Court of Justice of the European Union
PRESS RELEASE No 31/15
Luxembourg, 5 March 2015

Press and Information

Judgment in Case C-503/13 and C-504/13
Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and Others

Where a medical device has a potential defect, all products of the same model may be classified as defective

The manufacturer of such a defective device must reimburse the costs relating to the replacement of the product where such replacement is necessary and to restore the level of safety which a person is entitled to expect

The Product Liability Directive[1] provides that the producer is liable for damage caused by a defect in his product.

A company which sold pacemakers and implantable cardioverter defibrillators in Germany found, after carrying out quality control checks, that those products might be defective and constitute a danger to patient health. In view of that situation, the producer recommended physicians to replace the pacemakers implanted in patients with other pacemakers provided free of charge. At the same time, the manufacturer recommended treating physicians to deactivate a switch in the defibrillators.

The insurers of the persons whose pacemaker or defibrillator has been replaced claim reimbursement of the costs relating to the replacement from the manufacturer.

In proceedings between the insurers and the undertaking which markets those medical devices, the Bundesgerichtshof (Federal Court, Germany) has asked the Court of Justice whether devices that have been replaced in the case in point may be classified as defective, even though no defect has been specifically detected in those devices but the quality control checks carried out by the manufacturer on devices of the same model have disclosed a potential defect. The German court is also seeking to ascertain whether the cost of replacing those products constitutes damage for which the produce is liable under the directive.

In today's judgment, the Court finds that, in the light of their function and the vulnerability of patients using them, the medical devices in question are subject to particularly high safety requirements. The Court observes in that regard that the potential lack of safety of such products, which would give rise to liability on the part of the producer, stems from the abnormal potential for damage which they might cause to the person concerned.

Accordingly, the Court finds that where it is found that a medical device has a potential defect**; it is possible to classify as defective all products of the same model**, without there being any need to show that the product is defective in each individual case.

Moreover, with regard to pacemakers replaced following the producer's own recommendations, the Court finds that the costs relating to such replacement constitute damage for which the producer is liable under the directive.

In so far as concerns implantable cardioverter defibrillators, in respect of which the producer has recommended merely the deactivation of a switch, the Court states that it is for the German court to determine whether that is appropriate for correcting the defect in those products or whether it is necessary to replace the product for that purpose.

[1] Council Directive 85/374/EEC of 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).

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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