Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

5 March 2015 *

(Reference for a preliminary ruling — Consumer protection — Liability for damage caused by defective products — Directive 85/374/EEC — Articles 1, 6(1) and section (a) of the first paragraph of Article 9 — Pacemakers and implantable cardioverter defibrillators — Risk of product failure — Personal injury — Removal of the allegedly defective product and replacement with another product — Reimbursement of the costs of the operation)

In Joined Cases C-503/13 and C-504/13,

REQUESTS for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Germany), made by decisions of 30 July 2013, received at the Court on 19 September 2013, in the proceedings

**Boston Scientific Medizintechnik GmbH**

v

**AOK Sachsen-Anhalt — Die Gesundheitskasse** (C-503/13),

**Betriebskrankenkasse RWE** (C-504/13),

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, K. Jürimäe, J. Malenovský, M. Safjan (Rapporteur) and A. Prechal, Judges,

Advocate General: Y. Bot,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 3 September 2014,

after considering the observations submitted on behalf of:

— Boston Scientific Medizintechnik GmbH, by C. Wagner, Rechtsanwalt,

— AOK Sachsen-Anhalt — Die Gesundheitskasse, by R. Schultze-Zeu and H. Rien, Rechtsanwälte,

— the Czech Government, by M. Smolek and J. Vláčil, acting as Agents,

— the French Government, by D. Colas and S. Menez, acting as Agents,

— the Austrian Government, by C. Pesendorfer, acting as Agent,

* Language of the case: German.

— the European Commission, by P. Mihaylova and G. Wilms, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 21 October 2014,

gives the following

## Judgment

1 These requests for a preliminary ruling concern the interpretation of Articles 1, 6(1) and section (a) of the first paragraph of Article 9 of 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 (OJ 1985 L 210, p. 29).

2 The requests have been made in an appeal on a point of law between Boston Scientific Medizintechnik GmbH ('Boston Scientific Medizintechnik'), the defendant in the main proceedings, and AOK Sachsen-Anhalt — Die Gesundheitskasse (C-503/13) ('AOK') and Betriebskrankenkasse RWE (C-504/13), compulsory health insurance organisations, concerning requests for reimbursement of the costs relating to the implantation of pacemakers and an implantable cardioverter defibrillator imported and marketed in the European Union by G. GmbH ('G.'), a company which subsequently merged with Boston Scientific Medizintechnik.

### Legal framework

*EU law*

3 The first, second, sixth, seventh and ninth recitals in the preamble to Directive 85/374 are worded as follows:

'Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may … entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;

Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;

...

Whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances;

Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances;

...

Whereas the protection of the consumer requires compensation for death and personal injury as well as compensation for damage to property …'

4 Article 1 of Directive 85/374 provides as follows:

‘The producer shall be liable for damage caused by a defect in his product.’

5 Article 3(1) and (2) of Directive 85/374 is worded as follows:

‘1. “Producer” means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

2. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.’

6 Article 4 of Directive 85/374 states as follows:

‘The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.’

7 Article 6(1) of Directive 85/374 provides as follows:

‘A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

(a) the presentation of the product;

(b) the use to which it could reasonably be expected that the product would be put;

(c) the time when the product was put into circulation.’

8 The first paragraph of Article 9 of Directive 85/374 is worded as follows:

‘For the purpose of Article 1, “damage” means:

(a) damage caused by death or by personal injuries;

(b) damage to, or destruction of, any item of property other than the defective product itself …

…’

*German law*

9 Paragraph 1(1) and (4) of the Gesetz über die Haftung für fehlerhafte Produkte (Law on liability for defective products) of 15 December 1989 (BGBl. 1989 I, p. 2198) provides as follows:

‘1. If, due to a defect in a product, a person dies, is injured or his health is impaired or there is damage to an item of property, the producer of the product shall compensate the injured person for the damage which arises as a result thereof. In the case of damage to an item of property, this shall apply only if an item of property other than the defective product is damaged and this other item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for private use or consumption.

