Reports of Cases

OPINION OF ADVOCATE GENERAL
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delivered on 21 October 2014[1]

Joined Cases C-503/13 and C–504/13

Boston Scientific Medizintechnik GmbH
v
AOK Sachsen-Anhalt — Die Gesundheitskasse (C–503/13),
Betriebskrankenkasse RWE (C–504/13)

(Requests for a preliminary ruling from the Bundesgerichtshof (Germany))

(Reference for a preliminary ruling — Directive 85/374/EEC — Liability for defective products — Product defect — Characterisation — Pacemakers and cardioverter defibrillators implanted in the human body — Devices belonging to a product group with a significantly higher than normal risk of failure or in which failures have already occurred in a significant number)

1. By the present requests for a preliminary ruling, the Court is requested to rule on the interpretation of Articles 1 and 6(1) and point (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.[2]

2. In particular, the Bundesgerichtshof (Federal Court of Justice, Germany) asks the Court to delimit the notions of 'product deficiency' and 'reparable damage' for the purposes of that directive in the context of disputes arising following surgical operations to remove pacemakers and a cardioverter defibrillator.

3. In this Opinion, I will argue, first, that a medical device implanted in a patient's body must be regarded as defective within the meaning of Article 6(1) of Directive 85/374 if it has the same characteristics as other devices which are proven to have a significantly higher than normal risk of failure or in which a significant number of failures has already occurred. The fact that a certain product belongs to a defective product group suggests that it has potential for failure itself which is at odds with what a person is entitled to expect as regards patient safety.

4. I will explain, second, that loss or injury connected with preventive surgical operation to remove a defective medical device and to implant a new device constitutes damage caused by personal injuries within the meaning of point (a) of the first paragraph of Article 9 of Directive 85/374 and that the producer of the defective product is liable for that loss or injury where a causal relationship can be established between that loss or injury and the defect, which it is for the national court to determine, taking all relevant circumstances into account, including an examination whether the surgical operation was necessary to prevent the risk of failure associated in the product defect arising.

1 — Original language: French.
2 — OJ 1985 L 210, p. 29.

I – The legislative framework

A – *Directive 85/374*

5. Article 1 of Directive 85/374 sets out the principle that '[t]he producer shall be liable for damage caused by a defect in his product', whilst Article 4 of that directive states that '[t]he injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage'.

6. Article 6(1) of that directive provides:

'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.'

7. Furthermore, Article 9 of Directive 85/374 provides:

'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 …

This Article shall be without prejudice to national provisions relating to non-material damage.'

B – *German law*

8. Directive 85/374 was transposed into German law by the Law on liability for defective products (Gesetz über die Haftung für fehlerhafte Produkte) of 15 December 1989,[3] as amended.[4]

9. Under Article 1 of that Law:

'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 …'

3 — BGBl. 1989 I, p. 2198.

4 — 'The Law of 15 December 1989'.

10. Article 3 of that Law provides:

‘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. Under Article 8 of the Law of 15 December 1989:

‘Where a person has been injured or his health has been 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.’

II – The facts in the main proceedings and the questions referred for a preliminary ruling

12. B. Corporation, now B.S. Corporation, is a company governed by US law which manufactures and sells pacemakers and implantable cardioverter defibrillators (ICDs).

13. G. GmbH & Co. Medizintechnik KG,[5] which subsequently merged with Boston Scientific Medizintechnik GmbH,[6] imported and sold Guidant Pulsar 470 and Guidant Meridian 976 pacemakers and G. CONTAK RENEWAL ® 4 AVT ® 6 implantable cardioverter defibrillators, manufactured by B.S. Corporation.

A – *The facts in Case C–503/13*

14. By letter of 22 July 2005, with the heading ‘Urgent medical device safety information and corrective action’, G. GmbH informed physicians that its quality control system had determined that a hermetic sealing component utilised in pacemakers might experience a gradual degradation which could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning.

15. G. GmbH therefore recommended that, among other things, physicians consider replacing devices, undertaking to provide a replacement device at no charge for patients.

