Read this post online

Defective product liability: Where it is found that a medical device has a potential defect, it is possible to classify as defective all the products belonging to the same group or production series

Directive of July 25, 1985 on liability for defective products (the "Directive") has introduced a strict liability regime under which producers/manufacturers are liable for damage caused by the defectiveness of their products. To enforce this strict liability regime, the aggrieved person is required to prove the defect, the damage and the causal relationship between the defect and the damage.

In a decision issued on March 5, 2015 in relation to a case concerning medical devices, the Court of Justice of the European Union (the "CJEU") ruled on the interpretation of the notions of defective products and reparable damage within the meaning of the Directive.

The CJEU has notably held that where it is found that products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify

as defective all the products in that group or series, without there being any need to show that the product in question is defective.

In the commented case, a US manufacturer and seller of pacemakers and implantable cardioverter defibrillators had these devices imported and marketed, inter alia, in Germany.

Following quality control checks that had revealed the existence of a potential defect affecting the marketed medical devices, the manufacturer recommended physicians to consider replacing the pacemakers for the patients affected, and undertook to make replacement devices available free of charge for such patients. Concerning the defibrillators, the manufacturer merely recommended treating physicians to deactivate the magnetic switch in the relevant defibrillators.

The German compulsory health insurance organizations of the patients whose pacemakers and implantable cardioverter defibrillators were replaced brought an action against the manufacturer before German courts, and requested the reimbursement of the sums incurred in connection with the replacement of these medical devices.

Asked to adjudicate the dispute between the insurers and the manufacturer, the "Bundesgerichtshof" (German Federal Court of Justice) asked the CJEU for a preliminary ruling on whether:

- the replaced pacemakers and implantable defibrillators could be classified as defective within the meaning of the Directive where no defect has been specifically identified on such devices but where the quality control checks performed by the manufacturer on such products have revealed the existence of a potential defect;
- the costs relating to the replacement of such medical products could constitute a damage that the manufacturer must compensate under the Directive.

1. The impact that the existence of potential defect of a medical device may have on the products belonging to the same group or production series

In the first question referred to the CJEU, the referring court was asking "*in essence, whether Article 6(1) of Directive 85/374 is to be interpreted as meaning that, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers or implantable defibrillators, have a potential defect, it is possible to classify such a product as defective, without there being any need to establish that the product in question has such a defect*."

It should first be specified that, pursuant to Article 6(1) of the Directive, a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that the product would be put, and the time when the product was put into circulation.

Based on this definition, the CJEU recalled that the safety which the "*public at large*" is entitled to expect must be assessed "*by taking into account, inter alia, the intended purpose, the objective characteristics and properties of the product in question and specific requirements*".

Regarding the medical devices at issue in the dispute, the CJEU held 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*."

The CJEU also noted that the potential lack of safety for this type of products stems from "*the abnormal potential for damage which those products might cause to the person concerned*."

Based on these considerations, the CJEU held that Article 6(1) of the Directive ought to be interpreted as meaning that "*where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, have a potential defect, such a product may be classified as defective without there being any need to establish that that product has such a defect*".

The CJEU consequently considered that, in the matter at hand, where it is found that the pacemakers and implantable defibrillators belonging to the same group or forming part of the same production series have a potential defect, all the products in that group or series may be classified as defective without there being any need to establish that the relevant product has such a defect.

The solution adopted by the CJEU – which removes the need to establish the existence of the defect of the product at the origin of the damage – should not apply to all types of products. Indeed, the CJEU has, in its decision, relied on this presumption of defectiveness by taking into account, inter alia, the specificities of the product, the particularly vulnerable situation of patients as well as "particularly high" safety requirements for such products.

Yet, this solution could apply to a large number of medical devices, or maybe even to other types of products, the failure rate of which should be close to zero given the risk of death to which users are exposed if such products prove to be defective.

2. Reparable damage, within the meaning of the Directive, must be given broad interpretation

In the second question referred to the CJEU, the referring court was asking "*in essence, whether Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374 are to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes 'damage caused by death or by personal injuries' for which the producer is liable*."

As per the provisions of the Directive referred to in this request for a preliminary ruling, producers are liable

for the "*damage caused by death or by personal injuries*" which are the result of his product being defective.

In this respect, the CJEU observed that the notion of "damage caused by death or personal injuries", within the meaning of the Directive, is to be given a broad interpretation and that "*compensation for damage thus relates to all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect (…)*".

Consequently, in the matter at hand, the CJEU held that "*in the case of medical devices, such as pacemakers and implantable cardioverter defibrillators, which are defective within the meaning of Article 6(1) of Directive 85/374, compensation for damage must cover, inter alia, the costs relating to the replacement of the defective product*".

Pointing out that the manufacturer had recommended to surgeons that they should consider replacing the pacemakers in question, the CJEU found that the costs relating to the replacement of such pacemakers, including the costs of the surgical operations, constitute a damage that the producer is liable to repair.

Regarding the implantable cardioverter defibrillators, the CJEU, noting that the manufacturer had merely recommended that the magnetic switch of those medical devices should be deactivated, considered that it was up to the German 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 CJEU thus confirmed that the notion of damage that a producer must repair, within the meaning of the Directive, must be interpreted broadly. From this judgment, it appears notably that the damage caused by a surgical operation for the purpose of replacing a defective product must be compensated by the manufacturer insofar as such operation is necessary to eliminate the defect of the relevant product.