Trade and Health

The EU Court of Justice broadens the liability for damages caused by defective products of medical devices' producers, importers and distributors

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With a judgment destined to have far-reaching effects, on 5 March 2015 the Court of Justice of the European union ("***CJEU***") decided that, **if a medical device is found to have a manufacturing defect, the liability for damages of producers, importers or distributors shall automatically be extended, in the absence of evidence to the contrary, to all products part of the same production series, without no need to give evidence that the product in question is defective**.

This was the CJEU's response to the questions referred for a preliminary ruling by the German Court of last instance in relation to two actions brought by the company Boston Scientific Medizintechnik GmbH ("***BSC***"), an importer and distributor in the European Union of medical devices and, in particular – for our purposes –, of pacemakers and cardioverter defibrillators manufactured in the US.

The disputes in Germany arose due to some events of 2005: following a number of quality control checks, in June the BSC sent a letter to treating physicians who had used its products to inform them that the magnetic switch in implantable "G. Contak Renewal 4 AVT 6" defibrillators might be affected by a manufacturing defect. Since such component might remain stuck in the closed position, the defibrillator would not be able to recognize any cardiac dysrhythmia that could be fatal, and therefore, it would not give the patient the life-saving shock. In 2009, the mandatory health insurance agency which had covered the costs of a patient who had undergone an operation for the replacement of the defibrillator, asked BSC to reimburse the costs incurred in respect of the patient's treatment. Upon BSC's refusal, the agency started an action before the competent judge. Its claim was upheld by the court of first instance as well as by that of second instance.

In July 2005, the BSC sent a similar letter to inform treating physicians that, this time, a component utilized to hermetically seal the pacemakers could pose a risk of failure that could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output. Although such medical devices were no longer covered by warranty, the BSC undertook to make replacement devices available free of charge to patients with a defective product. After having covered the costs borne by two patients that underwent an operation for the replacement of the pacemaker they received free of

charge, the mandatory health insurance agency, on behalf of such patients, asked that BSC be condemned to reimburse the costs incurred in relation to the operation. Its request was upheld by both the German court of first instance and the court of appeal.
In solving the first of the two questions referred for a preliminary ruling, the CJEU first of all observed that Directive 85/374/CEE on liability for defective products states that 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 use to which it could reasonably be expected that the product would be put*". According to the EU judge, in accordance with such provision, "*the safety which a person is entitled to expect*" must therefore 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 it is intended. **Given the function of pacemakers and implantable cardioverter defibrillators, the safety requirements for such devices which patients are entitled to expect are particularly high**. As a consequence, **where it is found that such products that are part of the same production series have a defect, it is possible to classify as defective all the products in that series, without there being any need to show that the product in question is defective**.

Furthermore, on the second issue, aimed at establishing the extent of the costs that the producer must cover, in that they are related to damages caused by the defective product, the EU judge has clarified that, in order for a producer, an importer and/or distributor to incur liability, it is necessary to give evidence that there is a causal relationship between the defect and the damage suffered. **Therefore, the compensation relates to all costs borne to restore the level of safety which a person is entitled to expect**. So, apart from including the costs of damages caused to health, it shall also cover all replacement costs, those necessary for the operation and to restore the normal functioning of the medical devices at issue.

With this judgment, the CJEU has broadened the scope of liability of producers, importers and distributors of medical devices, who are required to constantly ensure particularly high safety requirements.

The innovative quality of judge's interpretation can be seen in the introduction of a "*presumption of potential defect*" for all products part of the same production series, without there being any need to show that every single product is defective. As a consequence, there is a reversal of the burden of proof according to which the damaged party is not required to prove the defect, the damage and the relevant causal relationship.

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