16. Following that recommendation, the pacemakers implanted in B in September 1999 and in W in April 2000 were replaced, on 27 September 2005 and 25 November 2005 respectively, with other pacemakers which the manufacturer had provided free of charge.

17. AOK Sachsen-Anhalt — Die Gesundheitskasse, a health insurance organisation, applied, on the basis of the devolved rights of B and W, for reimbursement from BS. GmbH of the costs for the initial implantation of the pacemakers, which amounted to EUR 2 655.38 for B and EUR 5 914.07 for W.

5 — ‘G. GmbH’.

6 — ‘BS. GmbH’.

18. By judgment of 25 May 2011, the Amtsgericht Stendal (Local Court, Stendal, Germany) granted that application. After the appeal brought by BS. GmbH against that decision had been dismissed, on 10 May 2012, by the Landgericht Stendal (Regional Court, Stendal, Germany), BS. GmbH lodged an appeal on a point of law with the Bundesgerichtshof.

B – *The facts in Case C–504/13*

19. By letter of June 2005, with the heading 'Urgent medical device safety information and corrective action for CONTAK RENEWAL ®', G. GmbH informed physicians that its quality control system had determined that defibrillators were subject to a component failure that could limit available therapy and that the United States Food and Drug Administration might classify that action as a recall. Engineering analysis had revealed that a magnetic switch may stick in the closed position and that, if the device's magnet mode was activated, this prevented treatment of ventricular or atrial arrhythmias. In those circumstances, G. GmbH recommended deactivating the defibrillators' magnet mode.

20. On 2 March 2006, there was a premature replacement of the defibrillator implanted in F.

21. Betriebskrankenkasse RWE, a health insurance organisation, applied, on the basis of the devolved rights of F, for reimbursement of the costs for inpatient and outpatient treatment for F, amounting to EUR 20 315.01 and EUR 122.50 respectively, connected with the operation to change the defibrillator.

22. By judgment of 3 February 2011, the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) granted that application. After BS. GmbH brought an appeal, by a judgment of 20 June 2012, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) varied that decision in part and ordered BS. GmbH to pay the sum of EUR 5 952.80 together with interest. BS. GmbH lodged an appeal on a point of law against that judgment with the referring court, contending that Betriebskrankenkasse RWE's claim should be dismissed in its entirety.

C – *The questions referred for a preliminary ruling*

23. In these circumstances, the Bundesgerichtshof decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(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 implant another pacemaker [or another defibrillator] constitute damage caused by personal injury for the purposes of Article 1 and point (a) of the first paragraph of Article 9 of Directive 85/374/EEC …?'

III – My analysis

A – *The first question*

24. The Bundesgerichtshof states, in Case C–503/13, that the pacemakers initially implanted belonged to a product group with a likelihood of failure 17 to 20 times greater than is normal and, in Case C–504/13, that the ICD implanted belonged to a product group in which a component failure could occur, which may limit available therapy. In the light of these considerations, the Bundesgerichtshof is inclined to take the view that the pacemakers implanted in the insured persons B and W and the ICD implanted in the insured person F must also be regarded as defective products since those devices did not provide the safety which a person is entitled to expect, taking all circumstances into account. The Bundesgerichtshof nevertheless is uncertain whether it is possible to accept the existence of a deficiency when it has not been established that the devices implanted in the insured persons B, W and F had the defect of which G. GmbH had informed physicians.

25. It is for that reason why the referring court has asked the question whether, in essence, an active implantable medical device must be regarded as defective where it belongs to a group for which the risk of failure is significantly higher than normal or where a defect has already occurred in a significant number of products of the same model.

26. In my view, that question should be answered in the affirmative.

27. The concept of a defective product is one that is fundamental to the application of the specific rules governing the strict liability of producers for the safety in their products established by Directive 85/374, as it constitutes the trigger for liability.

28. Under Article 6(1) of Directive 85/374, a defective product is a product which does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that the product would be put and the time when the product was put into circulation. The sixth recital in the preamble to that directive states that ‘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’.[7]

29. In accordance with the objective dimension of the rules laid down by Directive 85/374[8] and as is shown by the use [in French] of the indefinite pronoun ‘*on*’ [a person] and the adverb ‘*légitimement*’ [entitled], the concept of a defect is to be assessed in the abstract with reference not to a specific user, but to the public at large, having regard to standard safety which the consumer may reasonably expect. The objectivity of the concept of defect is tempered, however, by the fact that more specific circumstances are taken into account, ‘including’ the use to which it could reasonably be expected that the product would be put.

