Capsulas

The value of evidence in claims for damage caused by a defective product

Regarding the Judgment of the Provincial Court of Barcelona of 21 October 2025

On 9 December 2026, the deadline for Member States to transpose the Product Liability Directive will expire. The Judgment under review, concerning an allegedly defective hip prosthesis, addresses important issues in determining when a product is defective - issues that are particularly relevant in light of the Directive's new evidentiary presumptions.

Voluntary withdrawal does not imply that the product is defective

One of the first points made by the Court is that the mere voluntary withdrawal of a product from the market does not, in itself, constitute proof of its defective nature.

Safety measures such as the withdrawal of the product by a regulatory authority or by the company responsible may be taken into account by the court when assessing whether a product is defective. However, these actions should not, on their own, give rise to an automatic presumption of defectiveness. Their assessment must always be made in conjunction with the other circumstances and evidence of the specific case.

The existence of judicial precedents concerning the product

The Court also recalls that, when deciding on the alleged defective nature of a product, other judicial proceedings are not conclusive, even if they concern the same product.

Although precedents may be taken into account as one factor in the overall analysis, they do not by themselves determine whether the product is defective. Each proceeding must be resolved based solely on the evidence presented in that specific case and on the litigation strategy followed by each party.

In this regard, the Court emphasises that only evidence that is included in the case file and has been validly submitted within the framework of the proceedings in question is relevant.

The importance of clarifying that the product's failure was not due to a defect

Finally, it is worth highlighting an additional consideration that emerges from the Judgment: the importance of identifying possible causes other than the alleged defect that may have contributed to or caused the damage claimed.

In this case, the Court considers that if it is not possible to clearly determine the cause of the damage, or reasonably rule out other explanations, the product may be considered defective by resorting to indirect evidence or even presumptions.

Conversely, if it can be demonstrated that the damage was caused by external factors unrelated to the product's design or manufacture - such as incorrect use, improper handling, or lack of maintenance - such presumptions of defectiveness may be rebutted.

Evidentiary challenges and the impact of the new Directive

Overall, the Judgment underscores the central role of evidence in product liability claims.

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As noted, the deadline for transposing the new Product Liability Directive expires at the end of this year, introducing significant changes to the evidentiary framework and the allocation of the burden of proof.

In order to assist claimants in proving their case, the new Directive establishes a number of evidentiary rules that must be carefully considered and that make it advisable for companies to adopt measures aimed at avoiding presumptions of defectiveness.

The new Directive allows courts to order the defendant to disclose relevant documents - even confidential ones - to enable the claimant to substantiate their case. If the defendant fails to comply with such a disclosure order, a presumption that the product is defective may arise.

Furthermore, courts may presume defectiveness in three additional situations:

i. where the product fails to comply with applicable safety requirements;

ii. where the damage results from an obvious malfunction during normal use; or

iii. where, considering all relevant circumstances, the claimant faces excessive difficulties due to technical or scientific complexity in proving the defectiveness of the product, or provided the claimant demonstrates that it is likely that the product is defective.

These rules may, in practice, lead to a partial reversal of the burden of proof, requiring manufacturers and suppliers to demonstrate that their product was not defective. This makes it essential to comply with any court-ordered disclosure, to maintain documentation evidencing regulatory compliance, and, where appropriate, to provide evidence of the product's proper functioning under normal conditions.

For all these reasons, it is advisable to maintain documentation and records relating to product design and development, safety testing, manufacturing processes, storage conditions and quality control in a systematic and organized manner, as well as complete and traceable product file documentation. In addition, having protocols that facilitate compliance with any document disclosure request may be highly useful.

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