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PRODUCT LIABILITY IN THE EUROPEAN UNION—EXTINCTION OF THE RIGHT TO SUE AFTER 10 YEARS

Sanofi Pasteur S.A. of France advised by Arnold & Porter (UK) LLP has won an important victory in the Supreme Court of the United Kingdom in a case defining the limits of liability for damage caused by defective products imposed by the Product Liability Directive (Council Directive 85/374/EEC).[1] The judgment in *OB v Aventis Pasteur S.A. [2010 UKHL 23]* will interest all manufacturers selling consumer goods into the European Union and their insurers. It reinforces the original intention of the European legislators to limit strictly the temporal scope of liability for defective products under the Product Liability Directive to 10 years from the date when the product was put into circulation. The protracted attempts of the claimant in the last nine years that this case has occupied the courts of the United Kingdom and Europe to argue that national courts retain discretion to extend the strict limit on claims has now been forcefully rebuffed by the Supreme Court, interpreting a second judgment of the Court of Justice in Luxembourg.

The claim arose out of the vaccination of a child with a HiB vaccine, administered to prevent the serious complications of childhood infection with the bacterium, haemophilus influenzae Type B. He alleged that the product was defective and caused him brain damage. He began proceedings against Aventis Pasteur MSD Limited (APMSD), now a joint venture between Aventis Pasteur and Merck, but, at the time of supply, a wholly owned subsidiary of Aventis Pasteur. He asserted a claim against them as the manufacturer of the product pursuant to the Consumer Protection Act 1987, the domestic legislation transposing the Product Liability Directive into English law. In its defence, APMSD pointed out that it was not the manufacturer, but merely the distributor of the product. In response to a further request APMSD identified Aventis Pasteur S.A. (APSA, now Sanofi Pasteur S.A.) as the manufacturer of the product.

After a delay of six months, the claimant issued separate proceedings against APSA alleging that it was the producer of the product and claiming damages against it. APSA defended the action, *inter alia*, on the basis that it had put the product into circulation more than 10 years before those

1 A copy of the full judgment and a summary for the press can be found on the website of the Supreme Court at www.supremecourt.gov.uk.

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proceedings were launched, arguing in its defence that any claim was, therefore, extinguished. APSA relied on Section 11A(3) of the Limitation Act 1980 and Article 11 of the Product Liability Directive. Some further months later, the claimant applied for an order that APSA be substituted as defendant in place of APMSD, basing its application on Sections 35(5)(b) and (6)(a) of the Limitation Act 1980 and Rule 19.5(3)(a) of the Civil Procedure Rules (CPR).

The essence of the claimant's case on substitution was that he had been mistaken as to the identity of the producer and that the English courts had a discretion to take this subjective mistake into account to allow the substitution, despite the clear words of Article 11 of the Product Liability Directive. The Directive provides that:

> "Member States shall provide in the legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of ten years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer."

In order to determine whether such national discretion did indeed exist the parties agreed, before any trial of the issues took place, to a preliminary reference to the Court of Justice. The reference asked the Court of Justice, in addition to interpret the meaning of "put into circulation" in Article 11 of the Directive, as fixing this point would determine when the 10 years had begun to run.

The Court of Justice [2006] 1WLR 1606, at page 1622, rejected the claimant's argument that a product was not put into circulation until it was supplied by a distributor to a consumer instead determining that:

> "Article 11 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products is to be interpreted as meaning that a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed."

On the question of whether substitution is permitted the Court of Justice held:

> "When an action is brought against a company mistakenly considered to be the producer of a product whereas, in reality, it was manufactured by another company, it is as a rule for national law to determine the conditions in accordance with which one party may be substituted for another in the context of such an action. A national court examining the conditions governing such a substitution must, however, ensure that due regard is had to the personal scope of Directive 85/374, as established by Articles 1 and 3 thereof."

This ruling was memorably described to the House of Lords as truly delphic, each party understanding the Court of Justice to have ruled in its favour. Teare J and the Court of Appeal agreed with the claimant that the ruling meant that substitution could take place, the English court exercising a discretion to allow substitution outside 10 years despite the clear wording of Article 11 of the Product Liability Directive. Four members of the House of Lords agreed with the lower courts but Lord Rodger was not convinced that the matter was clear. A second preliminary reference was, therefore, made to the Court of Justice.

In December 2009, the Court of Justice returned an answer:

> "Article 11 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products must be interpreted as precluding national legislation, which allows the substitution of one defendant for another during proceedings, from being applied in a way which permits a "producer" within the meaning of Article 3 of that directive, to be sued, after the expiry of the period prescribed by that Article, as defendant in proceedings brought within that period against another person."

As Lord Rodger observed, when the judgment came to

be considered by the new Supreme Court, the answer could not be clearer. Once 10 years have passed since the producer put a product into circulation, that producer cannot be sued, unless proceedings have been taken against it within the 10-year period. No concept of subjective mistake may be relied upon by a national court to keep alive a claimant's rights once that uniform 10-year period has passed.

The Court of Justice had adopted this approach because, in its view, it gave effect to the balance which the Community legislature had intended to achieve between the interests of consumers and producers. The Court of Justice recognised that liability pursuant to the Product Liability Directive represents for the producer a greater burden than under the traditional system of liability and that the Community legislature's intention had been to limit in time the no fault liability established by the Product Liability Directive, taking into account the need not to restrict technical progress and to maintain the possibility of insuring against risks connected with that specific liability. The Court of Justice had confirmed that the Product Liability Directive laid down objective harmonised rules which meant that the national court had no discretion to take account of subjective elements such as mistake.

A further hearing before the Supreme Court was, nevertheless, necessary following the second judgment of the Court of Justice because the claimant argued that the clear words of the response to the preliminary reference were to be modified by further guidance given in the judgment. The claimant argued that this guidance effectively carved out from the scope of the judgment a situation where (1) a producer supplied a product to its wholly owned subsidiary, and (2) the producer determined that the product should be put into circulation by that supply.

Happily, a careful analysis by Lord Rodger of the Advocate General's opinion advising the Court of Justice on the second reference led him to conclude that that argument was "internally incoherent as well as being inconsistent with the reasoning of the Court of Justice". Lord Rodger found that any ambiguity in the judgment of the Court of Justice could be resolved by reading in the three words "whether the putting into circulation of the product in question *by the supplier* was, in fact, determined by the parent company which manufactured it". The Supreme Court, therefore, allowed Sanofi Pasteur's appeal and set aside the Order of Teare J substituting Aventis Pasteur S.A. for Aventis Pasteur MSD. One consequence of this judgment is that the decision of the Court of Appeal in *Horne-Roberts v SmithKline Beecham Plc & Another* [2002] 1 WLR 1662, in which a discretion to substitute an unrelated defendant was exercised after the 10-year period had expired is no longer good law.

It remains to be seen whether the claimant, who has been publicly funded throughout, continues his claim on a different basis against either Sanofi Pasteur S.A. or Sanofi Pasteur MSD Ltd.

The Opinion of Advocate General Trstenjak, the second judgment of the Court of Justice, in Grand Chamber, and the judgment of the Supreme Court, thus, emphatically restate what might have been thought to have been clear all along from Article 11 of the Product Liability Directive—that a producer's liability is extinguished 10 years from the date on which it put the product into circulation. Consumers have a much longer period under the Product Liability Directive than under most systems of national law to bring a claim in the event that they allege damage caused by a product but producers should now be able, with confidence, to arrange their affairs, including their insurance coverage, to meet any liability that may arise.

It has taken nearly 10 years to determine that 10 years in Article 11 really does mean 10 years.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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