7 — The concept of a ‘defective product’ within the meaning of Article 6(1) of Directive 85/374 should not be confused with that of a ‘dangerous product’ within the meaning of Article 2(b) and (c) of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ 2002 L 11, p. 4). Unlike the former, the latter is independent of the expectations of the public. See, with regard the complementarity of these two directives, Artigot i Golobardes, M., ‘A close look to European product regulation: an analysis of the interaction between European product safety regulation and product liability’, *Polish Yearbook of Law & Economics*, Vol. 3, Wydawnictwo C.H. Beck, Warsaw, 2013, p. 193.

8 — See, to that effect, judgment in *Aventis Pasteur* (C-358/08, EU:C:2009:744, paragraph 48 and cited case-law).

30. The concept of safety which a person is entitled to expect, which is relatively imprecise [9] and of indeterminate content, leaves scope for interpretation which must nevertheless be exercised having regard to the objectives of Directive 85/374. Interpreted in the light of the objective, set out in the second recital in the preamble to that directive, of adequately solving the problem of a fair apportionment of the risks inherent in modern technological production, that concept must be understood to refer to a product that poses risks jeopardising the safety of its user and having an abnormal, unreasonable character exceeding the normal risks inherent in its use. Accordingly, the lack of safety does not stem from the danger that may be posed by the use of the product, as a product may be dangerous even without having a safety defect, but from the abnormal potential for damage that the product could cause to the person or to the property of its user. In other words, the defect for the purposes of Article 6(1) of Directive 85/374 is a risk of damage of such a degree of seriousness that it affects the public's legitimate expectations in so far as concerns safety. [10]

31. In the light of that definition, I take the view that the mere possibility of failure in the pacemakers implanted in B and in W and the defibrillator implanted in F constitutes a defect for the purposes of that article, since it is reasonable to expect there to be such a safety failure, irrespective of whether it has been specifically established that those products actually had the inherent fault identified by the manufacturer.

32. First of all, this solution would seem to be largely dictated by the actual wording of that article, according to which the concept of product defect is to be assessed having regard only to safety and can exist irrespective of any internal fault in the product concerned.

33. As the Court has stated, liability for damage caused by defective products is based on a different ground from a warranty in respect of latent defects. [11] Its triggering factor does not reside in the product fault, but in the fact that the product does not provide the safety which a person is entitled to expect. However, notwithstanding the finding of the existence of a material fault, how could the public not have legitimate grounds for questioning the safety of a product that has exactly the same characteristics as other products which have been proven to have a significantly higher than normal risk of failure or in which failures have already occurred in significant numbers? From the point of view of users, it goes without saying that if a product's design and manufacture are identical to those of other products, that product is treated in the same way as the others as regards their risk of failure.

34. Second, the solution that I advocate is also dictated by consumer protection requirements.

35. It should be pointed out in this regard that although, by establishing a harmonised regime for the civil liability of producers for damage caused by defective products, Directive 85/374 addresses the objective of ensuring undistorted competition between economic operators and facilitating the free movement of goods, consumer protection is also one of its main objectives, as is shown, inter alia, by an examination of the *travaux préparatoires* which preceded its adoption and its preamble, in particular its first, fourth, fifth, eighth, ninth and twelfth recitals.

36. That conclusion is not affected by the fact that the legal basis of Directive 85/374 is Article 100 of the EEC Treaty, which became Article 94 EC, then Article 115 TFEU, concerning the approximation of such laws, regulations and administrative provisions of the Member States as directly affect the establishment or functioning of the common market. Even though that provision offers no possibility

9 — This concept probably finds its inspiration in US law, which made 'reasonable consumer expectations' the criterion for product defects. See, to that effect, Borghetti, J.-S., *La responsabilité du fait des produits, étude de droit comparé*, Bibliothèque de droit privé, Volume 428, LGDJ, Paris, 2004, No 437, p. 434.

