The legislative implementation is to be carried out according to the rules set out in Article 114 (3) TFEU:

“(3) The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.”

2.2 The Basics of European Union Law

In Europe, product liability law and product safety law have been designed to serve, in the public interest, consumer protection and general safety as societal cornerstones of the European Union. At the same time as the Product Liability Directive was adopted in 1985, the Commission, the Council, and the European Parliament also created various instruments to safeguard the cornerstones' foundation.¹⁷ They can only be briefly illustrated at this point: With the Council Decision 93/465/EEC of 22 July 1993 on the technical harmonization directives and the modules that have to be used for the various phases of the conformity assessment procedures, and on the rules for the affixing and use of the CE conformity marking¹⁸, binding provisions were imposed on manufacturers regarding production and marketing of safe products only. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008¹⁹ “on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC” is its amendment and revision²⁰. The Decision is complemented by Regulation 765/2008.²¹

The conformity assessment procedures are based on harmonized standards²², the compliance with which confers the “presumption of conformity to a legal provision”.²³

¹⁷ Council Resolution of 7 May 1985 on a New Approach to technical harmonization and standards; for an explanatory summary see: <http://www.cen.eu/boiss/supporting/guidance%20documents/gd009%20-%20guidance%20on%20the%20new%20approach/Pages/default.aspx>

¹⁸ Official Journal of the European Community, L 220 of 30.8.1993.

¹⁹ Official Journal of the European Union, L 218/82 of 13.8.2008.

²⁰ The “New Approach”, as set out in the communication of the Commission of 7 May 2003, and the Council Resolution of 10 November 2003 (OJ C 282/3 of 25.11.2003) were preceding Decision 768/2008/EC.

²¹ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, Official Journal of the European Union, L 218/30 of 13.8.2008. See Klindt in PHi 2011, 42.

²² Directive 93/34/EC of 22 June 1998, Official Journal of the European Communities, L 204/37 of 21.7.1998; adapted by Council Directive 2006/96/EC, Official Journal of the European Union, L 363/81 of 20.12.2006.

²³ Decision No 768/2008 of the European Parliament and the Council of 9 July 2008, Official Journal of the European Union, L 218/82 of 13.8.2008, Recital 9.

Recital 17 of Decision 768/2008/EC clarifies: „Products that are placed on the Community market should²⁴ comply with the relevant applicable Community legislation, and economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and of the environment, and to guarantee fair competition on the Community market.” According to Recital 19, this applies to the entire supply chain: “All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only products which are in conformity with the applicable legislation.”

2.2.1 Harmonized Standards

Harmonized standards form the centerpiece of the “New Approach” to achieve the Union’s safety goals. Recital 9 of Decision No 768/2008 sets out that the presumption of conformity “should enhance recourse to compliance with harmonised standards”. Harmonized standards are developed by CEN, CENELEC, and ETSI²⁵ due to a mandate given to these organizations by the Commission and the EFTA. Their publication in the Official Journal of the European Union as “European Standards” (EN) vests them with a binding character in the context of conformity assessments.

As of the 1990s, at the same time as European legislation on product safety was adopted, the industry established organizations for standardization, such as ISO or DIN, leading to an implementation of the conformity assessment procedures and detailed regulations and standards, which, today, set the benchmark at international level. This is particularly true as regards quality management systems according to the standards series ISO 9000 – 9004²⁶.

These standards, including sector-specific regulations, also apply to medical products. The standard DIN EN ISO 13485 (October 2007) “specifies requirements for a quality management system intended for use by organizations for the design and development, production, installation and servicing of medical devices.”

2.2.2 The Self-binding Effects of the Industry’s Standardizing Procedures

The industry’s standardization organizations establish the framework conditions as regards contents for legislation at European level, notably so with respect to safety requirements for products, their production, and suitability for a specific use. Due to

²⁴ The modal verb “should” is always of normative nature.

²⁵ <http://www.cen.eu/cen/aboutus/pages/default.aspx>: CEN is for Comité européen de normalisation (European Committee for Standardization); CENELEC is for Comité européen de normalisation électronique (Committee for Electrotechnical Standardization); ETSI is for European Telecommunications Standards Institute.

²⁶ A revision of this standards series which will address risk and safety requirements in greater detail is planned for 2015.

their expertise, which national and European legislators lack, these organizations contribute to legislation in a self-regulatory and self-binding, voluntary and goal-oriented way.²⁷ European legislation and the industry, the latter in turn with its adapted specific standards by standardizing organizations, are interdependent. The self-binding effects apply to governments as well as to the industry.²⁸ Thus, they form a coherent overall system to ensure goal-oriented product safety in the public interest of the European Union, which derives its legal sanction from European product liability law and European product safety law provided for by Directive 2001/95/EC at EU law level and from large authority granted by market surveillance bodies at public law level.²⁹

Regulation (EU) No 1025/2012, which entered into force on 1 January 2013, legally and politically manifested the symbiosis of standardization and European legislation. The subject matter of the Regulation (Article 1) entails far reaching objectives: “This Regulation establishes rules with regard to the cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the identification of ICT technical specifications [technical specifications for information and communication technology, author’s note] eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation.”³⁰

Where European legislators and the industry cooperate on this symbiotically, as it appears on the best of terms and without any contradictions, a common European legal culture emerges. This undermines any criticism on the part of the industry that legal requirements for product safety and product liability were too strict.

