CLIENT ALERT

European Court Expands Product Liability Exposure for Medical Device Producers

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On March 5, 2015, the Court of Justice of the European Union (CJEU) issued a ruling in *Boston Scientific Medizintechnik GmbH v. AOK Achsen-Anhait – Die Gesundheitskasse* (joined cases C-503/13 and C-504/13), interpreting the European Union's (EU) Product Liability Directive /374 (PLD). In its judgment, the court articulated a broad reading of the defect and damages e 85lements required by the PLD for certain medical devices, creating uncertainty about the future application of those provisions.

Case Background

The PLD requires persons alleging injury to prove that a produce was defective, the resulting damages, and a causal link between the defect and the damages.[1] Under the PLD, a product is defective when it "does not provide the safety which a person is entitled to expect."[2] Damages recoverable under the PLD include those caused by death or personal injury, and property damage (other than to the product itself).[3]

Boston Scientific concerned alleged injuries caused by pacemakers and implantable cardioverter defibrillators manufactured by a German medical device manufacturer. When the manufacturer's quality control system detected a potential issue in the devices, it took corrective action, informed physicians of the issue, and recommended replacing or deactivating of the devices for patients.

Thereafter, a dispute arose between the manufacturer and an insurer seeking compensation for surgical procedures to remove and replace the potentially affected devices in three patients. In none of the cases had there been an expert analysis to determine whether the products used by the three patients were defective. The German Bundesgerichtshof stayed the case pending a preliminary reference to the CJEU for an interpretation of the PLD requirements for proving defects and damages.

Court's Judgment

The CJEU decided that the medical device manufacturer could be liable, despite the lack of conclusive evidence of defect, and provided a structure for determining damages in this case. Specifically, the court held that where a party can establish "the same group … or production series" of products may be defective, "all the products in that group or series" may be considered defective under the PLD as a matter of law without having to demonstrate that the specific product at issue in the case is defective. The court concluded that consumers have a high expectation of safety for these devices, given the particular vulnerability of patients affected and the "abnormal potential for damage," and that allowing the manufacturer to be held liable reflects "a fair apportionment of the risks inherent in modern technological production between the injured person and the producer."

The Court further held that damages recoverable under the PLD for these defective medical devices include "costs relating to the replacement of the defective product." It noted that there must be "full and proper compensation for persons injured by a

defective product." This includes "all that is necessary to eliminate harmful consequences and to restore to the level of safety which a person is entitled to expect." Here, costs relating to the surgical removal and replacement of the pacemakers were recoverable. Costs for removal and replacement of the implantable cardioverter defibrillators, however, may not be recoverable since the recommended corrective action was that the devices simply be deactivated. The court left it to the German court to determine whether damages for the surgical procedures here were appropriate.

Comment

While the CJEU broadly interpreted the PLD in this case, the legacy of the judgment remains unclear. *Boston Scientific* is necessarily limited to a specific category of medical devices because the court drew from the nature of those devices in its ruling. The decision does not, however, provide any guidance or clue as to how these principles should apply to other types of products. The judgment will also be subject to another layer of interpretation and application by national courts, which could vary widely. It is clear that the CJEU's interpretation of the PLD is generous to consumers and should be carefully considered by manufacturers in analyzing product liability risks in the EU.

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[1] Dir. 85/374, Arts. 3, 4.

[2] Dir. 85/374, Art. 6(1).

[3] Dir. 85/374, Art. 9.

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