JUDGMENT OF THE COURT (First Chamber)

9 February 2006 *

In Case C-127/04,

REFERENCE for a preliminary ruling under Article 234 EC by the High Court of Justice of England and Wales, Queen's Bench Division (United Kingdom), made by decision of 18 November 2003, received at the Court on 8 March 2004, in the proceedings

Declan O'Byrne

v

Sanofi Pasteur MSD Ltd, formerly Aventis Pasteur MSD Ltd,

Sanofi Pasteur SA, formerly Aventis Pasteur SA,

* Language of the case: English.

THE COURT (First Chamber),

composed of P. Jann (Rapporteur), President of the Chamber, K. Schiemann, K. Lenaerts, E. Juhász and M. Ilešič, Judges,

Advocate General: L.A. Geelhoed,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 7 April 2005,

after considering the observations submitted on behalf of:

— Declan O'Byrne, by S. Maskrey QC and H. Preston, Barrister, instructed by K. Pickup, Solicitor,

— Sanofi Pasteur MSD Ltd and Sanofi Pasteur SA, by G. Leggatt QC and P. Popat, Barrister,

— the Italian Government, by I.M. Braguglia, acting as Agent, assisted by P. Gentili, avvocato dello Stato,

— the Commission of the European Communities, by X. Lewis and G. Valero Jordana, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 2 June 2005,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of 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 (OJ 1985 L 210, p. 29; 'the Directive').

2 The reference was made in the course of proceedings between Declan O'Byrne and Sanofi Pasteur MSD Ltd, formerly Aventis Pasteur MSD Ltd ('APMSD'), and Sanofi Pasteur SA, formerly Aventis Pasteur SA ('APSA'), concerning the putting into circulation by the latter of an allegedly defective vaccine, the use of which, it is claimed, had caused him serious injury.

Legal context

Community law

3 Article 1 of the Directive provides that '[t]he producer shall be liable for damage caused by a defect in his product'.

4 Article 3 of the Directive, which defines the term producer, is worded as follows:

'1. "Producer" means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

2. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

3. Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.'

5 Article 7 of the Directive provides:

'The producer shall not be liable as a result of this Directive if he proves:

(a) that he did not put the product into circulation;

...'

6 The 10th recital in the preamble to the Directive states that 'a uniform period of limitation for the bringing of action for compensation is in the interests both of the injured person and of the producer'. In that regard, Article 11 of the Directive provides:

'Member States shall provide in their legislation that the rights 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.'

National law

The Directive was implemented in the United Kingdom by means of Part I of the Consumer Protection Act 1987 ('the 1987 Act'), which came into force on 1 March 1988. Section 4 of the Act provides as follows:

'(1) In any civil proceedings by virtue of this Part against any person in respect of a defect in a product it shall be a defence for him to show:

...

(b) that the person proceeded against did not at any time supply the product to another; or

...

(d) that the defect did not exist in the product at the relevant time;

...'

8 In addition, the 1987 Act added to the Limitation Act 1980 a new section 11A, subsection 3 of which provides:

'An action to which this section applies shall not be brought after the expiration of the period of 10 years from the relevant time ...; and this subsection shall operate to extinguish a right of action and shall do so whether or not that right of action had accrued, or time under the following provisions of this Act had begun to run, at the end of the said period of 10 years.'

The main proceedings and the questions referred for a preliminary ruling

9 It follows from the terms of the order for reference that the child Declan O' Byrne was vaccinated on 3 November 1992 with an antihaemophilus vaccine in a medical surgery in the United Kingdom.

10 Following that vaccination the child suffered severe injury. He claims that his injuries were caused by the fact that the vaccine which was administered to him was defective.

11 The producer of the vaccine was Pasteur Mérieux Sérums et Vaccins SA, a company incorporated under French law which, on changing its name, became APSA.

12 On 18 September 1992 APSA had sent a consignment of units of the vaccine, including that which was administered to Declan O'Byrne, to Mérieux UK Ltd, a

company incorporated under the law of England and Wales, which changed its name to become APMSD. That latter company, which was a wholly-owned subsidiary of APSA and acted as a distributor of their products in the United Kingdom, received the consignment at issue on the following 22 September. On delivery APSA sent an invoice which was duly paid by APMSD.