…

4. The burden of proving the defect, the damage and the causal relationship between defect and damage shall lie with the injured person. …'

10 Paragraph 3(1) of that law is worded as follows:

'A product has a defect when it does not provide the safety which may reasonably be expected, taking all circumstances into account, including:

(a) its presentation,

(b) the use to which it could reasonably be expected to be put,

(c) the time when it was put into circulation.'

11 Paragraph 8 of that law provides as follows:

'Where a person has been injured or his health impaired, compensation shall be made in respect of the costs incurred in restoring the injured person's health and also the pecuniary loss which the injured person suffers because, as a result of the injury, his earning capacity is permanently or temporarily brought to an end or reduced or his needs are increased on a temporary or permanent basis.'

## The dispute in the main proceedings and the questions referred for a preliminary ruling

12 G. Corporation, now B. S. Corporation, a company established in Saint Paul (United States), manufactures and sells pacemakers and implantable cardioverter defibrillators.

13 G. imported and marketed in Germany 'Guidant Pulsar 470' and 'Guidant Meridian 976' pacemakers, which are manufactured in the United States by G. Corporation, and 'G. Contak Renewal 4 AVT 6' implantable cardioverter defibrillators, manufactured by the latter in Europe.

### *G.'s recommendations of 22 July 2005 concerning pacemakers and the subsequent events in Case C-503/13*

14 In a letter of 22 July 2005 sent, inter alia, to treating physicians, G. indicated that its quality control system had established that a component utilised to hermetically seal the pacemakers which it marketed may experience a gradual degradation. That defect could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning.

15 As a consequence, G. recommended physicians to consider, inter alia, replacing such pacemakers for the patients affected. Notwithstanding the fact that the warranty for the pacemakers may have expired, G. undertook to make replacement devices available free of charge for pacemaker-dependent patients and those deemed by their physicians to be best served by replacement.

16 Following that recommendation, the pacemakers previously implanted in B and W, who both had medical insurance cover with AOK, were replaced in September and November 2005, respectively, by other pacemakers provided free of charge by the manufacturer. The pacemakers that had been removed were destroyed without any expert opinion being obtained on their functioning.

17 AOK, on the basis of the devolved rights of B and W, brought proceedings before the Amstgericht Stendal (Local Court, Stendal) seeking an order that Boston Scientific Medizintechnik pay compensation in respect of the costs relating to the implantation of the original pacemakers, updated to the dates on which those pacemakers were replaced. Those costs were EUR 2 655.38 in respect of B and EUR 5 914.07 in respect of W.

18 The Amstgericht Stendal upheld that claim by judgment of 25 May 2011. As Boston Scientific Medizintechnik's appeal against that decision was dismissed by the Landgericht Stendal (Regional Court, Stendal), that company lodged on appeal on a point of law before the referring court.

*G.'s recommendations of June 2005 concerning implantable cardioverter defibrillators and the subsequent events in Case C-504/13*

19 By letter of June 2005, G. informed treating physicians that its quality control system had established that the functioning of implantable 'G. Contak Renewal 4 AVT 6' defibrillators might be affected by a defect in one of its components which could limit the device's therapeutic efficacy. It was apparent from the scientific analysis carried out that a magnetic switch in those defibrillators might remain stuck in the closed position.

20 As is apparent from the order for reference in Case C-504/13, if the 'enable magnet use' mode was activated and the magnetic switch became stuck in the closed position, treatment of ventricular or atrial arrhythmias would be inhibited. As a consequence, any cardiac dysrhythmia that could be fatal would not be recognised by the defibrillators and no life-saving shock would be given to the patient.

21 In those circumstances, G. recommended treating physicians to deactivate the magnetic switch in the defibrillators concerned.

22 On 2 March 2006, as a result of the information referred to at paragraph 19 above being disseminated, the implantable cardioverter defibrillator implanted in F, who was covered for insurance purposes by Betriebskrankenkasse RWE, was replaced prematurely.

23 By letter of 31 August 2009, Betriebskrankenkasse RWE requested Boston Scientific Medizintechnik to reimburse the costs incurred in respect of F's treatment, amounting to EUR 20 315.01 and EUR 122.50, in connection with the operation to replace the defibrillator.

