IADC COMMITTEE NEWSLETTER

# PRODUCT LIABILITY

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*While the proposal for a new Directive on liability for defective products is being discussed at European level, Courts are regularly questioned on how the risk of development defense (allowing the producer to argue that it did not know of all risks at the time the product was put into circulation) should be interpreted and how liability for defective products and liability for negligence should interact. This article discusses the recent findings of the French Supreme Court for the pharma industry, leading to even more questions, this industry being treated differently from others.*

# Liability for Defective Products and the Pharma Industry: What's New in the EU & France?

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## ABOUT THE COMMITTEE

The Product Liability Committee serves all members who defend manufacturers, product sellers and product designers. Committee members publish newsletters and *Journal* articles and present educational seminars for the IADC membership at large and mini-seminars for the committee membership. Opportunities for networking and business referral are plentiful. With one listserv message post, members can obtain information on experts from the entire Committee membership. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

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As the year has just started and as a proposal for a new Directive on liability for defective products is being discussed at the European level, this article focuses on two French decisions that mark the regime governing liability for defective products in 2023.

The first one concerns the so-called risk of development defense (allowing the producer to argue that it did not know of all risks at the time the product was put into circulation), and the other relates to the possible coexistence of liability for defective products and liability for negligence.

- **Conformity to the Constitution of the enforceability conditions of the exemption cause based on the risk of development (Constitutional Council, referral for a preliminary ruling (QPC), March 10, 2023, no. 2023-1036)**

Pursuant to the rules governing defective products, the producer is, in principle, automatically liable in the event of a defect in the product. However, there are several exemption causes, including the one provided for by Article 1386-11 of the former French Civil Code (now Article 1245-10, §1, 4°) according to which: "*The producer is automatically liable unless they can prove […] that the scientific and technical knowledge at the time when the product was put into circulation, did not enable to detect the existence of the defect". This is "the risk of development defense*".

Article 1386-12 of the former French Civil Code (now Article 1245-11 of the French Civil Code), subject-matter of the above-referenced referral for a preliminary ruling, however, provides that "*The producer cannot rely on the exemption cause of 4° of Article 1386-11 when the damage was caused by an element of the human body or by the products deriving therefrom*".

As a reminder, this exemption based on the risk of development is provided for by Article 7 of Directive 85/374/EEC of July 25, 1985, transposed into French law by Law 98-389 of May 19, 1998. The Member States were however free to dismiss it. In France, the choice was made to keep this exemption except "*when the damage was caused by an element of the human body or by the products deriving therefrom*". This choice has an historical explanation: the adoption of the transposition law during the years that followed the contaminated blood scandal (case relating to transfused blood contaminated with HIV), which rendered the concept of a possible exemption in this context unacceptable.

The referral at hand was decided in the scope of another judicial saga: the one related to Mediator®. Several patients brought a liability action against the laboratory having produced the product due to heart diseases allegedly attributed to this medicine. Whereas the Nanterre Civil Court had, by judgment dated January 16, 2020, acceded to the claims of one of them by ordering the laboratory to indemnify him, the Versailles Court of Appeal, by decision dated March 24, 2022 (no. 20/04766), reversed this decision by admitting an exemption to the benefit of the laboratory on the ground of the risk of development.

An appeal before the French Supreme Court was lodged against this decision, in the scope of which the plaintiffs requested a preliminary ruling from the Constitutional Council, which was referred to it by decision dated January 5, 2023 (French Supreme Court, 1st Civil Chamber, January 5, 2023, no. 22-17.439). The question was the following:

> "*Are the provisions of Article 1386-12 of the French Civil Code, identically reproduced in Article 1245-11 of the French Civil Code in its wording resulting from Order 2016-131 of 10 February 2016, insofar as they limit to the damage caused by an element of the human body or the products deriving therefrom the inability for the producer from relying on the exemption cause provided for by Article 4° of Article 1245-10, formerly 1386-11, leading to discrimination between the victims of bodily injury resulting from a health product depending on whether this product derives or does not derive from the human body, contrary to the principle of equality in law as defined by Articles 1 and 6 of the Declaration for the rights of Man and citizens of 1789?".*

In other words, the plaintiffs accused the provisions of Article 1386-12 of the former French Civil Code, now Article 1245-11 of the French Civil Code, of being at the origin of an unjustified difference in treatment between the victims of damage caused by an element of the human body or a product deriving therefrom, and the victims of damage caused by other health products, insofar as only the latter could be faced with the exemption cause based on a risk of development and hence be deprived of indemnification.

The Constitutional Council first of all affirmed that "*the principle of equality does not prevent the legislator from settling differently different situations, or from setting equality aside for reasons pertaining to general interest, provided that, in one case and the other, the resulting difference in treatment is directly related to the subject-matter of the law establishing it".* Secondly, admitting that Article 1386-12 of the former French Civil Code establishes a *"difference in treatment in the determination of the producer's liability"*[1], the Constitutional Council ruled that this difference in treatment is justified *"in light of the nature and specific risks of the elements of the human body and products deriving therefrom"*[2].

