JUDGMENT OF THE COURT (Grand Chamber)

2 December 2009 *

In Case C-358/08,

REFERENCE for a preliminary ruling under Article 234 EC, from the House of Lords (United Kingdom), made by decision of 11 June 2008, received at the Court on 5 August 2008, in the proceedings

Aventis Pasteur SA

v

OB,

THE COURT (Grand Chamber),

composed of V. Skouris, President, A. Tizzano, J.N. Cunha Rodrigues, K. Lenaerts (Rapporteur) and E. Levits, Presidents of Chambers, C.W.A. Timmermans, A. Rosas, A. Borg Barthet, M. Ilešič, J. Malenovský, U. Lõhmus, A. Ó Caoimh and J.-J. Kasel, Judges,

* Language of the case: English.

Advocate General: V. Trstenjak,
Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 30 June 2009,

after considering the observations submitted on behalf of:

— Aventis Pasteur SA, by G. Leggatt QC and P. Popat, Barrister,

— OB, by S. Maskrey QC and H. Preston, Barrister,

— the European Commission, by G. Wilms, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 8 September 2009

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation 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), as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 (OJ 1999 L 141, p. 20) ('Directive 85/374').

2 The reference was made in the course of proceedings between Aventis Pasteur SA ('APSA'), a company established in France, and OB following the putting into circulation of an allegedly defective vaccine.

Legal context

Community legislation

3 The first, 10th, 11th and 13th recitals in the preamble to Directive 85/374 provide:

'Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;

…

Whereas 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;

Whereas products age in the course of time, higher safety standards are developed and the state of science and technology progresses; whereas, therefore, it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product; whereas, therefore, liability should expire after a reasonable length of time, without prejudice to claims pending at law;

…

Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive; ….'

4 Article 1 of Directive 85/374 provides that '[t]he producer shall be liable for damage caused by a defect in his product.'

5 Article 3 of Directive 85/374 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.'

6 Article 11 of Directive 85/374 states:

'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.'

7 Under Article 13 of that directive, it '… shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.'

8 Directive 85/374 was notified to the Member States on 30 July 1985.

National legislation

9 Directive 85/374 was implemented in the United Kingdom by means of the Consumer Protection Act 1987 ('the 1987 Act').

10 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.'

11 Section 35 of the 1980 Act prohibits, in principle, the substitution of a new party after the expiry of the limitation period. Under subsections 5(b) and 6(a) of that section, however, by way of exception, rules of procedure may give the court the power, in certain circumstances, to make such a substitution with effect from the commencement of the original action. The substitution of the new party 'for a party whose name was given in any claim made in the original action in mistake for the new party's name' is thus provided for.

12 Rule 19.5(3)(a) of the Civil Procedure Rules confers such a power of substitution on the court, which the latter may exercise at its discretion. It provides however that, even where the condition for the exercise of that power is satisfied, the court must take into account that the substitution will have the effect of depriving the defendant of the liberating effect of the expiry of the limitation period and grant the substitution only where it considers that it is necessary for the purposes of justice in the circumstances of the case.

Background to the main proceedings and the question referred

13 Pasteur Mérieux Sérums et Vaccins SA ('Pasteur Mérieux'), a company incorporated under French law which, on changing its name, became APSA, produces pharmaceutical products, including an antihaemophilus vaccine.

14 Mérieux UK Ltd ('Mérieux UK'), a company incorporated under the law of England and Wales, was, in 1992, a wholly-owned subsidiary of APSA, acting as distributor, in the United Kingdom, of the products manufactured by that company.

15 On 18 September 1992, APSA sent a consignment of antihaemophilus vaccine units to Mérieux UK, which was received by the latter on 22 September 1992. At that time, APSA sent an invoice to its subsidiary, which duly paid it.

16 On a later date which remains unknown, but is in late September 1992 or early October 1992, part of that consignment was sold by Mérieux UK to the United Kingdom Department of Health and sent to a hospital nominated by that department. That hospital in turn supplied part of those units of vaccine to a medical surgery established in the United Kingdom.

17 On 3 November 1992, OB was administered a unit of the vaccine at issue in that surgery.

18 OB subsequently suffered from severe brain damage. OB's treating physicians considered that that damage had been caused by infection with the herpes simplex virus. OB claims, on the contrary, that his injuries are connected with the defective nature of the vaccine which was administered to him.

19 In 1994, APSA formed a joint venture with Merck Inc. of the United States. Mérieux UK became the United Kingdom subsidiary of that joint venture. Following a change of name, it became Aventis Pasteur MSD ('APMSD').