²⁷ Recital 8 of Decision No 768/2008 (c.f. footnote 23) clearly emphasizes this reasonable “division of work”: “Specific product legislation should, wherever possible, avoid going into technical detail but should limit itself to the expression of essential requirements.” Meeting these requirements by creating harmonized standards is the industry’s matter. ISO 26262 on Functional Safety in vehicles (Final Draft) expressly refers to the consistency of the industry’s norms and national legislation: “In addition to their evaluation as being acceptable for industrial, technological, commercial and user purposes, draft international standards may on occasion have to be considered in the light of their potential to become standards to which reference may be made in national regulations.”

²⁸ Recital 7 of the Decision clarifies: “Although the incorporation of the provisions of this Decision in future legislative acts cannot be required by law, the co-legislators adopting this Decision have entered into a clear political commitment which they should respect in any legislative act falling within the scope of this Decision.” The fact that, today, euroscepticism hinders a comprehensive implementation does not change the political will of the governments involved or their commitment to apply the Decision.

²⁹ Potinecke (interview) on recalls and liability risks, in: NJW-Aktuell 2013, 12. (Title: „Ein fehlerhafter Rückruf führt zu erheblichen Haftungsrisiken“).

³⁰ Official Journal of the European Union, L 316/20 of 14.11.2012.

Whoever binds themselves has to let themselves be measured against what binds them.

This inseparable relationship between legislation and the industry's self-binding actions, by way of participating in legislation procedures at European level, is scarcely reflected in German product liability law. If the BGH requests a preliminary ruling of the ECJ on its legal opinion, it would have stood to reason to at least mention this Union law context in the orders for reference.

2.3 Who Is a Consumer under European Union Law?

European Union law does not provide a comprehensively binding definition of who is actually meant by "the consumer". In Article 1 (2)(a), Directive 1999/44/EC on the sale of consumer goods defines that consumer "shall mean any natural person who, in the contracts covered by this Directive, is acting for purposes which are not related to his trade, business or profession". According to Article 1 (2)(b) "consumer goods" shall simply mean "any tangible movable item".

The Product Liability Directive only mentions the "injured person". The reference to the "consumer" is established under Article 9 by means of defining the private damage which is to be compensated. This disparity in terminology has historical reasons and is subject to constant semantic changes. Today's European legal concept of 'consumer' always includes individual consumers, too. The term used in European "consumer law" is no other than the one used in product liability law or product safety law because their protection objectives are identical.

2.4 What Are Consumer Goods?

The usual legal distinction to define consumer goods, i.e. whether natural persons acquire a consumer good for a purpose related to their business or profession, cannot be inferred from the Directive.

In addition, there is no clear-cut distinction between "private" actions and actions related to business or profession, either. Natural persons who, for instance, buy a car in their capacity as freelancer and use it for private and professional purposes, cannot be deprived of their rights set out in the Directive on grounds of distinguishing whether they mainly use the car for either of these purposes, or only occasionally. The Directive's objective is to ensure the highest possible level of consumer protection (Recital 23). Therefore, deciding that actions relate to business or profession has to be subject to strict legal interpretation. Only consumer goods which directly shape the profession or business of a natural person are not covered by the consumer goods purchase. The possibility of using such an item for other purposes, as well, is of no relevance. For a freelance taxi driver, a car is to be attributed to professional use. An architect who buys a car that s/he or a third person

uses in professional and non-professional contexts is a consumer because cars do not directly shape the architect's profession and because, vice versa, exercising this profession does not require a car.

This is also inferable from Directive 2001/95/EC. As laid down in Article 2 (a), "product" shall mean "any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned." The fact that a product is available on the market and used by a consumer makes it a consumer product due to its availability on the market for any other consumer and de facto use.³¹

Incidentally, the controversy surrounding these definitions will become obsolete. In the future, there will be no more distinction between consumer and non-consumer products or harmonized and non-harmonized products. In its report of 13 February 2013 on Regulation No 765/2008, the European Commission announced a new Regulation which will, inter alia, only mention "products" with the same safety level.³²

2.5 Whose Safety Expectations Are Essential?

The clarification of what constitutes a defect, which the ECJ is requested to provide, derives from the definition of a product's justifiably expected degree of safety provided for in Section 3 of the German Product Liability Act (ProdHaftG).

