CJEU: 'potentially defective' medical device can be held 'defective' in terms of product liability directive

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Joined cases C-503/13 and C-504/13 Boston Scientific Medizintechnik v. AOK Sachsen-Anhalt — Die Gesundheitskasse and Betriebskrankenkasse RWE

Introduction

On 5 March 2015 the Court of Justice of the EU (CJEU) ruled that a product can be found to be 'defective' within the meaning of article 6(1) of the Product Liability Directive[1] when the product belongs the same group or forms part of the same production series that have a *potential* defect. Under such circumstances, it is not required for the claimant to prove that the actually used product is itself defective. This may have a significant impact on the position of manufacturers in product liability cases throughout the EU.

Additionally, the CJEU ruled with regard to medical devices which need to be replaced by means of an surgical operation that the producer is liable for the costs incurred with such a surgical operation as such costs fall within the scope of the definition of "*damage cause by death or personal injuries*" as used in article 9 of the Product Liability Directive.

Background

The relevant facts of the proceedings which ultimately lead to this CJEU ruling can be summarized as follows.

Guidant Corporation, now Boston Scientific Medizintechnik Gmbh ("***Boston Scientific***") manufactures and sells pacemakers and implantable cardioverter defibrillators ("***ICDs***"). The pacemakers were imported and marketed in Germany by Guidant and the ICDs were manufactured by Guidant in Europe.

Pacemakers

In July 2005, Guidant sent a letter to treating physicians regarding the pacemakers which it marketed. The letter indicated that a component used to hermetically seal may experience a gradual degradation. That defect could lead to the battery depleting prematurely, resulting in loss of telemetry and/or loss of pacing output without warning.

Therefore, Guidant recommended the treating physicians to consider replacing the pacemakers and it also provided free replacement pacemakers. As a result, two patients, both having medical insurance cover with OAK, had their pacemakers replaced. However, the pacemakers had not been examined by an expert on their functioning.

AOK Sachsen-Anhalt-Die Gesundheitskasse ("***AOK***"), a compulsory health insurance organisation, claimed compensation from Boston Scientific for the costs relating to the implantation of the original pacemakers with these two patients: EUR 2,655.38 and EUR 5,914.07. The Amtsgericht in Stendal granted the claim, which decision was confirmed by the Landsgericht in Stendal. Subsequently, Boston Scientific lodged an appeal on the grounds of an erroneous interpretation of the law before the German Bundesgerichtshof.

ICDs

With regard to the ICDs, Guidant communicated with treating physicians that the functioning of the ICDs might be affected by a defect in one of its components which could limit the device's therapeutic efficacy. It appeared from the scientific analysis carried out that a magnetic switch in those defibrillators might remain stuck in the closed position, resulting in the inhibition of the treatment of ventricular or atrial arrhythmias. As a consequence, any cardiac dysrhythmia that could be fatal would not be recognized by the defibrillators and no life-saving shock would be given to the patient. Therefore, Guidant advised physicians to deactivate the magnetic switch.

Due to this recommendation, the ICD implanted in a patient who was covered for health insurance at the employer (RWE), was replaced prematurely.

Betriebskrankenkasse RWE, a compulsory health insurance company, requested Boston Scientific to reimburse the costs for that replacement surgery amounting to EUR 20,315.01 and EUR 122.50. The

[1] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

Landsgericht in Düsseldorf allowed the claim in full, which decision was partly adjusted in appeal by the Oberlandesgericht in Düsseldorf which ordered Boston Scientific to pay EUR 5,952.80 with interest. Boston Scientific lodged an appeal to that decision at the Bundesgerichtshof contending that the claim should have been rejected in full.

By means of an interim judgment in both proceedings, the Bundesgerichtshof requested the CJEU to determine whether devices which form part of a *group of products* that pose a risk of failure, these devices are themselves defective. The Bundesgerichtshof considered in that regard that it is of little consequence that it is accepted in specialist medical circles that it is not possible for an implanted pacemaker or ICD to be 100% safe. The CJEU considered that in view of the life-threatening risk presented by a defective device, the patient may in principle, reasonably expect the implanted device to have a failure rate of close to zero. With regard to the ICDs, the problem concerned does not constitute a danger to the patients' life or well-being; the patient monitor feature would remain unaffected and the problem would simply restrict the functions which such defibrillators can perform.

Hence, the Bundesgerichtshof referred the following questions to the CJEU for a preliminary ruling:

(1) Is Article 6(1) of Directive 85/374 to be interpreted as meaning that a product in the form if a medical device implanted in the human body is already defective if devices in the same product group have a significantly increased risk of failure but a defect has not been detected in the device which has been implanted in the specific case in point?

If the answer to the first question would be in the affirmative:

(2) Do the costs of the operation to remove the product and to implant another pacemaker constitute damage caused by personal injury for the purposes of article 1 and section (a) of the first paragraph of article 9 of Directive 85/374?

The ruling of the CJEU

Question 1

In answering question 1, the court decided that in accordance with article 6(1) Directive 85/374 and the sixth recital of the preamble of Directive 85/374, the safety which the public at large is entitled to expect, must be assessed taking into account:

a. the intended purpose of the product in question;

b. the objective characteristics and properties of the product in question and;

c. the specific requirements of the group of users for whom the product is intended.

Regarding medical devices, such as pacemakers and ICDs, the CJEU concluded that the safety requirements are particularly high due to their function and the particularly vulnerable situations of the patients using the devices. The concept of safety must be understood *"to refer to a product that poses risks jeopardizing the safety of its user and having an abnormal, unreasonable character exceeding the normal risks inherent in its use."*[2] The CJEU decided[3] that the potential lack of safety that can give rise to liability for pacemakers and ICDs stems "*from the abnormal potential for damage which those products might cause to the person concerned."*

Therefore, the CJEU concluded that a product may be found defective when the product is part of a product group of production series that consists of potentially defective products, without the need to establish the actual defect in that specific product.

