Client Alert

March 2015

European Court Ruling On Product Liability For Defective Medical Devices

On 5 March 2015, the European Court of Justice issued a preliminary ruling on two issues arising under the EU Product Liability Directive in a case involving defective pacemakers and defibrillators. Despite the wide range of issues arising under this directive, the Court has had only a few occasions to construe its ambiguous terms. This case, however, provided an opportunity to the Court to settle key issues relating to the defect test and the scope of damages compensable under the directive.

This alert summarizes the facts and the Court's judgment. It then discusses some of the consequences of the judgment for businesses, both producers and importers.

1. The Facts

A company now owned by Boston Scientific Corporation ("BSC") manufactures and sells pacemakers and implantable cardioverter defibrillators. It imported and marketed in Germany two models of pacemakers manufactured in the United States and an implantable cardioverter defibrillator manufactured in Europe.

By letter of 22 July 2005, addressed to treating physicians, BSC indicated that its quality control system had established that a component utilized to hermetically seal the pacemakers which it marketed may experience a gradual degradation which could adversely affect the device's therapeutic efficacy. That defect could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning. On this basis, BSC recommended that physicians consider replacing such pacemakers for the patients affected. Although the warranty for the pacemakers might have expired, BSC offered to provide replacement devices free of charge for pacemaker-dependent patients and those deemed by their physicians to be best served by replacement.

Not only did the pacemakers have issues, but also the defibrillators had issues. In a letter to physicians in June 2005, BSC announced that an investigation had shown that a magnetic switch in those defibrillators might remain stuck in the closed position. If the "enable magnet use" mode was activated and the magnetic switch became stuck in the closed position, treatment of ventricular or atrial arrhythmias would be inhibited. As a consequence, any cardiac dysrhythmia that could be fatal would not be recognised by the defibrillators and no potentially life-saving shock would be given to the patient. In light of these issues, BSC recommended that treating physicians deactivate the magnetic switch in the defibrillators concerned. If that function is deactivated, the patient monitor feature remains unaffected; it does not result in a health risk, but simply a restriction of the functions which the defibrillator can perform.

German patients received replacement pacemakers and defibrillators and the patients' insurer sought compensation from BSC. In the ensuing proceedings, two issues arose that the Bundesgerichsthof decided to refer to the Court of Justice for a preliminary ruling:

1) "Is Article 6(1) of Directive 85/374 to be interpreted as meaning that a product in the form of a medical device implanted in the human body (in this case, a pacemaker [and an implantable cardioverter defibrillator]) is already defective if [pacemakers] in the same product group have a *significantly increased risk of failure* [or where a *malfunction has occurred in a significant number*

of defibrillators in the same series], but a defect has *not been detected* in the device which has been implanted in the specific case in point?" (emphasis added)

2) "If the answer to the first question is in the affirmative, do the *costs of the operation to remove the product* and to implant another pacemaker [or another defibrillator] constitute *damage* caused by personal injury for the purposes of Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374?" (emphasis added)

2. Are These Medical Devices Defective?

The judgment is based on the Court's interpretation of the directive's "defect" test, which provides that a product is defective if it does not provide the safety which the "public at large" (emphasis supplied) is entitled to expect, taking all the circumstances into account, including "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."

With regard to medical devices such as the pacemakers and implantable defibrillators, the Court reasoned, "it is clear that, 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." (emphasis supplied)

The Court held that the pacemakers and the defibrillator implanted in the patients may be regarded as defective products under the Product Liability Directive without any defect having been proven in an individual device, if "it is found that products belonging to the same group or forming part of the same production series (…) have a *potential* defect." (emphasis supplied)

Unfortunately, the Court's defect ruling is phrased in broad language suggesting that it has application to all products, rather than only to implanted potentially life-saving medical devices. While the judgment does not consider a range of cases, by its terms, it could apply to any product. It is easy to see how this could result in unacceptable outcomes. For instance, if a line of thermostats for home use suffers from a deficiency in design, as a result of which there is a 1% chance of it not measuring the temperature accurately, would it be fine to treat all such thermostats as defective? The concept of a "potential defect" does not work well in this situation.