10 — See, to this effect, Borghetti, J.-S., op. cit., No 451, p. 447.

11 — See judgment in *González Sánchez* (C-183/00, EU:C:2002:255, paragraph 31).

for Member States to maintain or establish provisions departing from Community harmonising measures,[12] including the provision of a higher level of consumer protection, this does not mean that harmonising measures adopted on its basis do not have the objective of guaranteeing consumer protection.

37. The protection which Directive 85/374 seeks to grant consumers would be seriously undermined if, in the event that a number of products of the same model were placed on the market and a safety defect occurred in only some of those products, the probability that the defect was present in other products could not be taken into consideration. In actual fact, all EU legislation on product safety would be called into question if, in that situation, it was necessary to wait for the risk of failure in connection with a lack of safety shown to exist in certain products to materialise in other products through damage occurring.

38. Making proof of a lack of safety subject to the actual occurrence of damage would disregard the preventive function assigned to EU legislation on the safety of products offered on the market and to the specific liability regime established by Directive 85/374,[13] which manifestly pursues a preventive function by imputing liability to the person who, having created the risk most directly by manufacturing a defective product, is in the best position to minimise it and to prevent damage at the lowest cost.[14]

39. Third, my proposed approach is corroborated by the need for the integration of health concerns in European Union policy.

40. Account must be taken of Article 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights of the European Union, which require a high level of human health protection in the definition and implementation of all Union policies and activities.

41. In so far as human health protection requirements must be integrated into all Union policies, such protection must be regarded as an objective that also forms part of the policy calling for the harmonisation of the Member States' rules on liability for damage caused by defective products.

42. In the light of that objective, the function of health products for human use lends such products an indisputable specific character, which must be taken into account in assessing the concept of defect.

43. Whilst the provisions of Directive 85/374 are applicable to all products, whatever they may be, the fact remains that a pacemaker or an ICD are not just any product. These devices are active implantable medical devices within the meaning of Article 1(2)(c) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.[15] In order to obtain the 'EC' mark of conformity authorising their marketing, such devices must satisfy the essential requirements set out in Annex 1 to that directive. The first sentence of paragraph 1 in Section I of Annex I to that directive provides, in particular, that the devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients.

12 — See, to this effect, judgment in *González Sánchez* (EU:C:2002:255, paragraph 23).

13 — With regard to the preventive function of the liability regime for defective products established by Directive 85/374, see, inter alia, Borghetti, J.-S., op. cit., No 645, p. 613.

14 — Under Article 3(3) of Directive 85/374, the liability of the supplier may be invoked only in the alternative, where the producer cannot be identified.

15 — OJ 1990 L 189, p 17.

44. The specific character of the devices at issue in the main proceedings is also illustrated by their position in the classification established by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.[16] In accordance with the rules in Annex IX to that directive, those products are in Class III,[17] which, according to the fourteenth recital in the preamble to that directive, corresponds to the most critical devices for which explicit prior authorisation with regard to conformity is required for them to be placed on the market.

45. Although the notion of legitimate expectation is particularly difficult to define and its perception involves some degree of subjectivity, it may be argued that the expected degree of safety, which depends, among other things, on the nature of the product and its intended use, will be greater for a device implanted in the human body, in respect of which it is difficult to conceive of a situation in which it could be improperly used by the patient, than for a bottle of water or for a cleaning product.

46. Contrary to the claims made by BS. GmbH at the hearing, it seems clear to me that the legitimate expectations of a patient in whose body a pacemaker or an ICD has been implanted because of a disease suffered by him are not comparable with those of a user of a mobile phone whose battery becomes depleted prematurely.

47. The arguments expounded at the hearing by BS. GmbH lead me to dwell for a moment on the irreducible specific character of medical devices implanted in the human body. In order to obtain a slightly more accurate idea of the therapeutic functions of pacemakers and ICDs, I will refer to the information sheets and consent forms produced by the French Society of Cardiology.[18]

48. The pacemaker is described there as ‘a small box containing electronic circuits powered by a battery, [which is] linked to the heart by one, two or three leads, depending on the case, [and which is] capable of continuously monitoring the heart rate, in particular where it is abnormal, and of stimulating it if necessary without any discomfort’. The information sheet states that the implantation of a pacemaker is ‘a common, reliable and effective treatment for certain heart diseases (usually taking the form of a significantly decreased heart rate) that cannot be controlled by the use of medicines’, adding that ‘cardiac stimulation is also sometimes used in the treatment of congestive heart failure’. It mentions that, after a number of years, the box will have to be changed due to battery depletion.

