



## European Court of Justice: Potential Defects Constitute Product Defects

**The European Court of Justice issued a judgment stating that even a *potential* defect may constitute a defect as defined in the European Product Liability Directive and therefore constitutes a product liability claim against the producer.**

### Ruling

In a case concerning defective pacemakers and implanted cardioverter defibrillators, on 5 March 2015 (*Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt - Die Gesundheitskasse (C-503/13)* und *Betriebskrankenkasse RWE (C-504/13)*) the European Court of Justice (ECJ) issued a judgment deciding that if a medical device has a *potential* defect, all products of the same model may be classified as defective without the claimant having to prove that the product in question is defective. As a result, the costs related to replacing the products are reimbursable because the operation required to replace the defective products constitutes "damage caused by death or by personal injuries" as defined in the European Product Liability Directive 85/374/EEC.

### Background

Two German health insurance companies claimed reimbursement of the costs related to the replacement of medical devices from the German distributor of a US pacemaker and defibrillator manufacturer. After carrying out quality control checks, it was found that the pacemakers and cardioverter defibrillators might be defective and constitute a danger to patients' health. Based on this, the US manufacturer recommended that physicians consider replacing implanted pacemakers with other pacemakers provided free of charge. At the same time, it was recommended that physicians deactivate a switch in the defibrillators.

In some medical cases, the physicians found it necessary to replace the devices. The patients' insurance companies then requested reimbursement of these costs. The German Local Court granted the claim and the appeal was dismissed. The manufacturer then decided to take the matter to the German Federal Supreme Court (*Bundesgerichtshof*), which referred the issue to the European Court of Justice (ECJ).



The ECJ was tasked with clarifying whether devices that have been replaced may be classified as defective, even though no defect had been specifically detected in those devices and only a potential defect was revealed during the quality control checks carried out by the manufacturer on devices of the same model. The German court is also seeking clarification whether the cost of replacing those products constitutes damages "caused by death or by personal injuries" as defined in the Product Liability Directive for which the producer is liable.

### Decision of the ECJ

The ECJ confirmed the opinion of the Local Court. In light of the medical device's function and the vulnerability of patients using them, the devices are subject to particularly high safety requirements, especially considering the abnormal potential for possible personal injuries. As a result, the court found that if a medical device has a potential defect, it is possible to classify all products of the same model as defective without there being any need to show that the products are defective in each individual case.

Furthermore, the ECJ stated that in these cases the compensation for damages includes everything necessary to eliminate harmful consequences and restore the person's entitled level of safety. Therefore, the costs related to replacement can be included in the compensation for damages.

### Impact of the decision in practice

The ECJ's judgment constitutes a substantial expansion of the definition of "defect" in regard to life-sustaining implants: A suspected defect is sufficient to be classified as a defect under product liability law. There is now a greater risk for manufacturers and importers to face product liability lawsuits because of the greater incentive for consumers and health insurances to file suits that are based on merely a suspected defect. It remains to be seen whether national courts of the member states will apply the principles of the ECJ only to life-sustaining implants or if they will also apply the ECJ principles to other products.

Please do not hesitate to contact us for any questions.



### Impressum

#### avocado rechtsanwälte

schillerstraße 20

60313 **frankfurt**

t +49 [0]69.9133010

f +49 [0]69.91330119

frankfurt@avocado.de

www.avocado.de

www.brak.de

ust-id-nr. de 814 17 29 76

steuer nr. 13/225/62722

fa berlin-charlottenburg

avocado rechtsanwälte is the registered trademark of berger, figgen, gerhold, kaminski, voß rechtsanwälte part mbb.

The partnership is registered with the partnership register of the local court (Amtsgericht) Berlin-Charlottenburg under pr 331 b nr. 1.

This publication is distributed to our clients and contacts from time to time updating them on legal developments and/or services offered by the firm which we believe may be of interest to them. If you do not wish to receive such communications, please inform us by sending an e-mail to [j.walter@avocado.de](mailto:j.walter@avocado.de) or by telephoning our marketing department (Ms Julia Walter) on +49 [0]69 913301-132 to be removed from our mailing list.

Responsible Editor:

Tarec Alio, LL.M.