20 On 2 November 2000, OB brought an action for damages against APMSD before the High Court of Justice of England and Wales, Queen's Bench Division. In his particulars of claim served on 1 August 2001, he claimed that the vaccine had been manufactured by APMSD and that it was defective, so that he sought a finding of liability against that company under the 1987 Act.

21 In its defence served on 29 November 2001, APMSD contended that it was merely the distributor of the vaccine administered to OB, and not the manufacturer.

22 On 17 April 2002, APMSD responded to a request for confirmation whether it was the manufacturer by reaffirming that it was not the manufacturer of the vaccine. It identified Pasteur Mérieux as the manufacturer, without clarifying that that was the former name of APSA.

23 On 16 October 2002, OB brought an action for damages against APSA before the High Court of Justice.

24 Whilst admitting that it is the manufacturer of the vaccine at issue, APSA contended that the action brought against it was time-barred, as the 10-year period for bringing an action under the 1987 Act had, in its opinion, expired on 18 or 22 September 2002, depending on whether the start of that period is the date on which the vaccine was sent by APSA to Mérieux UK or the date on which the latter received the vaccine.

25 On 10 March 2003, OB applied for an order that APSA be substituted for APMSD in the action instituted against that latter in November 2000. He based that application on the fact that, at the time of bringing that action, he wrongly believed that the manufacturer of the vaccine at issue was APMSD.

26 It is common ground that that application for substitution was made after the expiry of the 10-year period for instituting proceedings against the producer of the allegedly defective product.

27 APSA contended that, in so far as it permits such a substitution after the expiry of that period, the national law is inconsistent with the true interpretation of Article 11 of Directive 85/374, which is disputed by OB.

28 By decision of 18 November 2003, received at the Court on 8 March 2004, the High Court of Justice requested a preliminary ruling, to which the Court replied by its judgment in Case C-127/04 *O'Byrne* [2006] ECR I-1313.

29 The second and third questions referred by the High Court of Justice in the case which gave rise to the judgment in *O'Byrne* were worded as follows:

> '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?'

30 In *O'Byrne*, the Court replied as follows to those two questions:

'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.'

31 Following the judgment in *O'Byrne*, the High Court of Justice granted, on 20 October 2006, the application for substitution made by OB, on the ground that APMSD had been wrongly named as defendant instead of APSA.

32 APSA brought an appeal against that decision before the Court of Appeal. On 9 October 2007, the latter dismissed its appeal.

33 Ruling on an appeal brought by APSA, the House of Lords decided to stay its proceedings and to refer the following question to the Court for a preliminary ruling:

'Is it consistent with [Directive 85/374] for the laws of a Member State to allow substitution of a new defendant to a claim brought under [that] directive after the 10-year period for enforcing rights under Article 11 of the directive has expired in circumstances where the only person named as a defendant in proceedings instituted during the 10-year period was someone who does not fall within Article 3 of the directive?'

The question referred for a preliminary ruling

34 By its question, the referring court asks, in essence, whether Directive 85/374 must be interpreted as precluding national legislation which, in the context of proceedings instituted on the basis of the system of liability laid down by that directive, allows the substitution of one defendant for another after the expiry of the 10-year period laid down in Article 11 of that directive, although the person named as a defendant in those proceedings before the expiry of that period did not fall within the scope of the directive, as defined in Article 3 thereof.

35 In paragraph 34 of *O'Byrne*, the Court held that, since Directive 85/374 does not determine the procedural mechanisms which it is appropriate to apply when an injured person brings an action for liability for a defective product and makes an error as to the identity of the producer, it is, 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.

36 After having observed, in paragraph 35 of *O'Byrne*, that, in the light of the complete harmonisation pursued by Directive 85/374 in the matters it regulates, the definition in Articles 1 and 3 of the class of liable persons against whom an injured person is entitled to bring an action under the system of liability laid down by that directive must be regarded as exhaustive, the Court pointed out, in paragraph 38 of that judgment, that a national court, when it examines the conditions governing such a procedural substitution, must nevertheless ensure that due regard is had to the personal scope of the directive, as established by Article 3 thereof.

37 Article 11 of Directive 85/374 derives from the same intention to harmonise completely, at Community level, rules on the limitation of rights conferred upon an injured person pursuant to that directive.