According to the BGH's interpretation in its orders for reference and according to the lower courts' interpretations, a product is defective as defined by Section 3 ProdHaftG if it does not provide the degree of safety which can be expected. This is inferred from the broad wording of the law when it states "can be expected" as well as from the Directive. According to prevailing opinion, safety expectations are contingent on what the general public and the manufacturer's target group, or whoever comes into contact with the products, expects.³³ Therefore, the BGH and

³¹ This, of course, poses severe risks to all product manufacturers who assume their products are only intended for use related to business or profession of experts, but their products can be purchased by any consumer via internet. A significant example is E-commerce with vehicle accessories and spare parts. Their use requires particular know-how in order to avoid safety risks that might arise, for instance, from using brake components or airbags, the latter's ignition units being subject to the German Explosives Act (SprengG).

³² http://ec.europa.eu/consumers/safety/psmsp/docs/psmsp-communication_en.pdf

³³ Palandt/Sprau BGB, 73rd ed. 2014, § 3 ProdHaftG, note 3. The Higher Regional Court Düsseldorf decided likewise in its judgment of 20 June 2012 (I-15 U 25/11, BeckRS 2013, 14716) preceding the order for reference VI ZR 327/12, but also points out that those expectations of patients concerned, who acquired ownership of the pacemaker, are essential.

the lower courts do not deem the degree of safety essential which an individual consumer of a cardiac pacemaker who is concerned by potential defects expects, but those safety expectations of patients in general who need and use such a medical device. This appears to be the dominant opinion.³⁴

This hardly exact interpretation is not binding. The wording of the law “can be expected” does not provide a basis for a view holding that the defectiveness of a product depends on the safety expectations of an anonymous general public that can neither be defined quantitatively nor qualitatively. This interpretation sticks to the wording and completely neglects the goal-oriented safety degrees and safety expectations under the Union legal system.

Incidentally, following this interpretative path would allocate the burden of proof for such safety expectations of the general public to the injured person. Yet, there is no identifiable general public or definable group with regard to a given product.³⁵ Generally, the courts hardly possess the expertise to define safety expectations of the general public as known to the courts, especially so with respect to products of a highly technical nature; not to mention the procedural issue of whether expert opinions by means of a consumer survey require appropriate submissions and expensive production of evidence on the part of the injured person.³⁶ Such an allocation of the burden of proof can neither be found in the pertinent domestic statute nor in the Directive. The de facto complications for liability claims proceedings which result from this allocation are unlawful under EU law as they wear out and undermine the Directive’s protective purpose.³⁷

Defective products invariably constitute a breach of contract, always injure individuals, and always infringe safety provisions at national public law level as well as

³⁴ Günes in PHi 2013, 229.

³⁵ C.f. Kullmann, *Produzentenhaftung* (manufacturer’s liability), 3604, 2, who, however, also refers to the concept of average users or consumers, which is just as ambiguous.

³⁶ Juretzek dissents in PHi 2011, 68; Graf von Westphalen also dissents, *Produkthaftungs-handbuch*, 3rd ed. 2012, § 48, note 19. According to his opinion, consulting expert opinions in order to establish objective facts should be required so as to provide a clearer notion of the individual – justified – safety expectations that the actually injured product user had (Section 286 of the German Civil Procedure Code, ZPO). Consumer surveys, however, are to be excluded right from the outset, because they cannot be reconciled with attributing ‘justified safety expectations’ to the category of an undefined legal term that has yet to be given a normative definition. His opinion hardly seems plausible insofar as neither context nor criteria for the safety expectations are mentioned. The question of what the expert opinion is to prove, which has to be specified by the injured person, would be a shot in the dark and would at best result in evidence that was gained by a discovery process, which is forbidden under German law.

³⁷ Accordingly, the Regional Court Stuttgart, has not simply linked product safety expectations to the average expectations of those consumers for whom the product is intended. In addition, the concept depends on the degree of safety which can be reasonably achieved according to the relevant state of knowledge of science and technology (decision of 10 April 2012, 26 O 466/10, NJW-RR 2012).

European level.³⁸ They contradict the industry's self-binding effects resulting from, for instance, established quality management systems which always require compliance with statutory provisions, as well. By way of establishing certified quality management systems, e.g. according to ISO 9001 for the industry in general, ISO 13485 for medical devices, or ISO/TS 16949 for the automotive industry, a company proves that, with its organizational structure, it is able to manufacture products which meet statutory provisions, i.e. first and foremost safety requirements. The manufacturing processes set out in these systems are part of the conformity assessment procedure and are documented by the manufacturer's declaration of conformity. It is the manufacturer's responsibility to ensure that these processes are interpreted and mastered in a way so as to manufacture no defective products.³⁹ The declaration of conformity invariably constitutes a part of the product and its quality (Section 434 (1) Sentence 3 BGB) which individual consumers purchase or use. Therefore, the declaration's defectiveness under German sales law which, at least in this context, equals defectiveness under product liability law, necessarily results in the product's defectiveness. Where it is certain that products of a given series are defective, the Union law presumption that the manufacturer's declaration of conformity regarding this series is true is refuted.