49. The implantable cardioverter defibrillator is described as ‘a box powered by a battery … capable of continuously monitoring the heart rate, of detecting arrhythmias and of treating them either by rapid stimulation, which is not felt, or by an internal electric shock’. It is also stated that the device performs the function of a pacemaker and that, placed in the upper chest in a surgical procedure, it is linked to the heart by one, two or three leads through a vein. The medical indications for these devices are set out as follows:

‘It is suggested that you have an implantable cardioverter defibrillator (ICD) implanted because you are in one of the two following situations:

— you have a heart disease which puts you at risk of sudden death due to the occurrence of serious cardiac rhythm disorders in the coming months and years. These serious cardiac rhythm disorders are due to unpredictable increases in the heart rate and in some cases can be fatal if they are not treated in time,

— you have recently suffered a serious cardiac rhythm disorder. There is a high risk of reccurrence, despite the treatments that could be offered, and this may lead to sudden death.’

16 — OJ 1993 L 169, p. 1.

17 — See Rule 8 in that Annex.

18 — These are available on the website of the Société française de cardiologie at www.sfcardio.fr.

50. It is clear from this brief description that pacemakers and ICDs are implanted in people who are made vulnerable by disease and at risk of death.

51. I will now briefly recall the factual findings made by the Bundesgerichtshof concerning the pacemakers and ICD models at issue in the main proceedings.

52. With regard to the pacemakers, first of all, it is clear from the order for reference in Case C–503/13 that, in its letter sent to physicians in July 2005, G. GmbH acknowledged the existence of a design fault affecting the hermetic sealing component utilised in the boxes, which could lead to premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning. The order also states that the pacemakers implanted in the insured persons B and W belonged to a product group which had a risk of failure 17 to 20 times greater than is normal for this kind of device.

53. With regard to the defibrillators, the referring court stated, in Case C–504/13, that there was a potential for failure of the magnetic switch, which may stick in the closed position, thereby inhibiting treatment of ventricular or atrial arrhythmias.

54. In both cases, the fact that devices of the same model are by their manufacturer's own admission, subject to potential failure inhibiting treatment of cardiac rhythm disorders clearly creates an abnormal danger for patients in whom such devices have been implanted. Contrary to the claims made by BS. GmbH at the hearing, I consider that it is irrelevant that the devices are not dangerous per se, and that they are not likely to explode in the patient's chest or to cause an injury. The defect affecting them makes them abnormally dangerous by exposing patients to a risk of heart failure or death.

55. In the light of all the above considerations, I propose that the Court answer the first question to the effect that a medical device implanted in a patient's body must be regarded as defective within the meaning of Article 6(1) of Directive 85/374 if it has the same characteristics as other devices which have been proven to have a significantly higher than normal risk of failure or in which a significant number of failures has already occurred. The fact that a certain product belongs to a defective product group suggests that it has potential for failure itself, which is at odds with what a person is entitled to expect as regards patient safety.

B – *The second question*

56. By its second question, the referring court asks, in essence, whether the costs of operations to remove and replace pacemakers or ICDs constitute damage caused by personal injury for the purposes of Article 1 and point (a) of the first paragraph of Article 9 of Directive 85/374.

57. It should be stated at the outset that it is clear from a reading of Article 1 in conjunction with point (a) of the first paragraph of Article 9 of Directive 85/374 that the producer who incurs liability by reason of the defect in his product is obliged to compensate for 'damage caused by death or by personal injuries'.

58. As the European Commission mentioned in its written observations, the wording used in that article to designate physical damage is not identical in all language versions. For example, in the German version, that provision states that 'damage' means damage caused by death or by 'bodily harm' (Körperverletzung),[19] thereby suggesting that the producer is under an obligation applies only in respect of damage occurring as a result of an accident characterised by sudden and violent action with an external cause, as the Czech Government claims.