Question 2

In regard to the second question, whether the producer is also liable for damage caused by a surgical operation for the replacement of a defective product, A-G Bot stated that it would be entirely contrary to the general objective of Directive 85/374 to protect consumer health and safety by excluding the loss or injury caused by a surgical operation to remove a defective medical device.[4] The Court did not go as far as A-G Bot, but did agree that the *"damage caused by death or by personal injuries"* as used in Article 9 (a)(1st

[2] A-G Bot, para. 30.

[3] Para 40, as also observed by the A-G, para 30.

[4] A-G Bot, para. 63.

paragraph) Directive 85/374 must be interpreted broadly.

Also, in order for the damages to be compensated, the causal relationship between the defect and damage must be proven by the injured person.[5] The Court found that compensation for damage must cover *"all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect."* As a consequence, in the case of medical devices, such as pacemakers and ICDs, which are defective in the meaning of the Product Liability Directive, compensation for damage must also cover the costs relating to the replacement of the defective product.

In the present case, the manufacturer recommended surgeons to consider replacing the pacemakers concerned. In that case, the Court finds that the costs relating to the replacement of such pacemakers, including the costs of the surgical operation, constitute damage within the meaning of the Product Liability Directive for which the manufacturer is liable.

With respect to the ICDs, the CJEU left it up to the national (referring) court to decide whether or not the deactivation of the magnetic switch was sufficient for overcoming the defect in the ICDs or whether a replacement was indicated.

In conclusion, the Court's answer to Question 2 is that the damage caused by a surgical operation for the replacement of a defective medical device, such as a pacemaker or ICD, constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question. It is for the national court to verify whether that condition is satisfied in the main proceedings.

Discussion

In conclusion, where it is found that products with an abnormal potential for damage to the patient concerned for which the manufacturer is liable under Directive 85/374, belong to the same product group or form part of the same production series, have a potential defect, it is possible (for a national court) to classify all products in that group or series as defective. The essential element of this decision is that the plaintiff will be helped as he will not have to prove the individual defectiveness of the product *in question*. This ruling cannot be applied to any allegedly defective product: the Court underscored that under the circumstances at hand, *i.e.* products for which the safety requirements are particularly high due to their function and the particularly vulnerable situations of the patients, this is justified. Nevertheless, it should be stressed that the scope of this ruling is not limited to such medical devices, but also pertains to medicinal products or other products qualifying as such.

The Court concludes that such interpretation is consistent with the objectives pursued by the EU legislation which seeks to ensure a fair apportionment of the risks inherent to modern technological production between the injured person and the manufacturer.

In addition, this judgment entails that in the case of medical devices which are defective, compensation for damage must cover, inter alia, the costs relating to the replacement of the defective product. The Court states that as in the present case the manufacturer recommended to surgeons to consider replacing the pacemakers in question, the replacement costs constitute damages within the meaning of article 9 of Directive 85/374 for which the manufacturer is liable. Thus, the information provided by the manufacturer as to the way forward with respect to the prevention of health risks due to the defect is deemed relevant.

Nevertheless, the Court built in a safety switch by stressing that the assessment of whether the recommendation by the manufacturer (in this case a surgical operation with the goal of replacing the pacemaker) was appropriate in the specific circumstances, is being performed by the national courts.

For manufacturers of high-risk products, such as medical devices, it is relevant to underline that product liability concerns strict liability; liability cannot be restricted or excluded in relation to the patient or consumer involved.

Furthermore, it should be remarked that it has not been established yet whether the manufacturer is liable for the damage caused by a defect in the medical device. With the exception of the issue of proof of defectiveness of the product used, the normal range of potential defenses in any product liability case still applies.

The manufacturer may therefore still put forward that it is plausible that the defect causing the damage did not exist at the time the product was put into circulation. In the case of the pacemakers, a component utilized to hermetically seal the pacemakers has experienced a gradual degradation. That defect could lead to premature battery depletion,

[5] Article 4 Directive 85/374

resulting in loss of telemetry and/or loss of pacing output without warning.

The manufacturer may also put forward the so-called 'development risk defense'. This entails that in view of the state of scientific and technical knowledge at the time of putting the product onto the market, it was impossible to discover the defect.

Please note that this judgment may (indirectly) also be relevant to health care institutions and hospitals. The concept of (potentially) defective products as laid down in this ruling, may be used by the Dutch courts as guiding principle in cases where such parties are being held liable for using unsuitable medical devices based on liability for auxiliary materials (article 6:77 Dutch Civil Code). It should be noted as well that the Den Bosch Court of Appeal[6] decided in a provisional judgment that the implanting hospital was liable as the manufacturer of the (series of fraudulent PIP) breast implants had gone bankrupt. Therefore, it may be advisable for health care institutions and hospitals to select the manufacturers from which they purchase the medical devices they use, with extra care.

In conclusion, it is anticipated that this decision on the issue of potential defects as to high-risk medical devices, which shall - in the light of the multiple incidents with medical devices lately - be adopted broadly and be welcomed from the part of the patient or consumer.

However, the question is justified whether the Court's apparent wish to help the patients to alleviate their burden of proof will lead to balanced and fair results. Manufacturers of medical devices and their insurance companies will potentially face massive claims and the mere anticipation of that substantial risk may lead to not only a higher level of prior warnings, but may also lead to price increases which are not in the best interest of patients and the medical sector as a whole.

[6] Court of Appeal Den Bosch 25 November 2014, ECLI:NL:GHSE:2014:4936, para. 3.6.3.5.