2.6 Relationship of Trust Inferred from Presumption of Conformity

The industry's standards for quality management systems and the verifying documents required therein are effective within the context of European conformity assessments as well as contractual provisions. The presumption of conformity creates confidence, on the part of the general public and of each individual person who purchases or uses the product, in the fact that the presumed safety expectations will be fulfilled. This is what constitutes the safety expectations according to Section 3 (1) ProdHaftG and Article 6 of Directive 85/374/EEC.

Therefore, the justified expectations of every individual consumer are essential. The Higher Regional Court Hamm decided accordingly that the attending doctor's interpretation is not essential, but the patients', since they are the ones who use the cardiac pacemaker and who are implanted the device.⁴⁰ Koyuncu/Müller⁴¹ point out that the patient's expectations are shaped significantly by the information and explanations provided by the attending doctor. However, this does not pose any changes whatsoever to the fact that the individual safety expectations of the pa-

³⁸ Directive 1999/44/EC of 25 May 1999 on the sale of consumer goods, Official Journal of the European Communities, L 171/12 of 7.7.1999.

³⁹ Regional Court Stuttgart, decision of 10 April 2012, 26 O 466/10, NJW-RR 2012, 1169.

⁴⁰ Higher Regional Court Hamm, decision of 26 October 2010, I-21 U 163/08, VersR 2001, 637, 639.

⁴¹ Koyuncu/Müller in PHi 2013, 108, 113.

tient, who has to live with the device physically and, above all, psychologically, remain essential.

2.7 Medical Devices and Traceability

Suffice it to say that the same requirements apply to medical products as to every other industrial product. Where sealing components were defective, as was the case in the BGH's orders for reference, the manufacturer's obligatory incoming goods inspection for purchased parts might have failed. According to DIN EN ISO 13485 – 7.4.3, purchased products have to be verified. The inspection has to be capable of "ensuring that purchased product meets specified purchase requirements". The standard puts particular emphasis on traceability: DIN EN ISO 13485 – 7.5.3.1 requires that every product be identifiable throughout the entire product realization process and that the organization establish documented procedures thereto. The latter's extent is set out in chapter 7.5.3.2.2: "In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements." Correspondingly, chapter 7.5.1.1 of the standard (Control of production and service provision) says: "The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent in 7.5.3. and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved."

At least under the conditions of these processes the potentially defective pacemakers could and should have been identified. The fact that throughout all procedures only rates of potentially defective pacemakers were determined but the devices themselves could not be identified shows that the manufacturer did neither ensure traceability according to DIN EN ISO 13485 nor Directive 93/42/EEC⁴² nor obligatory conformity assessment procedures.

2.8 The Burden of Proving Traceability

The burden of proving each product's freedom from defects or deficiencies is allocated to the manufacturer for systemic reasons: According to the binding rules and regulations, especially those applying to quality management systems, the manufacturer must maintain complete records of the products' freedom from defects. In order ensure this in a twofold way all quality management systems require records of congruent internal and external traceability processes.⁴³

⁴² Medical Devices Directive, Official Journal L 169 of 12.7.1993.

⁴³ Module D, point 5.2 of the conformity assessment procedure set out in Decision No 768/2008.

Documented controlled procedures must be in place, which at least prevent the delivery of still defective products if manufacturing defects are not entirely avoidable. Where defective products are placed on the market nevertheless, at least one of the manufacturer's processes – for the most part the usually insufficient process of internal traceability –⁴⁴ or one of the external traceability processes in the distribution chain has failed; i.e. processes which individually or put together ought to avoid safety risks in the first place. According to the European Commission, compliance with comprehensive traceability requirements will be one of the key subject matters for the planned revision of product liability law as of 2014.⁴⁵

2.9 Disappointed Safety Expectations

Under the regime of European Union safety law, based on Article 169 (1) and Article 114 (3) TFEU, and European conformity assessments, the issue examined by the BGH and lower courts, whose safety expectations are essential according to Section 3 ProdHaftG, depends on the degree of safety expected by the user concerned, which is where the safety risk might be realized. This safety expectation always remains unfulfilled where a defective product is placed on the market and cannot be identified as such in the course of traceability procedures. Defining safety expectations according to a significant risk rate is unlawful. The expected degree of safety required by the statute and the Directive aims at the freedom from defects of every product, not at risk assessments based on the significance of a certain defect rate⁴⁶; because therewith the unacceptable argument that defects cannot be avoided and are tolerable to a certain extent would be supported.⁴⁷ This does not impose an unreasonable burden on manufacturers since they, by way of their standardizing organizations, have themselves participated in drafting the statutory provisions which lay down safety expectations. This justifies the approach of the Higher Regional Court Hamm⁴⁸ which deems potential for defectiveness as sufficient to consider the conditions of Section 3 ProdHaftG fulfilled.