59. However, the Spanish, French and Portuguese versions of the same provision refer to the notion of 'physical injuries', without any qualification, whilst the English and Italian versions make reference, even more generally, to damage caused by personal injuries.

60. According to settled case-law, a purely literal interpretation of one or more language versions of a multilingual text of EU law, to the exclusion of the others, cannot prevail since the uniform application of EU rules requires that they be interpreted, inter alia, in the light of the versions drawn up in all the languages.[20] Moreover, where there is divergence between two language versions of a European Union legal text, in order to ensure uniform interpretation and application, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part.[21]

61. With respect to the general scheme of point (a) of the first paragraph of Article 9 of Directive 85/374, it should be noted that the preamble to that directive, and in particular its first and sixth recitals, shows that the concept of damage caused by death or personal injuries must be given a broad interpretation covering, unlike damage caused to property, all damage caused to the actual person of the user of the defective product. According to the first recital in the preamble to that directive, the directive is intended to ensure protection of the consumer against 'damage caused … to his health'. Similarly, the sixth recital in the preamble to Directive 85/374 mentions the objective of protecting the 'physical well-being' of the consumer.

62. The lack of any limitation on liability for personal injury is confirmed by the Annex to the Council Resolution of 14 April 1975 on a preliminary programme of the European Economic Community for a consumer protection and information policy,[22] which cites protection against the consequences of personal injury caused by defective products as one of the objectives of Community consumer protection policy,[23] and by the Explanatory Memorandum for the Proposal for a Directive presented by the Commission on 9 September 1976,[24] which states that personal injury covers the cost of treatment and all expenditure incurred in restoring the injured person to health and any impairment of earning capacity as a result of the personal injury sustained.

63. Furthermore, the exclusion of loss or injury caused by a surgical operation to remove a defective medical device would be entirely contrary to the general objective of protecting consumer health and safety pursued by Directive 85/374.

19 — It is interesting to note, however, that the Law of 15 December 1989, which transposes Directive 85/374 into German law, does not reproduce that wording, as it imposes an obligation on the producer to compensate for damage suffered by a person who dies, is injured or whose health is impaired.

20 — See judgment in Vnuk (C-162/13, EU:C:2014:2146, paragraph 46 and cited case-law).

21 — See, to this effect, judgment in Bark (C-89/12, EU:C:2013:276, paragraph 40 and cited case-law).

22 — OJ 1975 C 92, p. 1.

23 — See paragraph 15(a)(ii) of that Annex.

24 — Proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1976 C 241, p. 9). For the Explanatory Memorandum, see *Bulletin of the European Communities*, Supplement 11/76, p. 17, paragraph 17.

64. Moreover, the Court has already ruled, in *Veedfald*,[25] that although Article 9 of Directive 85/374 neither contains any express definition of the term damage nor determines the precise content of the heads of reparable damage, it must be interpreted as requiring full and proper compensation for persons injured for the heads of damage covered by the term, save for non-material damage whose reparation is governed solely by national law.[26]

65. The fact that Directive 85/374 covers damage caused by death or by personal injuries is ultimately 'the very least that can be expected',[27] since 'the primary aim of product liability, in all countries, has always been to ensure compensation for personal injury'.[28]

66. Accordingly, all material loss or damage resulting from personal injury must be compensated for in full.

67. In those circumstances, I consider that to deny compensation for loss or injury resulting from surgery to remove a defective device and to replace it with a new, defect-free device on the ground that the injured person decided on and planned that surgery would effectively create an additional condition under Directive 85/374, relating to the sudden and external nature of the damage suffered, which is not to be found in the directive.

68. Furthermore, taken to its extreme, any reasoning which relies on the injured person's initiative to deny him compensation for his loss or injury results in an absurd and iniquitous outcome, requiring the injured person to have died in order to be able to claim reparable loss or injury. It goes without saying that this outcome would be completely contrary to the effectiveness of Directive 85/374.