13 At a later date, which remains unknown, part of the consignment was sold by APMSD to the Department of Health of the United Kingdom and delivered by APMSD directly to a hospital nominated by the Department of Health. The hospital in turn supplied it to the surgery where the child was vaccinated on 3 November 1992.

14 On 2 November 2000, the claimant in the main proceedings brought a first action for damages against APMSD, claiming that the latter was the producer of the product.

15 On 7 October 2002, proceedings were lodged in a second action against APSA. Those advisers indicated that it was not until during 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.

16 In those second proceedings, APSA maintains that the action against it is statute-barred. It maintains that, since the product was put into circulation by its delivery of 18 September 1992 to APMSD, which received it on the following 22 September, the action, the proceedings in which were lodged only on 7 October 2002, was commenced after the expiry of the period of 10 years for bringing an action provided for by Section 11A(3) of the 1987 Act, which transposed Article 11 of the Directive.

17 According to the claimant in the main proceedings, the action is not statute-barred. The putting into circulation of the product did not take place until the moment when it was supplied by APMSD to the hospital nominated by the Department of Health. That delivery was effected on a date less than 10 years prior to the bringing of the second action.

18 On 10 March 2003, however, those advisers applied to the referring court for an order in the first action, brought on 2 November 2000, that APSA be substituted for APMSD.

19 It was in those circumstances that the High Court of Justice of England and Wales, Queen's Bench Division, decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'1. On a true interpretation of Article 11 of the ... Directive, when a product is supplied pursuant to a contract of sale by a French manufacturer to its wholly-owned English subsidiary, and then by the English company to another entity, is the product put into circulation:

(a) when it leaves the French company; or

(b) when it reaches the English company; or

(c) when it leaves the English company; or

(d) when it reaches the entity receiving the product from the English company?

2. Where proceedings asserting rights conferred on the claimant pursuant to the ... Directive in respect of an allegedly defective product are instituted against one company (A) in the mistaken belief that A was the producer of the product when in fact the producer of the product was not A but another company (B), is it permissible for a Member State under its national laws to confer a discretionary power on its courts to treat such proceedings as "proceedings against the producer" within the meaning of Article 11 of the ... Directive?

3. Does Article 11 of the ... Directive, correctly interpreted, permit a Member State to confer a discretionary power on a court to allow B to be substituted for A as a defendant to proceedings of the kind referred to in Question 2 above ("the relevant proceedings") in circumstances where:

(a) the period of 10 years referred to in Article 11 has expired;

(b) the relevant proceedings were instituted against A before the 10-year period expired; and

(c) no proceedings were instituted against B before the expiry of the 10 year period in respect of the product which caused the damage alleged by the claimant?'

Concerning the first question

20 By its first question the referring court asks essentially whether, in the case where a product is transferred by a producer company to a distribution subsidiary and sold by that subsidiary to a third party, Article 11 of the Directive is to be interpreted as meaning that the putting into circulation of the product occurs at the time of the transfer of the product from the production company to the subsidiary, or instead when that product is transferred by the subsidiary to the third party.

21 The claimant in the main proceedings, the Italian Government and the Commission of the European Communities consider that the putting into circulation of a product depends on the producer's loss of control over that product or that it occurs when the product was transferred to a person over whom the producer does not have any authority. It is the entry of the product into the chain of distribution by delivery to a third party which is important. According to them, it is possible for a wholly-owned subsidiary of the producer, such as that involved in the main proceedings, not to be regarded as a third party.

22 The defendants in the main proceedings consider, on the contrary, that the fact that the product leaves its actual place of production is relevant to the definition of being put into circulation, and the fact of its being sent to a subsidiary cannot have a determining role in that regard.

23 At the outset, it should be stated that the Directive does not define the concept of 'put into circulation', which is referred to, in particular, in Article 7(a) of the Directive, dealing with the circumstances where the producer will be exempt from liability and Article 11, which lays down the rights conferred on the injured person pursuant to the Directive.