⁴⁴ Potinecke (interview) cit. op. footnote 29.

⁴⁵ http://ec.europa.eu/consumers/safety/psmsp/docs/psmsp-communication_en.pdf

⁴⁶ According to the Commission's guidelines (Annex II) "for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors, in accordance with Article 5 (3) of Directive 2001/95/EC", when it comes to potential defects in a series "the probability of the defect/hazard being present in the product should be considered" in order to decide which measures the market surveillance authorities have to take. The risk estimation table attached to the Decision is to be applied. Official Journal of the European Union, L 381/74 of 28.12.2004.

⁴⁷ This argument also contradicts the requirement of zero defect quality which is fundamental to quality management systems. In the automotive industry, so called ppm rates (parts per million) are specified as quality goals. Yet, they do not allow this rate of defects to actually occur, but merely determine the necessity to intervene in such processes which turned out to be uncontrolled or unstable when the ppm rate was realized.

⁴⁸ VersR 2011, 637, incl. concurring note by Schultze-Zeu.

The confirmation of the ECJ regarding the BGH's questions on the definition of 'defect' will probably draw on EU law rather than German legal doctrine. The fact that the cases referred to in the orders dealt with cardiac pacemakers doubtlessly makes the matter more sensitive, but in my opinion this is not of decisive importance to the underlying fundamental issue of the European definition of 'defect' applicable to all products.

3 The Concept of Damage

In order for the ECJ to answer the BGH's question it will be fundamental to clarify whether the costs claimed for the operation to remove the device and implant a different ICD constitute damage caused by personal injuries as defined by Sections 1 (1) and 8 ProdHaftG and Article 9 (1)(a) of Council Directive 85/374/EEC.

In both cases referred to the ECJ by the BGH, operation costs incurred which can be traced back to defective cardiac pacemakers. In both cases, the defects' causes were originated by the manufacturer. As regards case VI ZR 284/12, the pacemaker had to be replaced due to possible danger to the patient's life. The entitlement to claim damages for the operation costs derives from Section 1 ProdHaftG. There appear to be no serious contradicting problems under the Union legal order.

The BGH's completely plausible question concerning the damage needs to be examined more closely since the two cases before the Regional Higher Court (OLG) Düsseldorf and the Regional Court (LG) Stendal were not identical with respect to their legal approach in evaluating the causality behind the damage.

Subject matter of the action brought before the OLG Düsseldorf were the costs claimed by the social security institution for replacing the allegedly defective cardiac pacemaker. According to the OLG's opinion, the operation to replace the pacemaker, which was necessary due to a defect in the product, constitutes an adequate causal personal injury under German tort law.⁴⁹ The BGH consents⁵⁰ by raising the issue of whether the costs of the operation to remove the device and implant a different ICD constitute damage caused by personal injuries. The OLG Hamm decided likewise.⁵¹

The case before the LG Stendal did not deal with the costs incurred in replacement surgery but with the proportionate costs for the initial implantation while taking into account the usually expected 91 to 100 months period before the regular replacement of the pacemaker.⁵² The BGH ignores this distinction. In paragraph 16 of its

⁴⁹ BGH, VI ZR 327/12, para. 26

⁵⁰ Ibid., para. 23

⁵¹ VersR 2011, 637, incl. concurring note by Schultze-Zeu.

⁵² BGH VI ZR 284/12, para. 4

judgment, the court only raises concerns over the calculation of the damage by the LG Stendal because the replacement surgery was carried out due to the occurred risk of failure within the product series; this risk, however, did not cause the personal injury inflicted by the initial implantation surgery. The BGH accepts the contested calculation as it is neither proven nor apparent that the costs incurred in the replacement surgery could be lower than those for the initial surgery. Thus, the causality issue remains unresolved.

As the ECJ stated in its judgment of 10 May 2001 in Case C-203/99 (Veedefald), the term ‘damage’ is not defined in Directive 85/374/EEC.⁵³ According to this ECJ decision, ‘damage’ as laid down by Article 9 of the Directive must include damage caused by death or personal injuries as well as damage to or destruction of an item of property. In both cases of damage (by death or personal injuries), “full and proper compensation for persons injured by a defective product must be available [...]. Application of national rules may not impair the effectiveness of the Directive [...] and the national court must interpret its national law in the light of the wording and the purpose of the Directive [...]” (Para. 27). The ECJ further states (Para. 28): “A Member State cannot therefore restrict the types of material damage, resulting from death or personal injury, or from damage to or destruction of an item of property [...]”.

