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Europe - Germany

The distributor's liability for defective medical devices – latest judgment of the Court of Appeals Düsseldorf

INTRODUCTION

Judgment of Court of Appeals Düsseldorf of 14 March 2012¹

A recent judgment of the Court of Appeals Düsseldorf gives reason to re-examine the liability of a distributor of defective medical devices.

The claimant, who had been implanted with a cardioverter defibrillator ("ICD") in order to treat his ventricular tachycardia, sought damages after he had allegedly suffered several electric impulses that, according to him, were not indicated. Claimants will often prefer to bring claims against a local entity before their own courts, and in this particular case the claimant brought his claim in Germany against the German distribution company, which is an affiliate of the American manufacturer. The ICDs had been imported into the European market by a Dutch company.

The case shows the practical significance of the distributor's liability, which takes on particular importance in cases where the producer or importer is insolvent.

LIABILITY UNDER GERMAN LAW

The concepts of "distribution company" or "distributor" are not defined in the German Civil Code (*Bürgerliches Gesetzbuch*, "BGB") or in the German Product Liability Act (*Produkthaftungsgesetz*, "ProdHaftG"), which implements the Product Liability Directive 85/374/EEC. However, the ProdHaftG uses the term "supplier" synonymously. The distributor/supplier do not themselves manufacture products, but offer them as a wholesaler or retailer. The concept covers all forms of product distribution carried out in the context of a professional activity or serving any other economic purpose, except for the direct distribution by the producer.²

The German Medical Devices Act (*Medizinproduktegesetz*, "MPG") does not contain provision for civil damage claims due to product defects. Civil damage claims will instead be based on the ProdHaftG and/or German tort law according to Sec. 823 et seq. BGB.

With regard to liability under the ProdHaftG, it is decisive whether the distributor is a "producer" or otherwise shall be treated as such - the so called "quasi-producer" according to Section 4 ProdHaftG. Only the producer and quasi-producer

are subject to the strict, no-fault liability according to Sec. 1 para. 1 ProdHaftG. In contrast, in the context of German tort law, pursuant to Sec. 823 et seq. BGB the focus lies on whether and to what extent the distributor is subject to safety obligations. In so far as medical devices are concerned, product monitoring obligations are specified by the Medical Devices Security Plan Regulation (*Medizinprodukte-Sicherheitsplanverordnung*, "MPSV").

THE DISTRIBUTOR AS A PRODUCER ACCORDING TO SECTION 4 PRODHAF TG

Product liability under the ProdHaftG refers to the no-fault liability of a producer for damages to body, life and/or property caused by defective products.³ A distributor is liable for damages under Sec. 1 para. 1 ProdHaftG only if he falls within the definition of "producer" according to Sec. 4 ProdHaftG. Besides the producer, Sec. 4 ProdHaftG includes the quasi-producer, the importer and, in more limited cases, the supplier. There are no specific regulations for the medical devices sector in this respect and, therefore, the ProdHaftG's liability provisions apply to damage caused by medical devices as they do to damage caused by other products.

The producer according to Sec. 4 para. 1 sentence 1 ProdHaftG

"Producer" within the meaning of the ProdHaftG is defined in the first sentence of Sec. 4 para. 1 ProdHaftG as a person who has produced a final product, a basic substance or a component part of the product. This legal definition contains three requirements deriving from the *ratio legis* and the statutory system of the ProdHaftG

- he must work on his own account and not only as an employee or as an officer of a company⁴
- his activity must concern the production of a new movable object⁵
- his activity must not be limited to the mere supply of a product.⁶ A distributor whose activity does not involve the production, but merely the sale, of goods is consequently not a producer within the meaning of Sec. 4 para. 1 ProdHaftG.

Particularly interesting in this context is a question that the Court of Appeals Düsseldorf had to deal with:⁷ can a distributor be treated as a producer for no reason other than

¹ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), available on http://www.justiz.nrw.de/nrwe/olgs/duesseldorf/j2012/I_15_U_122_10urteil20120314.html. A version of this article was published in the German-language journal on medical devices law, *Medizin Produkte Recht* (MPR), 3/2012.

² MüKo/Wagner, 5th edition 2009, Sec. 4 ProdHaftG recital 34; Staudinger/Oechsler, revised edition 2009, Sec. 4 ProdHaftG, recital 97 f.