3. Is the Cost of Replacement Surgery Compensable Damage?

The patients who received the defective pacemakers that posed the increased risk of malfunctioning underwent surgery to replace these pacemakers. The German health insurance organizations claimed reimbursement of the cost they incurred, on the grounds that the cost of replacement surgery involves "damage caused by personal injuries" covered by the Product Liability Directive.

According to the European Court, in light of the objective of protecting consumer health and safety pursued by the directive, the phrase "damage caused by personal injuries" must be given a broad interpretation. This would imply that "[c]ompensation 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." Thus, the Court concludes, in the case of defective medical devices, such as pacemakers and implantable cardioverter defibrillators, "compensation for damage must cover, inter alia, the costs relating to the replacement of the defective product." Given that the manufacturer in the *Boston Scientific* case recommended to surgeons that they consider replacing the pacemakers in question, the Court finds that the replacement costs, including the costs of the surgical operations, constitute damage for which the producer is liable.

With respect to the defibrillators, given that the manufacturer recommended merely that the magnetic switch be deactivated, the Court ruled that "it is for the national court to determine whether, having regard

to the particularly vulnerable situation of patients using an implantable cardioverter defibrillator, the deactivation of the magnetic switch is sufficient for the purpose of overcoming the defect in that 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."

The "*all that is necessary*" formula is particularly vague and leaves open the prospects for claims for compensation of consequential damage, including loss of income and lost profits. In the *Boston Scientific* case, such claims were not asserted and the Court did not explicitly address the issue. Clearly, however, compensation for loss of income and lost profits would be "necessary to eliminate harmful consequences." That does not mean that national courts are now likely to begin to award such claims, not until a further Court ruling clarifies this point.

4. Business Implications

The Product Liability Directive is an undeveloped civil liability regime that leaves many questions unanswered. In the same vein, the Court's ruling answers a few questions, and raises other issues. With this judgment, the defect test and the scope of compensable damages under the directive are not yet settled. The defect test set forth in the Court's *Boston Scientific* judgment is phrased in broad and ambiguous terms. Apparently, the Court believes that medical devices do not meet safety expectation entitlements where no actual patient injuries have occurred due to device malfunctioning, and the statistical chance that a device functions properly is over 99%.

Under the *Boston Scientific* ruling, products from computers and televisions, smoke detectors and sprinklers, thermostats and video cameras, wires, conduits, and pipes incorporated into office buildings and homes, to parts of cars, trains, and airplanes, could expose the producer to extensive liabilities for replacement costs without any product actually having failed and caused damage. Given that the Court's judgment does not attempt to limit the applicability of the potential defect concept to specific product categories or types of users, all producers and importers of products will have incentives to limit its effect by providing extensive risk-related information, including information about potential risks and defects. Potential defects include both lack of performance and positive safety risks. The supply of additional information about such risks may reduce the liability exposure by defining the public's expectations, if the presentation of the product is allowed to play a role in a specific case.

In the case of medicinal products and medical devices, producers will also take great care in drafting alerts and communications addressed to health care professionals about possible product-related issues; a key question is whether the producer will merely inform about such issues or recommend specific remedial steps. In any event, the producer will have reason to anticipate the possible actions that physicians or patients might take, and to consider ways to limit their exposure to the costs associated with such actions, including through prevention, monitoring, supply of risk-related information, and insurance.

How Hunton & Williams Can Help

Hunton & Williams has extensive experience in assisting clients with product liability. We advise clients on a wide range of regulatory and liability matters, including product recall, liability assessment and legal remedies. Working closely with our clients and technical experts, we ensure that our clients' interests are effectively protected.

Hunton & Williams is a global law firm with a strong focus on regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, and in its offices in Brussels, Richmond, Washington, DC and Beijing offices.

Contacts

Prof. Lucas Bergkamp
lbergkamp@hunton.com

Gary C. Messplay
gmessplay@hunton.com

Ann Marie Mortimer
amortimer@hunton.com

Geneviève Michaux
gmichaux@hunton.com

Nicolas Herbatschek
nherbatschek@hunton.com