The BGH does not address the issue⁵⁴ of distinguishing whether the costs of the initial operation, during which a defective pacemaker was implanted and under the condition that the surgery is already considered a personal injury, constitute adequate causal damage or rather the costs incurred in replacement surgery if personal injury had not been considered before.

Whoever argues that, according to European safety and liability law, placing potentially defective products on the market disappoints safety expectations as defined by Section 3 ProdHaftG, has to conclude that only the initial implantation constitutes personal injury. The costs incurred in this surgery are adequate causal damage. The costs incurred in replacement surgery constitute adequate damage in individual cases if they exceed the initial costs due to the patient’s disposition or other complications or difficulties caused by the product.⁵⁵

3.1 Equivalent Interest and Integrity Interest

It remains to be seen whether, and to what extent, the ECJ will examine the BGH’s distinction between delictually protected integrity interest (*Integritätsinteresse*, sta-

⁵³ Case C-203/99, Henning Veedefald vs. Århus Amtskommune, para. 25.

⁵⁴ This is consistent with the BGH’s point of view since, as the BGH states, in this context only calculating the damage is of importance, and not the causality.

⁵⁵ The BGH leaves this issue unresolved in case VI ZR 284/12 (para. 16).

tus quo) and equivalent interest (*Äquivalenzinteresse*, status ad quem) which can only be claimed on grounds of a contract. The order for reference in case VI ZR 327/12 gives reason to consider this issue. In this case, too, the cardiac pacemaker was defective, but this only had therapeutic consequences. According to the BGH⁵⁶, the device's limited suitability for use does not constitute a health risk, but merely a decreased suitability for use of the device. The disadvantage resulting therefrom would not concern the integrity interest of insurance policyholder F. but rather his equivalent interest which is neither delictually protected nor protected under the German Product Liability Act (see Senate's judgment of 16 December 2008 – VI ZR 170/07, BGHZ 179, 157 note 24; this is the so called nursing bed decision [*Pflegebett-Entscheidung*], author's note).

Concerns over the BGH's distinction between equivalent interest and integrity interest already arise due to the assumption that only the patient's equivalent interest could be concerned because the patient purchased a pacemaker that had been defective from the beginning. This interpretation neglects that the ownership of the pacemaker is not at issue, but rather its therapeutic function which can only be achieved if the pacemaker is implanted by surgery, i.e. by an invasive procedure.

3.2 Orders for Reference Lack Question of Equivalent Damage

The BGH does not give any reason whatsoever for its interpretation that the German Product Liability Act does not protect a party's equivalent interest. Yet, this is a decisive question of European Union law, the answer of which is essential for the BGH-decision's conformity with European law, and on which there is apparently no ECJ case law. The logical consequence for the BGH would have been to include its apodictic statement, that the German Product Liability Act did not cover equivalent damage – or any damage the BGH subsumes under the Act –, into the order for reference to the ECJ; because patients who know that they were implanted a defective pacemaker are not inclined to struggle with their property of inferior quality. They cannot be calmed down by the trivialization that the defect was not life-threatening. They at least feel a psychological strain and insecurity imposed on them. They cannot be sure that failure of an electronic function will not affect the overall functioning of the pacemaker due to software reasons. This strain is permanently compromising the patient's physical integrity and therefore falls under German tort law. This results in the direct application of Section 823 (1) BGB and/or Section 1 ProdHaftG. There is no reason to consider contractual equivalent interests. To attribute this matter to equivalent interests would compromise the pertinent Directive's purpose, which the ECJ has rightly pointed out in its judgment in Case C-203/99 (Veedefald).

⁵⁶ BGH, VI ZR 327/12, para. 23.

In this context, and broaching the subject shall suffice, the reference question arises of whether the German concept of 'delictual acts', including the restrictions under Section 823 (1) BGB and the legal consequences thereof, can still be reconciled with Union law. The EU concept of liability for damage arising out of 'tort/delict' has, at the latest, been accorded increased importance by Articles 2 and 4 of the Rome II Regulation of 11 July 2007 (Official Journal of the European Union, L 199/40 of 31.7.2007).

It remains to be seen whether the ECJ will address this issue although the order for reference is not specifically asking for it, because there is much to suggest that the BGH's interpretation lacks conformity with the Directive.

As a consequence, it would not be surprising if the ECJ were to conclude that the damages claimed in both orders for reference are justified according to Directive 85/374/EEC and Directive 2001/95/EC and were not to address the distinction between equivalent interest and integrity interest.

4 Conclusion and Outlook

If European Union law were of decisive relevance in the application of the German Product Liability Act, any ensuing entitlement to claim damages for defective products would have to be judged according to European law. National law must not impair the effectiveness of claims deriving from the goals and purpose of Directive 85/374/EEC and Directive 2001/95/EC. The ECJ's preliminary ruling on the two orders for reference will therefore influence German product liability law and product safety law regarding all products.