³ Palandt/Sprau, 71st edition 2012, Intro. ProdHaftG recital 1.

⁴ Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 8, 9 ff.; Palandt/Sprau, Sec. 4 ProdHaftG, recital 2.

⁵ Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 8, 12 ff.

⁶ Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 8, 36 ff.

⁷ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 87 et seq.

the fact that he is an affiliate of the entity that did produce the product?

In the first place, there exists the formal argument that affiliate companies in the same corporate group are legally independent from each other. Independent legal persons have different rights and obligations. This separation therefore also has to be adhered to in respect of liability issues.

Further, the basis for liability under the ProdHaftG is clear: the production of a defective product. A close relationship between distributor and producer, implying that the distributor is involved in the production process, may lead one to reach an assessment that, besides the actual producer, the distributor is also a producer within the meaning of Sec. 4 para. 1 sentence 1 ProdHaftG. On the contrary, if the distributor is not involved in the production process he cannot be treated as a producer within the meaning of Sec. 4 para. 1 sentence 1 ProdHaftG.⁸ This is consistent with the legal definition of the concept of "producer": only persons or entities that actually participate in the production process are producers. As a consequence, except in cases where the legal fictions stipulated in Sec. 4 ProdHaftG are met, the assessment of whether or not a person or entity is to be treated as producer under the ProdHaftG has to focus on the factual circumstances of the production process. A mere legal link between producer and distributor is not itself sufficient.

The "quasi-producer" according to Sec. 4 para. 1 sentence 2 ProdHaftG

Whoever represents himself as a producer by attaching his name, trademark or other distinctive mark is regarded as a producer pursuant to Sec. 4 para. 1 sentence 2 ProdHaftG. This fiction leads to the liability of anyone representing himself as the producer, even if he is not actually so. By attaching this label, the quasi-producer not only directly associates himself with the product but he also gives the impression that he has an influence on its quality and safety. This is of particular significance in cases where the quasi-producer is more well-known than the actual producer and has a better reputation. If their product is defective and causes damage according to Sec. 1 para. 1 ProdHaftG, then not only the actual producer, but also the quasi-producer, is responsible for the damages, having created the impression of being responsible for the product.⁹ It is not required, however, that the injured party must have trusted in the

responsibility of the quasi-producer. Moreover, the fact that the actual producer would be liable does not exclude the quasi-producer's liability¹⁰ - whereas a supplier can exonerate himself by indicating the actual producer according to Sec. 4 para. 3 ProdHaftG, the quasi-producer does not have this possibility.

In order to prevent the false appearance of being the actual producer, a distributor should avoid attaching any label to the product that implicates his responsibility for it. However, if the label points out that the distributor is only the supplier of the product, he will not be treated as quasi-producer. Ideally, the product should also be equipped with a label stating who the producer is. At the least, the distributor's mere supply activity should be pointed out clearly. The mere indication that the product has been produced abroad will, however, be insufficient.¹¹

At the same time, the actual ownership of the label is irrelevant; what is decisive is the appearance the label creates among the public. If a domestic affiliate attaches a mark to a product, it is irrelevant that it is the foreign parent company that is registered for the mark. What is important is that the domestic affiliate, by putting the mark on the product, has created the impression that it is responsible for the product's safety.¹²

In this context, the Court of Appeals Düsseldorf pointed out that a mark/label must not be considered in isolation, but rather within the overall context, which consists of the label, the instruction manual and the packaging.¹³ In the case decided by the Court of Appeals Düsseldorf the producer was explicitly named as producer in the instruction manual, while the distributor was not mentioned at all. Under these circumstances, the use of the label of the producing parent company could not lead to the false impression that the distributing affiliate company has an actual influence on the quality and safety of the medical devices concerned. Also, the fact that, on the claimant's request, the distributor offers to provide further information about the product does not lead to the conclusion that he is a quasi-producer.¹⁴

Finally, the time when the product was acquired by the party who suffered damage shall be considered when assessing the liability of a quasi-producer. If the product defect is as a result of any circumstance occurring after this point in time,

⁸ ECJ, judgment of 9 February 2006 (case reference C-127/04), recital 29 et seq.

⁹ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 93; Palandt/Sprau, Sec. 4 ProdHaftG, recital 6; MüKo/Wagner, Sec. 4 ProdHaftG, recital 21; Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 53 et seq.; BGH, NJW 2005, 2695, 2696.

