The importance of quality and safety controls for medical devices

Judgement of the Supreme Court of 1 March 2021

Background

A manufacturer of a hip prosthesis, after becoming aware that the product had to be revised more often than expected, issued a safety notice recommending wearers of the affected prosthesis to follow a specific monitoring and control plan. Several months later, the manufacturer voluntarily withdrew the product from the market. Afterwards, a patient underwent a clinically indicated surgery for the replacement of one of the manufacturer's prosthesis that had previously been implanted to her. Such patient filed a product liability claim against the manufacturer which was dismissed by the lower Courts because the prosthesis could not be proven as defective.

In this judgement, the Supreme Court reverses the decisions of the lower Courts and provides interesting statements regarding how the concepts "defective product" and "safety which may reasonably be expected", both very relevant to determine the liability of manufacturers for defective products, should be interpreted.

Safety which may reasonably be expected

As per the Supreme Court, a manufacturer may be held liable under product liability regulations not only for damages caused by products infringing safety and quality regulations but also for damages caused by products that, despite having undergone safety and quality controls, remain "unsafe".

The relevant time to determine whether a product is unsafe/defective is the time when the product is put into circulation. According to the Supreme Court, although the voluntary withdrawal of a product from the market does not necessarily mean that the product was defective at the time it was put into circulation, it may indeed constitute an indication that at that time the product did not comply with the safety standards which may reasonably be expected from it.

In the proceeding, the manufacturer alleged that the prosthesis only had minor and punctual failures and that, in the majority of cases, it worked well in accordance with its purpose. Further, the manufacturer alleged that there was no proof that the damages were caused by the prosthesis itself and that the withdrawal of the product from the market had been entirely voluntary.

The Supreme Court does not accept these claims and considers that the fact that the prosthesis had an unexpected high rate of revisions must prevail. As per the Court, this high rate of revisions, which was neither identified nor disclosed by the manufacturer at the time the product was put into circulation (and therefore was not known by the medical community and the relevant notified bodies at that time), shows that the risks posed by the prosthesis were higher than expected. In these circumstances, the Supreme Court concludes that it falls on the manufacturer to prove why it was not possible to identify and disclose the true risks of the device (that ultimately caused the need to withdraw the product from the market) at the time the product was put into circulation.

Loss of the allegedly defective prosthesis

The lower Courts dismissed the claims of the plaintiff because, among other reasons, the allegedly defective prosthesis was lost, and it was therefore impossible to prove that it was defective.

The Supreme Court rejects this argument and considers that the fact that the prosthesis was lost does not prevent the Court to determine that the prosthesis was unsafe to the extent it posed a higher risk than expected. Further, the Court notes that the plaintiff's need for a prosthesis replacement was related to the reasons why the manufacturer previously withdrew the product from the market.

No causes attributable to the plaintiff

To uphold the product liability claim, the Supreme Court takes into account that the replacement of the prosthesis was not attributable to the plaintiff. Blood values consistent with the wear of the prosthesis and the absence of other reasons explaining the need to replace it are the proven facts that allow the Court to conclude that the replacement of the prothesis was not attributable to the plaintiff. Finally, the Court clarifies that the consequences of the replacement of the prosthesis cannot be deemed as an "unavoidable risk" of the product.

Conclusions

Safety and quality controls performed by manufacturers before putting a medical device into circulation are of utmost importance. If such controls are not adequate to identify a defect of the product, the manufacturer may be liable for such defect. If unexpected risks arise after the product is put into circulation, it falls on the manufacturer to prove why it was not possible to identify and disclose such risks at the time the product was put into circulation. Finally, it will be on the Court to decide on a case-by-case basis whether the allegations of the manufacturer are sufficient to exonerate manufacturer from liability or not.