Can a normally functioning medical device be a defective product?

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

On 5 March 2015, the European Court of Justice ('ECJ') issued an important ruling on the European Product Liability Directive 85/374/EEC ('the Directive'). Although the decision is limited to life-sustaining medical devices with an elevated risk of premature failure, it has raised some questions as to whether national courts will interpret the Directive more widely to apply to all medical devices, or other products which have such a risk. We examine the scope of the decision below.

Background

Boston Scientific (BS) manufactured and sold pacemakers and implantable cardioverter defibrillators. It identified a defect in certain of its pacemakers, which could lead to premature battery depletion without warning. It undertook to make replacement devices available free of charge for patients. Patients B and W both had medical insurance cover and underwent the replacement surgery. The pacemakers were then destroyed without being examined to determine if the potential for battery depletion existed on the particular pacemakers. The insurer, on the basis of the subrogated rights of B and W, brought proceedings seeking compensation from BS in respect of the costs relating to the replacement.

BS also identified that the functioning of its defibrillators might be affected by a defect in one of its components that could limit the device's therapeutic efficacy with potentially fatal consequences. BS recommended that physicians deactivate the magnetic switch. Patient F decided to have his defibrillator replaced prematurely, and his insurer sought recovery from BS of the costs of the replacement operation.

The ECJ was asked to make a preliminary ruling on the following questions:

- Is Article 6(1) of the Directive to be interpreted as meaning that a product in the form of a medical device implanted in the human body is already defective if products in the same 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 is yes, do the costs of the operation to remove the product and to implant another pacemaker or defibrillator constitute damage caused by personal injury for the purposes of Article 1 and Article 9(a) of the Directive?

The Product Liability Directive

Article 1 of the Directive provides that the producer of a product shall be liable for damage caused by a defect in his product. Pursuant to Article 9, 'damage' in Article 1 means damage caused by death or by personal injuries; and damage to, or destruction of, any item of property other than the defective product itself.

Article 6(1) states that 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:

- (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.

The ECJ's findings

Question 1

The ECJ's view was that the safety which the public at large is entitled to expect must 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." The ECJ stated that with regard to medical devices such as pacemakers and implantable cardioverter defibrillators, "it is clear that, in 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." The court considered the potential lack of safety for such products arose from the "abnormal potential for damage" which those products might cause to the user.

Accordingly, the ECJ ruled 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."

The ECJ stressed that the ruling was consistent with the objectives of the Directive for a fair apportionment of the risks inherent in modern technological production between the injured person and the producer.

Question 2

The ECJ considered the notion of 'damage caused by death or personal injury' within the meaning of Article 9(a) must be given a broad interpretation, having regard to the Directive's objective of protecting consumer health and safety. The court's view was that "compensation for damage 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 the Directive." Therefore, compensation for damage must cover the costs of the operation to replace the pacemakers as this amounted to a personal injury within the scope of 'damage' under Article 9.

In the case of the defibrillators, the ECJ said the finding may be different as BS recommended that the magnetic switch should be simply deactivated. The ECJ considered it is for the national court to determine whether, having regard to the particularly vulnerable situation of patients using the defibrillators, the deactivation of the magnetic switch is sufficient for the purpose of overcoming the defect in the 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.

Comment

The requirement for the Claimant to demonstrate a defect in an implanted medical device has caused practical difficulty in a number of cases besides pacemakers and defibrillators, not least PIP breast implants and Metal on Metal hip implants.

The ECJ's conclusion that it is possible for a product to be defective without there being the need to establish that an individual product has an actual defect may be seen as a significant extension of the Directive's requirements to prove defect, damage and causation. The ECJ's reliance on the fair apportionment of risk underlines the scope for such a liberal interpretation.

It will remain to be seen whether national courts will restrict the ruling as applying only to life sustaining products or whether it will be extended beyond those. The ECJ did note that the safety requirements, which patients are entitled to expect are particularly high for the products in these cases "in light of their function and the particularly vulnerable situation of patients using such devices." The court also referred to the "abnormal potential for damage" those products might cause to the user, given that heart failure or death can follow. If a product meets these criteria, then it will be sufficient to establish that the product is part of the same group or production series of products, without needing to prove the specific item is defective.

It is to be anticipated that Claimants will argue that other products which might not result in fatal consequences if defective, but nevertheless give rise to the need for explanation due to the inherent risks, deserve similar levels of patient expectation as to safety. For example, products used by children such as cochlear implants might be regarded as falling into this category due to the abnormal potential for damage to a vulnerable user in the event an implant failed. It will be interesting to see how this case is interpreted by the national courts, starting with the German court's determination of whether the defibrillator was defective. The ruling, unless interpreted narrowly, certainly has the potential to change significantly the understanding of the fair apportionment of risk between the user and the manufacturer which is the basic tenet of the Product Liability Directive.

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