¹⁰ MüKo/Wagner, Sec. 4 ProdHaftG, recital 22.

¹¹ MüKo/Wagner, Sec. 4 ProdHaftG, recital 26; Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 64.

¹² Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 65; Judgment of Court of Appeals Düsseldorf (case reference I-15 U 122/10), recital 97.

¹³ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 98.

¹⁴ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 99.

eg a subsequent reference to the product made by the distributor, does not have retroactive effect.¹⁵

The importer, Sec. 4 para. 2 ProdHaftG

The legal fiction created by Sec. 4 para. 2 ProdHaftG also extends the concept of "producer" to include the importer. According to Sec. 4 para. 2 ProdHaftG a person is treated as a producer if, within the range of his commercial activity, he imports into the European Economic Community a product for the purpose of sale, hire, hire-purchase or any other form of distribution. As a result of the jurisdictional rules contained in Council Regulation (EC) No 44/2001,¹⁶ this prescription enables the consumer to initiate legal proceedings in his home country.¹⁷

The burden of proving that the distributor is an importer within the meaning of Sec. 4 para. 2 ProdHaftG lies with the injured party.¹⁸ As the latter usually does not have sufficient insight into the distributor's business procedures, the distributor may have a secondary burden of proving that he is in fact not the importer. This will require the distributor to demonstrate who imported the respective products into the European Economic Area, and that the distributor has bought the products from that importing person and then distributed them.¹⁹

The supplier, Sec. 4 para. 3 ProdHaftG

Sec. 4 para. 3 ProdHaftG specifically deals with the liability of the distributor. In cases where the producer of the product cannot be ascertained by the injured party, then according to Sec. 4 para. 3 sentence 1 ProdHaftG every distributor is treated as its producer unless he indicates to the injured party, within one month of receiving the latter's request, who is the producer or the person who supplied him with the product.²⁰ The same applies, according to Sec. 4 para. 3 sentence 2 ProdHaftG, to an imported product where the importer cannot be ascertained by the injured party (even if the name of the producer is known). This provision is

intended to prevent situations in which the injured party, due to the anonymity of the product, lacks an opponent or has to sue a producer in a third country.

If the supplier indicates the producer, importer or the person who supplied him with the product, his indication is sufficient to absolve him from liability. Also, he does not have to prove the fact that the indicated person is actually the producer or importer. Consequently, the injured party is able to claim against the person indicated by the supplier. The supplier's liability will revive²¹ only if, during legal proceedings, it cannot be proven that the appointed person has produced or imported the product in question.

THE DISTRIBUTOR'S DUTIES TO MAINTAIN SAFETY... ...UNDER GERMAN TORT LAW

Alongside the no fault liability deriving from the ProdHaftG, the distributor of medical devices may be liable under German tort law in the event that the device causes injury. Sec. 823 para. 1 BGB requires that the distributor must have violated his legal duty to maintain safety.

Defects in construction and manufacture

As a basic principle, the distributor is not liable for defects in construction and manufacture,²² even if there is a corporate link between the distributor and the producer.²³ For example, when the distributor is an affiliate of the producing parental company, as in the case decided by the Court of Appeals Düsseldorf, this does not mean that the distributor is bound by tort law to duties imposed on the producer. Therefore, the distributor usually has no reason to ensure a product's safety by implementing separate procedures independently from the producer. It will usually be sufficient for the distributor to fulfill his obligation to maintain safety if he examines the products for obvious defects.²⁴

In each individual case it is therefore decisive whether the distributor had knowledge of the defect or if he should have recognized it. However, an assumption that the defect could have been detected by the distributor based on concrete evidence will not be made too easily, particularly in the case of highly technological and complex medical devices. Rather, the defect must be one that would immediately catch the distributor's eye.

¹⁵ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 100.

¹⁶ Article 5.3 of Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters stipulates that a person domiciled in a member state may, in another member state, be sued in matters relating to tort, delict or quasi-delict, in the courts of the place where the harmful event occurred or may occur. The same Regulation ensures that the respective judgment is recognized and enforced in the member state where the importer is domiciled.

¹⁷ Palandt/Sprau, Sec. 4 ProdHaftG, recital 7.

¹⁸ MüKo/Wagner, Sec. 1 ProdHaftG, recital 69; Staudinger/Oechsler, Sec. 1 ProdHaftG, recital 156.