24 An action was brought by Betriebskrankenkasse RWE for an order that Boston Scientific Medizintechnik reimburse the sums in question before the Landgericht Düsseldorf (Regional Court, Düsseldorf), which upheld that claim by judgment of 3 February 2011. After Boston Scientific Medizintechnik appealed against that judgment, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) varied that decision in part, ordering that company to pay the sum of EUR 5 952.80, together with interest. Boston Scientific Medizintechnik lodged an appeal on a point of law before the referring court, contending that Betriebskrankenkasse RWE's claim should be dismissed in its entirety.

*The considerations set out by the Bundesgerichtshof in Cases C-503/13 and C-504/13*

25 The Bundesgerichtshof states that the outcome of the disputes in the main proceedings depends on whether the pacemakers and the cardioverter defibrillator implanted in the insured persons concerned are defective products within the meaning of Article 6(1) of Directive 85/374. In that regard, it has not yet been determined whether, as those devices form part of a group of products that pose a risk of failure, they are themselves defective.

26 That court considers that, in that context, it is of little consequence that it is accepted in specialist medical circles that it is not possible for a pacemaker or a cardioverter defibrillator that has been implanted to be 100% safe. 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.

27 With regard to implantable cardioverter defibrillators, it is apparent from the order for reference that the fact that the therapeutic benefit of the 'enable magnet use' function is lost if it is deactivated does not constitute a danger to the patient's life or physical well-being. If that function is deactivated, the patient monitor feature remains unaffected. The fact that temporary suspension of tachyarrhythmia treatment may be performed only with the aid of a programmer in such a case does not result in a health risk but simply a restriction of the functions which such defibrillators can perform.

28 In those circumstances, the Bundesgerichtshof decided to stay the proceedings and to refer to the Court of Justice for a preliminary ruling the following questions, which are formulated in a similar manner in both Case C-503/13 and Case C-504/13:

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

(2) If the answer to the first question is in the affirmative:

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

29 By decision of the President of the Court of 2 October 2013, Cases C-503/13 and C-504/13 were joined for the purposes of the written and oral procedure and judgment.

**The request to have the oral procedure reopened**

30 The oral procedure was concluded on 21 October 2014, following the presentation of the Advocate General's Opinion.

31 By letter of 10 November 2014, received at the Court the same day, Boston Scientific Medizintechnik requested the Court to order that the oral procedure be reopened.

32 In support of that request, it submitted, in particular, that the Advocate General's Opinion is based on legal considerations on which the parties to the proceedings have not had the opportunity to exchange views, namely the considerations relating to Article 168 TFEU and Article 35 of the Charter of Fundamental Rights of the European Union. Boston Scientific Medizintechnik also contends that the Advocate General's Opinion is vitiated by a number of errors.

33 It should be noted in that regard that the Court may, at any time, after hearing the Advocate General, order that the oral procedure be reopened, in accordance with Article 83 of its Rules of Procedure, in particular if it considers that it lacks sufficient information or that the case must be dealt with on the basis of an argument that has not been debated by the parties or the interested persons referred to in Article 23 of the Statute of the Court of Justice of the European Union.

34 In the present case, the Court, having heard the Advocate General, considers that it has all the information necessary to answer the questions referred and that that information has been the subject of debate before it.

35 Accordingly, Boston Scientific Medizintechnik's request that the oral procedure be reopened must be rejected.

## Consideration of the questions referred

*Question 1*

36 By its first question, the referring court is asking, in essence, whether Article 6(1) of Directive 85/374 is to be interpreted as meaning that, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers or implantable cardioverter defibrillators, have a potential defect, it is possible to classify such a product as defective, without there being any need to establish that the product in question has such a defect.

37 For the purposes of answering that question, it should be recalled that, as is apparent from Article 6(1) of Directive 85/374, a product is defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that it would be put and the time when the product was put into circulation. Moreover, according to the sixth recital in the preamble to that directive, that assessment must be carried out having regard to the reasonable expectations of the public at large.

