Defective Products: Proof of defect and recoverable damages

Boston Scientific Medizintechnik v AOK Sachsen-Anhalt

By Lawrence West QC

1. In **Boston Scientific Medizintechnik GmbH v AOK Sachesen-Anhalt**, the ECJ considered two questions:

(1) Whether pursuant to the Defective Products Directive (85/374/EEC), where it is shown that products belonging to the same group or production series have a potential defect, an individual product within that group or production series can be classified as defective without proof that the individual product in question has that defect; and

(2) Whether the cost of a surgical operation to replace that individual product constitutes damages for personal injury.

Proof of Defect

2. There were two products involved – a pacemaker in respect of which the feared defect was premature battery depletion resulting in a failure of pacing output without notice; and an implantable cardioverter defibrillator in respect of which

the feared defect was a tendency of a switch to stick if the defibrillator was used in a particular mode, the "enable magnet use" mode.

3. The Court held that the safety which the public is entitled to expect of a product must be assessed by taking into account "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 Court noted that in respect of such medical products "in the 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." It also noted that in the circumstances, such a defect in such a product would have an "abnormal potential for damage." The Court therefore held that where it is found that products of that nature belonging to the same group or production series have a potential defect, it is "possible to classify as defective all products within that group or production series" without there being any need to show that the particular product in issue has that defect.

4. It is important to bear in mind the expressed limitations on this ruling of the Court. It does not apply to all products but to products in respect of which the public is entitled to expect a high standard of safety by reason of the nature of the product, the vulnerability of its users and its abnormal potential for damage.

Damages

5. In respect of whether the costs of surgery to replace the product constitute recoverable damage, the Court held that the issue is to be resolved by determining what is essential to eliminate the harmful consequences of the feared defect and to restore the level of safety which a person is entitled to expect of the product.

6. It was clear that the only appropriate remedy for the defective pacemakers was the surgical removal and replacement of the product. Therefore, the cost of that surgery was recoverable damage.

7. However, the manufacturer of the defibrillators contended that the product could be rendered safe without inhibiting its efficacy by disabling the "enable magnet use" mode. The Court remitted the question whether that was in fact so to the national Court.

Comment

8. It is inevitable that attempts will be made to extend the ratio of that part of this decision to all products in respect of which proof of a defect in an individual product is problematic. However, the Court was clear that the

applicability of the judgment was limited to products having the unique qualities which the Court carefully described – products having peculiar functions used by vulnerable individuals where the potential for damage is abnormally high.

9. The Court's resolution of the damages issue was particularly nuanced.

5th March 2015 **Lawrence West QC**