Although it is not possible to define potential types of cases in the context of this article, the following shall serve as an example: Passenger vehicles are consumer products. The number of recalls increases on an almost daily basis.⁵⁷ Nowadays, there are more vehicles being recalled around the world than new vehicles sold. The year 2013 marked global records in recalls. In the first half of 2013, the global recall rate was at 142% with a German manufacturer reaching a maximum of 334%.⁵⁸

Usually, vehicles which are affected by safety recalls have been defective from the beginning. Thus, according to the majority's current opinion, "only" the buyer's

⁵⁷ To mention but one further example of 27 December 2013: The U.S. manufacturer General Motors and its Chinese partner have to recall approximately 1.5 million cars in China because defects in the fuel pumps may cause fuel leakages. <http://online.wsj.com/news/articles/SB1000142405270230448380457928373121483693>

⁵⁸ http://www.welt.de/print/welt_kompakt/print_wirtschaft/article118913801/Maengel-am-laufenden-Band.html

equivalent interests are concerned. After the warranty period or guarantee by the manufacturer has expired, the buyer is responsible for risks posed by defectiveness as well as the costs incurred in repairing defects. It is doubtful whether this jurisprudence can be maintained under European law. Vehicles which do not meet European safety requirements are “dangerous products”.⁵⁹ Placing them on the market invariably violates the manufacturer’s duty of care and is forbidden under the EU legal order.

Vehicles have to be manufactured in compliance with strict regulations and provisions anchored in EU law regarding type-approval as well as regarding the organization of the manufacturing process, including a declaration of conformity⁶⁰ by the manufacturer.⁶¹ Many vehicles are offered by praising their high level of technology by way of emphasizing the vehicle’s safety functions and quality and with a special guarantee⁶² by the manufacturer.⁶³ Both requirements form the justified expectations of all citizens of the European Union, including other traffic participants as “innocent bystanders”,⁶⁴ and not only of the consumers.⁶⁵ They can collectively expect economic actors to meet these requirements (Recital 18 of Decision No 768/2008/EC). The requirements exist outside of individual contracts and have to be fully taken as a given by the buyers; because it is only under these conditions that the buyers are themselves actually allowed to drive the vehicle on public streets.

The public-law approval of their vehicle causes the buyers to trust in its freedom from defects.⁶⁶ Any information on the use of products has to be correct and com-

⁵⁹ Article 2 (c) of Directive 2001/95/EC; Commission Decision of 14 December 2004 laying down guidelines relating to the General Product Safety Directive (GPSD), Official Journal of the European Union, L 381/63 of 28.12.2004.

⁶⁰ Placing products with safety defects on the market is at least negligent. The Regional Court Stuttgart decided accordingly in its judgment of 10 April 2012 (26 O 466/10, NJW-RR 2012, 1169). The court rightly assumes knowledge of all safety provisions under European Union law on grounds of the manufacturer’s declaration of conformity.

⁶¹ EC type-approval Directive 2007/46/EC, Official Journal of the European Union, L 263/1 of 9.10.2007; Regulation (EC) No 661/2009, Official Journal of the European Union, L 200/1 of 31.7.2009; ISO/TS 16949.

⁶² According to Article 6 (2) of Directive 1999/44/EC, the guarantee offered by the manufacturer must not prejudice the buyer’s legal rights under national legislation.

⁶³ According to Article 1 (2)(e) of Directive 1999/44/EC, the manufacturer’s guarantee does not only cover the specifications in the guarantee statement, but also those “in the relevant advertising”.

⁶⁴ Stöhr, “Innocent bystanders”, in: Festschrift für Gerda Müller, Cologne 2009.

⁶⁵ A product’s conformity is verified by the CE marking. The details are regulated by Regulation (EC) No 765/2008 of 9 July 2008, Official Journal of the European Union, L 218/30 of 13.8.2008.

⁶⁶ According to Decision (EC) No 768/2008, harmonized standards are to be legally binding. This is why they are also of binding probative value. Recital 12 of the Decision emphasizes the relationship of trust established therewith: “The successful accomplishment of the required conformity assessment procedure enables economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the requirements applicable.”

plete (c.f. for instance Sections 3 and 6 ProdHaftG)⁶⁷. Therefore, the buyers do not expect the vehicle's defectiveness. At any rate, these circumstances constitute an essential element of the definition of 'defect' under European law: The justified safety expectations of the buyers, deriving from the manufacturer's compliance with statutory provisions and adherence to safe development and production processes, are disappointed.⁶⁸ The question of whether there is an underlying deception⁶⁹ shall be left open at this point.⁷⁰

The delictual definition of 'damage' does not pose any insurmountable problems, either: Hardly any technical defect in a vehicle can be seen in isolation. The vehicle's technical complexity always results in components or parts being affected and – at the latest when the car breaks down or is in an accident – damaged by others. According to the dominant view, a vehicle which is damaged in an accident constitutes an 'item of property other than the defective product' as defined by Section 1 (1) ProdHaftG and Article 9 of the Directive.⁷¹ Whether this will be decisive in the end remains doubtful.