The Constitutional Council concluded that *"the difference in treatment resulting from the challenged provisions, based on a difference in situation, relates to the subject-matter of the Law"*[3] and ruled that these provisions were compliant with the Constitution.

While this decision is in line with previous decisions of the Constitutional Council on

[1] Recital 11 of the decision
[2] Recital 12 of the decision
[3] Recital 14 of the decision.

the principle of equality[4], one can nevertheless regret that its concise explanations fail to address two issues which are yet essential. On the one hand, the Council does not explain the real difference between the elements of the human body and the products deriving therefrom, and the other products justifying such a difference in treatment. Indeed, the obscure wording according to which the elements of the human body entail *"specific risks"* is not satisfactory. Only the historical context seems to still today justify this difference in treatment.

Furthermore, the Council does not provide any explanation on the definition of the *"elements of the human body and products deriving therefrom*", merely referring to the chapter of the French Public Health Code, which does also not provide any actual definition.

Lastly, it ought to be noted that, while its deletion had been contemplated, Article 10 e) of the proposal for a new Directive on liability for defective products[5] still provides for an exemption based on the risk of development. However, unlike the current Directive, the proposal no longer provides for the possibility for Member States to dismiss this exemption. Consequently, should this proposal be definitively adopted, the French legislature would be compelled to delete the current Article 1245-11 of the French Civil Code.

- **Action against the producer: possible coexistence between the rules on defective products and fault liability (French Supreme Court, 1st Civil Chamber, November 15, 2023, nos. 22-21.174, 22-21.178, 22-21.179, 22-21.180)**

In 2023, the judicial saga relating to Mediator® also led the French Supreme Court to rule on the possibility for a patient to seek liability for fault of the producer rather than the latter's liability on the ground of defective products. The implementation of the rules governing liability for defective products and the other liability rules is provided for in Article 1245-17 of the French Civil Code, according to which: "*the provisions of this Chapter shall not prejudice the rights that the victim of damage may seek on the ground of contractual or extracontractual liability or special liability rules. The producer shall remain liable for the consequences of their fault and of the persons acting on their behalf*".

Therefore, the rules governing defective products do not necessarily exclude all other contractual or extracontractual liability rules. Indeed, pursuant to a long line of case law, the French Supreme Court affirmed that "the rules governing liability for defective products exclude the application of other ordinary contractual or extracontractual

[4] See, for instance: Constitutional Council, 23 July 2010, no. 2010-18 referral for a preliminary ruling (*QPC*); Constitutional Council, 13 June 2014, no. 2014-401 QPC; Constitutional Council, 28 April 2017, no. 2017-626 QPC; Constitutional Council, 27 January 2023, no. 2022-1033 QPC.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0495

liability rules based on the defect of a product that does not offer the safety one can legitimately expect, with the exception of fault liability and the warranty for hidden defects" (French Supreme Court, Commercial Chamber, May 26, 2010, no. 08-18.545, see in the same line: French Supreme Court, Commercial Chamber, December 10, 2014, no. 13-14.314).

Nevertheless, the difficulty in making a distinction between the safety defect of a product and a potential wrongful breach committed by the producer in safety matters led to case law dismissing nearly each application of the fault liability in the presence of a safety issue. It is in this line that the Court concluded: "*it is now a well-established principle that if, pursuant to Article 1386-18, now 1245-17 of the French Civil Code, the rules governing liability for defective products do not harm the rights that the victim of damage may seek on the ground of contractual or extracontractual liability or special liability rules, it is provided that they rely on different grounds, such as the warranty for hidden defects or a fault*". The Versailles Court of Appeal, pursuant to several decisions handed down on July 7, 2022 (nos. 21/06054, 21/06045, 21/06052, 21/06043), ruled that the claimant's action was time-barred on the ground that it had not been brought within the three-year period provided for by Article 1245-16 of the French Civil Code.

The Court ruled that "*a claim based on the breach of the duty of care and surveillance can only be invoked in the scope of the action on the ground of liability for defective products and cannot constitute a different fault than the alleged defect*", meaning that the fact that a laboratory sold a product knowing it presents risks without informing patients, did not constitute a different fault likely to trigger the tort liability of the laboratory. The Court even added that "*the distinction made by the appellant between the sale of the defective product, involving the exclusive implementation of the rules governing liability for defective products, and the continuation of this sale, which itself would be wrongful and would hence lead to the right to apply the rules governing fault liability is artificial and is not based on any relevant arguments*".

This is the reasoning that was quashed by the First Civil Chamber of the French Supreme Court in four decisions handed down on November 15, 2023. The Supreme Court affirmed its standard position according to which the victim of a defective product can also act against the producer to seek the latter's contractual or extracontractual liability, provided that they establish that the damage results from a different fault committed by the producer. It then specified that such a fault is constituted by "*keeping the product into circulation when [the producer] was aware of the defect or a breach of the latter's duty of care regarding the risks entailed by the product*".

While the principle of this decision is not new, it provides new insight in what this "*different fault*" can be, hence allowing the claimant to avoid the application of the statute of limitations of the rules governing defective products, which is sometimes

stricter. It is also in line with a trend of case law in favour of the victims and requires paying attention to the procedural choices to which these decisions could lead.

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