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Judgment of the Court of Justice in Case C-127/04

Declan O’Byrne v Sanofi Pasteur MSD Ltd, formerly Aventis Pasteur MSD Ltd & Sanofi Pasteur SA, formerly Aventis Pasteur SA

THE COURT OF JUSTICE STATES, IN RELATION TO LIABILITY FOR DEFECTIVE PRODUCTS, THAT THE TERM ‘PRODUCER’ CAN INCLUDE A DISTRIBUTION SUBSIDIARY

Where one of the entities in a distribution chain for medication is closely connected to the producer, it is necessary to determine whether as a consequence of that link, that entity is in reality involved in the manufacturing process of the medication

In November 1992, the child plaintiff Declan O’Byrne was vaccinated with an antihaemophilus vaccine dose in a medical surgery in the United Kingdom. Following that vaccination, he suffered severe injury.

Eight years later, he brought an action for damages against Aventis Pasteur MSD Ltd (‘APMSD’), a company incorporated under the law of England and Wales, claiming that the damage inflicted on him had been caused by a defective vaccine produced by that company. The company was a wholly-owned subsidiary of Aventis Pasteur SA (‘APSA’), a company incorporated under French law, and acting as a distributor of APSA’s products in the United Kingdom.

In October 2002, proceedings were lodged in a second action against APSA. Legal counsel for Declan O’Byrne indicated to the referring court that it was not until the summer of 2002 that it became clear to them for the first time that the producer of the product was in fact APSA and not APMSD. APSA maintained, however, that the action against it was statute-barred in so far as the action lodged in October 2002 was commenced after the expiry of the period of 10 years for bringing an action provided for in the directive on liability for defective products.¹

¹ 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 provides that ‘the rights

The High Court of England and Wales (Queen's Bench Division), before which this case has been brought, asks the Court of Justice of the European Communities whether, where a product is transferred by a producer to a distribution subsidiary and sold by that subsidiary to a third party, the putting into circulation of the product occurs at the time of the transfer of the product from the producer to the subsidiary, or later, when that product is transferred by the subsidiary to the third party. It asks, furthermore, whether it is possible to view such an action as being brought against the producer and to substitute the latter, as defendant to the action, for the company against which proceedings were initially taken.

The Court of Justice notes that the Directive does not define the concept of 'put into circulation', which is referred to in the provision which lays down the rights conferred on the injured person pursuant to the Directive. That provision is of a neutral character, its aim being to satisfy the requirements of legal certainty, and must therefore be interpreted on the basis of objective criteria. It follows that **a product must be considered as having been put into circulation when it leaves the production 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.**

However, **where one of the entities in the distribution chain is closely connected to the producer**, for example, in the case of a wholly-owned subsidiary, **it is necessary to establish whether it is a consequence of that link that that entity is in reality involved in the manufacturing process of the product concerned.** The examination of such a close relationship must not be influenced by the question of whether or not distinct legal persons are involved. The fact that the products are invoiced to a subsidiary company and that the latter, like any purchaser pays the price is not conclusive. The same applies to the question of knowing which entity is to be considered as owner of the products. **It is for the national courts to establish, having regard to the circumstances of each case, whether the links between the producer and another entity are so close that the concept of producer also includes that latter entity and that the transfer of the product from one to the other of those entities does not amount to putting it into circulation.**

Finally, as regards the possibility of substituting the producer, as defendant to the action, for the subsidiary initially proceeded against, the Court concludes that **it is for national law to determine the conditions in accordance with which a substitution can take place in such an action**, ensuring that due regard is had to the scope of the term "producer" within the meaning of the Directive.²

conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 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' (OJ 1985 L 210, p.29).

² Article 3 of the Directive defines the term "producer".

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Languages available: CS EN FR DE HU SK

*The full text of the judgment may be found on the Court's internet site
<http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-127/04>
It can usually be consulted after midday (CET) on the day judgment is delivered.*

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