69. Of course, under Article 4 of Directive 85/374, the obligation upon the producer to pay compensation will be subject to proof of the causal relationship between the defect associated with the risk of failure of the devices and the damage suffered by the patients resulting from preventive surgical operations to remove defective devices and replace them with new devices.

70. As the French Government rightly argues, in order to assess whether such a relationship exists, the national court must establish that the operations undergone by the insured persons were necessary and proportionate, that is to say they were likely to avert the risk of failure in question and that there was no less damaging alternative.

71. In this instance, in Case C–503/13, the referring court has disclosed nothing that might create any doubt in this regard. On the contrary, according to its findings, G. GmbH itself recommended that physicians consider replacing devices and offered to provide replacement devices at no charge. Another relevant factor for the referring court to consider is to be found in the letter sent by G. GmbH on 22 July 2005 containing, under the heading 'Important Note', the statement that while interrogation of the device 'may'[29] identify devices that have already experienced the failure mode, it has not been possible to identify any test that will predict if a device will exhibit this failure mode in the future.

25 — C-203/99, EU:C:2001:258.

26 — Paragraph 27.

27 — In the words of Borghetti, J.-S., op. cit., No 504, p. 485.

28 — Ibid.

29 — This lack of certainty is hardly reassuring.

72. On the other hand, in Case C–504/13, the referring court stated that the health risk which the defective switch might give rise to could be 'effectively' countered by simply deactivating the magnet mode, which did not place the patient in physical danger. Accordingly, the referring court will have to ascertain whether that action represented an alternative that provided an equivalent level of safety to the replacement of the defibrillator and whether it would be more detrimental to health than replacement.

73. Lastly, is there any need to state that the present cases are taking place against the specific background of an increase in the number of health scandals involving health products, in particular implantable medical devices such as artificial hip joints, cardiac leads, knee joints or breast implants? [30] As these scandals have highlighted the gaps and weaknesses in the present authorisation and control system, the Commission and the Member States have adopted, as an urgent response, a Joint Plan for Immediate Actions in order to restore patient confidence. [31]

74. Recognising that compensation may be awarded in respect of damage caused by action intended to avert a risk of much more serious damage is likely to prompt producers to improve the safety of their products and to create a better balance between the need for compensation for injured persons and the objective of preventing damage.

75. In the light of the above, I propose that the Court answer the second question to the effect that loss or injury connected with a preventive surgical operation to remove a defective medical device and to replace it with a new device constitutes damage caused by personal injuries within the meaning of point (a) of the first paragraph of Article 9 of Directive 85/374. The producer of the defective product is liable for that loss or injury where a causal relationship can be established between the loss or injury and the defect, which is a matter to be determined by the national court, taking all relevant circumstances into account, including an examination whether the surgical operation was necessary to prevent the risk of failure associated with the product defect arising.

IV – Conclusion

76. In the light of the foregoing considerations, I propose that the Court answer the questions referred for a preliminary ruling by the Bundesgerichtshof as follows:

(1) A medical device implanted in a patient's body must be regarded as defective within the meaning of 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 if it has the same characteristics as other devices which have been proven to have a significantly higher than normal risk of failure or in which a significant number of failures has already occurred. The fact that a certain product belongs to a defective product group suggests that it has potential for failure itself, which is at odds with what a person is entitled to expect as regards patient safety.

(2) Loss or injury connected with a preventive surgical operation to remove a defective medical device and to replace it with a new device constitutes damage caused by personal injuries within the meaning of point (a) of the first paragraph of Article 9 of Directive 85/374. The producer of the defective product is liable for that loss or injury where a causal relationship can be established between that loss or injury and the defect, which is a matter to be determined by

30 — The 'PIP' scandal occurred after the discovery that for several years a French breast implant manufacturer had used industrial-grade silicon rather than medical-grade silicon. According to available estimates, more than 400 000 women around the world received a PIP implant, many of them in Europe, in particular in the United Kingdom (40 000), France (30 000) and Spain (18 500).

31 — See Commission staff working document, 13 June 2014, Implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation (SWD(2014) 195 final).

the national court, taking all relevant circumstances into account, including an examination whether the surgical operation was necessary to prevent the risk of failure associated with the product defect arising.