38 The safety which the public at large is entitled to expect, in accordance with that provision, must therefore be assessed by taking into account, inter alia, the intended purpose, the objective characteristics and properties of the product in question and the specific requirements of the group of users for whom the product is intended.

39 With regard to medical devices such as the pacemakers and implantable cardioverter defibrillators at issue in the main proceedings, it is clear that, in the light of their function and the particularly vulnerable situation of patients using such devices, the safety requirements for those devices which such patients are entitled to expect are particularly high.

40 Moreover, as observed, in essence, by the Advocate General at point 30 of his Opinion, the potential lack of safety which would give rise to liability on the part of the producer under Directive 85/374 stems, for products such as those at issue in the main proceedings, from the abnormal potential for damage which those products might cause to the person concerned.

41 Accordingly, where it is found that such products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective.

42 Moreover, such an interpretation is consistent with the objectives pursued by the EU legislature, seeking to ensure, in particular, as is apparent from the second and seventh recitals in the preamble to Directive 85/374, a fair apportionment of the risks inherent in modern technological production between the injured person and the producer.

43 It follows from all the foregoing considerations that the answer to Question 1 is that Article 6(1) of Directive 85/374 must be interpreted as meaning that, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, have a potential defect, such a product may be classified as defective without there being any need to establish that that product has such a defect.

*Question 2*

44 By its second question, the referring court is asking, in essence, whether Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374 are to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes 'damage caused by death or by personal injuries' for which the producer is liable.

45 First, it should be noted that it is apparent from a reading of Article 1 in conjunction with section (a) of the first paragraph of Article 9 of Directive 85/374 that the producer is liable for damage caused by death or personal injuries which are the result of his product being defective.

46 It is apparent from the Court's case-law that full and proper compensation for persons injured by a defective product must be available for the kind of damage referred to in the preceding paragraph (see judgment in *Veedfald*, C-203/99, EU:C:2001:258, paragraph 27).

47 As observed by the Advocate General at points 61 to 63 of his Opinion, the notion of 'damage caused by death or personal injuries' within the meaning of section (a) of the first paragraph of Article 9 of Directive 85/374 must, having regard to the objective of protecting consumer health and safety pursued by that directive in accordance with the first and sixth recitals in the preamble thereto, be given a broad interpretation.

48 In order for a producer to incur liability for the damage caused by a defective product, it is necessary to prove, as stated in Article 4 of Directive 85/374, that there is a causal relationship between the defect and the damage suffered.

49 Compensation for damage thus relates to all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect, in accordance with Article 6(1) of Directive 85/374.

50 As a consequence, in the case of medical devices, such as pacemakers and implantable cardioverter defibrillators, which are defective within the meaning of Article 6(1) of Directive 85/374, compensation for damage must cover, inter alia, the costs relating to the replacement of the defective product.

51 In the present case, as is apparent from the order for reference in Case C-503/13, G. recommended to surgeons that they should consider replacing the pacemakers in question.

52 In that case, the Court finds that the costs relating to the replacement of such pacemakers, including the costs of the surgical operations, constitute damage within the meaning of section (a) of the first paragraph of Article 9 of Directive 85/374, for which the producer is liable in accordance with Article 1 of that directive.

53 That finding may be different in the case of implantable cardioverter defibrillators, as G. recommended, as is apparent from the order for reference in Case C-504/13, that the magnetic switch of those medical devices should simply be deactivated.

54 In that regard, it is for the national court to determine whether, having regard to the particularly vulnerable situation of patients using an implantable cardioverter defibrillator, the deactivation of the magnetic switch is sufficient for the purpose of overcoming the defect in that product, bearing in mind the abnormal risk of damage to which it subjects the patients concerned, or whether it is necessary to replace that product in order to overcome the defect.

55 It follows from the foregoing that the answer to Question 2 is that Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374 are to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question. It is for the national court to verify whether that condition is satisfied in the main proceedings.

## Costs

56 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

1. **Article 6(1) of 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 must be interpreted as meaning that, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, have a potential defect, such a product may be classified as defective without there being any need to establish that that product has such a defect.**

2. **Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374 are to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question. It is for the national court to verify whether that condition is satisfied in the main proceedings.**

[Signatures]