Where vehicle owners, who do not even have to have knowledge of the defect, are concerned by a safety defect, not only their confidence in the contract is shaken. In the event of a technical failure in the vehicle, they are exposed to the risks of being injured themselves, of injuring others, of being liable for others and for the violation of provisions under public law, civil law (e.g. according to Sections 7 and 17 of the German Road Traffic Act, StVG), and criminal law, as well as to the risk of possibly losing insurance coverage. They are therefore at least injured with respect to their right to dispose of their property and their personality rights, both of which are covered by Section 823 (1) BGB. In the context of European product safety and product liability law, the question thus arises whether the current domestic case law can be maintained which deems warnings sufficient in recall cases, but rules out that

⁶⁷ Article 1 (3) of Decision (EC) No 768/2008.

⁶⁸ In the automotive supplier industry, a product's conformity always has to be affirmed by a Part Submission Warrant. This is common knowledge and is part of the consumer's trust in the final product. It says: "I hereby affirm that the samples represented by this warrant are representative of our parts, which were made by a process that meets all Production Part Approval Process Manual 4th Edition Requirements. I further affirm these samples were produced at the production rate of ... hours. I also certify that documented evidence of such compliance is on file and available for review. I have noted any deviations from this declaration below."

⁶⁹ In a judgment handed down by the Regional Court Stuttgart, the court reproached the manufacturer with consciously pretending that a certain machine complied with the relevant safety provisions because the manufacturer had made a declaration of conformity (case 26 O 466/10, in: NJW-RR 2012, 1169; judgment of 10 April 2012).

⁷⁰ In any case, there is an open discussion on this issue with respect to the food industry in Germany: <http://www.welt.de/politik/deutschland/article118185317/Zwischen-legaler-und-illegaler-Verbrauchertauschung.html>; This also applies to other consumer goods: <http://www.handelsblatt.com/unternehmen/handel-dienstleister/geplanter-verschleiss-heute-gekauft-morgen-aussortiert/8220926.html>

⁷¹ Palandt/Sprau, § 1 ProdHaftG, note 6.

the costs incurred therein constitute delictual damage, as was the case in the nursing bed decision handed down by the BGH (VI ZR 170/07). And if one were to interpret false declarations of conformity as an element of deception then the application of Section 826 BGB would have to be considered.

Liability according to Section 823 (2) BGB in Conjunction with Protective Laws

Furthermore, the question arises to what extent European regulations and statutory provisions on the production of vehicles and on placing them on the market are protective laws as defined by Section 823 (2) BGB. The German Product Liability Act is such a protective law.⁷² At any rate, the protective purpose of more recent European legislation is more comprehensive and more general than the definition of 'consumer' according to Section 13 BGB or the definition of 'damage' in Directive 85/374/EEC.⁷³ The above mentioned Recital 8 of Decision No 786/2008 states: "This Decision builds on and complements the standardization system provided for by that Directive [Directive 98/34/EC, author's note]. However, where health and safety, the protection of consumers or of the environment, other aspects of public interest, or clarity and practicability so require, detailed technical specifications may be set out in the legislation concerned." Health and safety are mentioned separately alongside consumer protection – as in Recital 17 and the second subparagraph of Article 3 (1).⁷⁴ Health and safety do not form parts of consumer protection but are independent objects of legal protection under the European Union legal order.⁷⁵

The preliminary ruling of the ECJ on the BGH's orders for reference will not address every issue raised by this article. But the judgment is likely to spark a debate thereon. It cannot be ruled out that the Court will give new impetus to necessary revisions of German dogmatics on delictual law caused by the relevance of European Union law.

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The original was published in PHi 1/2014

⁷² Regional Court Stuttgart, decision of 10 April 2012, 26 O 466/10, NJW-RR 2012, 1169.

⁷³ In contrast to Directive 1999/44/EC, Section 13 BGB does not mention consumers, but 'buyers' and 'sellers'. These terms are not synonymous. The European definition of consumer goes beyond the contractually defined terms of 'buyer' and 'seller'. The ECJ correctly pointed this out in its judgment in the *Quelle*-case C-404/06 of 15 November 2007, para. 47.

⁷⁴ Likewise to be found in Recital 1 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, Official Journal of the European Union, L 218/30 of 13.8.2008.

⁷⁵ Interestingly enough, Recital 48 mentions "a risk to the health and safety of persons" in a general manner.