¹⁹ Court of Appeals Düsseldorf, MPR (3/2012), S. 50, 56.

²⁰ MüKo/Wagner, Sec. 4 ProdHaftG, recital 36; Staudinger/Oechsler, Sec. 4 ProdHaftG, recital 93 et seq., 99.

²¹ Palandt/Sprau, Sec. 4 ProdHaftG, recital 9; Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 119.

²² Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 129; BGH, NJW 1987, 1009, 1010.

²³ Staudinger/Hager, Sec. 823 recital F 30; MüKo/Wagner, Sec. 823 recital 606, 615.

²⁴ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 129; Staudinger/Hager, Sec. 823 recital F 30.

As regards medical devices it has to be noted that a defect may often develop gradually as a result of external influences. In the case decided by the Court of Appeals Düsseldorf it was taken into account that, according to the state of the art of science and technology, it was not possible to exclude the risk of a breakage of the electrodes of ICDs. For this reason, the Court decided that the distributor did not have to assume that the particular ICD was defective even though he knew that there was a certain probability of breakage of the electrodes in ICDs. As long as a certain defect occurs only with a reasonable frequency, which is comparable with similar models of the same or a different producer, the distributor has no reason to take stricter measures.²⁵

Duty to instruct

As a general principle, the distributor is not bound to a duty to instruct. The distributor may have a duty to instruct only when he takes over such a duty from the producer.

Product monitoring duty and duty to react

From the general duty to maintain safety stems the resulting obligation to monitor the product once it is placed on the market. This duty is not derived from the ProdHaftG but from German tort law. It extends the producer's responsibility for the product to the time after it has been placed on the market. As a result, the producer has to take into account technical or scientific developments.²⁶ In order to meet his monitoring duty, the producer must accept and systematically analyze customer complaints regarding damage caused by the product or safety deficiencies.²⁷ This monitoring duty results in the producer's duty to react. If unknown defects, dangers or risks occur, it can be necessary to issue a warning or even to recall the concerned products.

A distributor generally does not have to take such measures actively,²⁸ except for special cases, for instance when the distributor is the sole importer of the concerned products. Even the passive product monitoring duty can be applied to the distributor only within narrow limits.²⁹

...ACCORDING TO THE MPSV

As far as medical devices are concerned, certain particularities have to be taken into account when it comes to the product monitoring duty and the corresponding duty to react. According to the judgment of the Court of Appeals

Düsseldorf, the German MPSV exhaustively defines these duties. Thus, as regards medical devices, the duty to monitor the product and to react will be infringed only in case of a violation of the prescriptions of the MPSV.³⁰

(i) Duty to report

According to Sec. 3 para. 1 MPSV the responsible person within the meaning of Sec. 5 MPG, which is either the producer or the importer, has to report incidents or recalls to the competent authorities. In Sec. 2 no. 1 MPSV an incident is defined as any malfunction, deficit, change of the characteristics or of the performance of a device, or any inadequacy in the labeling or the instructions for use, which have led, may have led or will lead directly or indirectly to death of the patient, user or any other person, or a serious deterioration in his/her state of health. The notion of recall within the meaning of Sec. 2 no. 3 MPSV refers to a corrective measure initiating the return, replacement, backfitting, segregation or elimination of the medical device, or instructing the users, operators or patients on how to ensure a safe use or installation of a medical device.

According to Sec. 3 para. 1 MPSV, the duty to report does not concern the domestic distributor, because he is neither the producer nor the importer, and consequently not a responsible person within the meaning of Sec. 5 MPG. However, according to Sec. 3 para. 3 sentence 1 MPSV he is bound by a duty to report if he distributes medical devices directly to lay persons. In any other cases the distributor is generally not obliged to report to the competent authorities. He has only to inform the responsible person within the meaning of Sec. 5 MPG about any incidents that have come to his knowledge as provided for in Sec. 3 para. 3 sentence 2 MPSV.