24 In relation to the concept of putting into circulation referred to in Article 7 of the Directive, the Court has held that exemption from liability because the product has not been put into circulation covers, primarily, the cases in which a person other than the producer has caused the product to leave the process of manufacture. Uses of the product contrary to the producer's intention, for example where the manufacturing process is not yet complete, and use for private purposes or in similar situations are also excluded from the scope of the directive (Case C-203/99 *Veedfald* [2001] ECR I-3569, paragraph 16).

25 In the same context, the Court decided, at paragraph 15 of *Veedfald*, that the cases exhaustively listed by Article 7 of the Directive by which a producer may exempt himself from liability, are to be interpreted strictly. Such an interpretation seeks to protect the interests of the victims of damage caused by a defective product.

26 Article 11 of the Directive, the purpose of which is to place a time-limit on the exercise of the rights conferred by the Directive on the victim, is, on the other hand, of a neutral character. As is clear from the 10th recital in the preamble to the Directive, the aim of that provision is to satisfy the requirements of legal certainty in the interests of the parties involved. The establishment of the time-limits within which the victim's action must be brought must therefore satisfy objective criteria.

27 In light of those considerations, a product must be considered as having been put into circulation, within the meaning of Article 11 of the Directive, 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.

28 Generally, it is not important in that regard that the product is sold directly by the producer to the user or to the consumer or that that sale is carried out as part of a distribution process involving one or more operators, such as that envisaged in Article 3(3) of the Directive.

29 When one of the links in the distribution chain is closely connected to the producer, for example, in the case of a wholly-owned subsidiary of the latter, 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.

30 The examination of such a close relationship must not be influenced by the question whether or not distinct legal persons are involved. On the other hand it is of relevance whether those are companies carrying out different production activities or are, on the contrary, companies one of which, i.e. the subsidiary company, acts simply as a distributor or depository for the product manufactured by the parent company. It is for the national courts to establish, having regard to the circumstances of each case and the factual situation of the matter before them, whether the links between the producer and another entity are so close that the concept of producer within the meaning of Articles 7 and 11 of the Directive 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 within the meaning of those provisions.

31 In any case, contrary to what is maintained by the defendants in the main proceedings, 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.

32 Therefore the reply to the first question must be that Article 11 of the Directive 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.

Concerning the second and third questions

33 By its second and third questions, which it is appropriate to examine together, the referring court asks essentially whether, 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 open to the national courts to view such an action as being brought against that production company and to substitute the latter, as defendant to the action, for the company initially proceeded against.

34 In that regard it must be observed that the Directive does not determine the procedural mechanisms which it is appropriate to apply when a victim brings an action for liability for defective products and makes an error as to the identity of the producer. It is therefore, as a rule, for national procedural law to determine the conditions in accordance with which one party may be substituted for another in the context of such an action.

35 However, it must be observed that the class of persons liable against whom an injured person is entitled to bring an action under the system of liability laid down by the Directive is defined in Articles 1 and 3 of the Directive (Case C-402/03 *Skov and Bilka* [2006] ECR I-199, paragraph 32). Since the Directive seeks to achieve a

complete harmonisation in the matters it regulates, its determination in those provisions of the class of persons liable must be regarded as exhaustive (*Skov and Bilka*, paragraph 33).

36 The liability imposed by the Directive is attributed by Articles 1 and 3(1) thereof to the producer, who is defined, in particular, as the manufacturer of a finished product.

37 It is only in the cases exhaustively listed that other persons can be considered to be a producer, namely, any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer (Article 3(1) of the Directive), any person who imports a product into the Community (Article 3(2) of the Directive) and the supplier who, where the producer of the product cannot be identified, does not inform the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product (Article 3(3) of the Directive).

38 A national court, when it examines the conditions governing the substitution of one party for another in a particular dispute, must ensure that due regard is had to the personal scope of the Directive, as established by Article 3 thereof.

39 Therefore the reply to the second and third questions must be that, when an action is brought against a company mistakenly considered to be the producer of a product whereas, in reality, the product 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 the Directive, as determined by Articles 1 and 3 thereof.

Costs

10 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

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, 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.**

2. **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.**

[Signatures]