(ii) Duty to react

The duty to react is set down in Sec. 14 MPSV. From this provision stems the resulting obligation of the responsible person within the meaning of Sec. 5 MPG to effect the appropriate corrective measures and to inform all concerned persons. The MPSV, however, does not provide for the responsibility of the domestic distributor as a substitute. If the producer and/or importer have not taken measures according to Sec. 14 MPSV, the competent authorities will take measures according to Sec. 15 MPSV. The distributor is affected only by an obligation to co-operate with regard to the corrective measures. Only once the producer or importer has charged a distributor located in Germany with the task of bringing the correcting measures into effect would Sec. 14 para. 2-4 MPSV apply (see Sec. 14 para. 5 MPSV).

²⁵ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 131 et seq.

²⁶ MüKo/Wagner, Sec. 823 recital 646.

²⁷ MüKo/Wagner, Sec. 823 recital 645.

²⁸ MüKo/Wagner, S. 823 recital 646; Staudinger/Hager, Sec. 823 recital F 31.

²⁹ BGH, NJW 1994, 517, 519; BGH NJW-RR 1995, 342, 343.

³⁰ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 146.

Duties of a medical device distributor beyond those stipulated in the MPSV?

The jurisprudence imposes an independent obligation on the distributor to observe the product and to react only in restricted and exceptional cases, because generally the distributor does not share the same responsibilities as the producer. A distributor is imposed with a duty to observe the product in a passive way, so far as he detects defects on his own or is made aware of a defect by customers, in which case he has to report such observations to the producer.³¹ In addition, the German Bundesgerichtshof (Federal Court of Justice, "BGH") has assumed an independent duty to avert danger in particular cases if the distributor is aware of "so far unknown" dangers and risks.³²

In the case at hand, the Court of Appeals Düsseldorf denied observation and reaction duties going further than those provided by the MPSV.³³ On the one hand, it has to be considered that according to the state of science and technology it is not possible to exclude the risk of breakage of electrodes in ICDs. If such breakages occur, it is consequently not at all "so far unknown", but a well-known risk which could not have been avoided.³⁴ On the other hand, the ability of the distributor to take notice of defects has to be considered. As far as high-tech and complex medical devices, such as an ICD, are concerned, the ability of the distributor to become aware of new risks, and to examine them in an accurate way will be quite limited.³⁵

It also has to be borne in mind that if the distributor were expected to take its own measures, this could have serious consequences. For example, a warning, even if it were restricted to a specific customer circle or a specific market, or a recall initiated by the distributor, would have serious consequences for products that are distributed worldwide. As regards high-tech and complex medical devices the distributor is usually not able to conduct the necessary analysis and therefore he has to rely on the information and instructions of the producer.³⁶

The judgment of the Court of Appeals shows that it cannot be determined in an abstract way whether and how far a distributor is concerned by independent duties to observe the product and to react which go beyond those provided by the MPSV. First, it is of great importance which medical device is in question. The more complex the product in terms of its construction and functioning, the more difficult it usually is to detect dangers and risks. As a consequence, the distributor's duty should be to observe the product only in so far as he is actually able to detect product defects. The role he has during the marketing process shall be considered here as well: has he been charged by the producer to fulfill the latter's obligations, does he have a particular position being the only importer, or is it only the producer being responsible for the observation of the product? Finally, the definition of product defects and risks that could actually be detected by the distributor represents quite a difficult task. The options for reacting range from reporting to the producer and issuing a warning to the customers to the independent recall of the product in question.

COMMENT

The Court of Appeal Düsseldorf's conclusion that the MPSV exclusively concretises the distributor's product observation duty in so far as medical devices are concerned and, therefore, rejecting an obligation of the distributor to observe products beyond the stipulations of the MPSV, is to be welcomed.³⁷ The MPSV already contains a well-considered concept for the recognition and assessment of risks and counteractive measures related to medical devices.³⁸ The legal certainty regarding product observation duties will be remarkably improved by this decision. Considering the

³¹ Staudinger/Hager, Sec. 823 recital F 31; MüKo/Wagner, Sec. 823 recital 646.

³² BGH NJW 1994, 517, 519; BGH NJW-RR 1995, 342, 343.

³³ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 170.

³⁴ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 174.

³⁵ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 175 et seq.

³⁶ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 177 et seq.

³⁷ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 146, 147, 168.

³⁸ Judgment of Court of Appeals Düsseldorf of 14 March 2012 (case reference I-15 U 122/10), recital 168.

complexity of medical devices, the distributor's liability must not be widened by extending his duties to maintain safety. An independent duty for distributors to warn and recall based on the law of tort shall be assumed only in exceptional cases.

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