38 That article provides for a uniform 10-year period after which those rights are extinguished. It fixes, in a binding manner, the starting point of that period as the date on which the producer put into circulation the product which caused the damage. It specifies the institution of proceedings against that producer as the only reason for that period to be interrupted.

39 As is apparent from the 10th recital in the preamble to Directive 85/374, the harmonisation of the rules on limitation pursued by that directive was intended by the Community legislature in the interests both of the injured person and of the producer.

40 That harmonisation contributes, first, to the general aim, expressed in the first recital in the preamble to Directive 85/374, which consists in putting an end to the divergences between national rights liable to entail differences in the degree of protection of consumers within the Community.

41 Pursuant to the 11th recital in the preamble to Directive 85/374, the latter seeks, second, to limit, at Community level, the liability of the producer to a reasonable length of time, having regard to the gradual ageing of products, the increasing strictness of safety standards and the constant progressions in the state of science and technology.

42 As is stated by the Advocate General in points 49 and 50 of her Opinion, the Community legislature's intention to limit in time the no-fault liability established by Directive 85/374 is also intended to take account of the fact that that liability represents, for the producer, a greater burden than under a traditional system of liability, so as not to restrict technical progess and to maintain the possibility of insuring against risks connected with that specific liability (see, to that effect, paragraph 3.2.4 of the Report from the Commission of 31 January 2001 on the Application of Directive 85/374 on Liability for Defective Products, COM(2000) 893 final).

43 It follows that, without prejudice to the possible application of the rules on contractual or non-contractual liability or a special liability system existing at the moment when Directive 85/374 was notified, the application of which is not prejudiced by the latter, as is apparent from Article 13 thereof and the 13th recital in the preamble thereto, the 'producer', as defined in Article 3 of that directive, is, under Article 11 of that directive, relieved of his liability under that article upon the expiry of a period of 10 years from the putting into circulation of the product in question, unless, in the meantime, proceedings have been instituted against him.

44 In those circumstances, a rule of national law which allows the substitution of one defendant for another during proceedings cannot, under Directive 85/374, be applied in

a way which permits such a producer to be sued, after the expiry of that period, as defendant in proceedings brought within that period against another person.

45 An outcome to the contrary would amount, first, to accepting that the 10-year limitation period set out in Article 11 of Directive 85/374 can be interrupted with regard to a producer for a reason other than that proceedings have been instituted against him, which would be inconsistent with the complete harmonisation pursued by that directive on that issue.

46 Such an outcome would involve, second, a lengthening of the limitation period with regard to such a producer, disrupting the latter's expectations concerning the exact date on which he is deemed, pursuant to Article 11 of Directive 85/374, to be relieved of his liability under that directive. That would be inconsistent not only with the harmonisation of the length of that period intended by the Community legislature, but also with the legal certainty which Article 11 seeks to grant the producer in the context of the system of no-fault liability established by that directive.

47 It should be recalled in that regard that, according to settled case-law, the principle of legal certainty, the corollary of which is the principle of the protection of legitimate expectations, requires, in particular, that the application of rules of law must be foreseeable by those subject to them, that requirement being particularly important in the case of rules liable to entail financial consequences, in order that those concerned may know precisely the extent of the obligations which those rules impose on them (see Case C-201/08 *Plantanol* [2009] ECR I-8343, paragraph 46 and the case-law cited).

48 It should also be added that subjective elements deriving, for example, from the wrongful attribution, by the injured person, of the status of manufacturer of the allegedly defective product to a company which is not the manufacturer, or from the injured person's genuine intention to proceed against that manufacturer by way of its action against such other company, cannot, without infringing the objective dimension of the harmonisation rules laid down by Directive 85/374, justify the substitution, after

the expiry of the 10-year period set out in Article 11 thereof, of that manufacturer in proceedings initiated during that period against another person (see, to that effect, *O'Byrne*, paragraph 26 and, by analogy, Case C-51/05 P *Commission* v *Cantina sociale di Dolianova and Others* [2008] ECR I-5341, paragraphs 59 to 63).

49 In light of the foregoing, Article 11 of Directive 85/374 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.

50 However, the Court, giving a preliminary ruling on a reference, has jurisdiction, in the light of the information in the case-file, to give clarifications to guide the referring court in giving judgment in the main proceedings (see, to that effect, Case C-366/98 *Geffroy* [2000] ECR I-6579, paragraph 20, and Case C-446/07 *Severi* [2009] ECR I-8041, paragraph 60).

51 It should be noted in that regard, first, that it is apparent from the reference for a preliminary ruling that APMSD (formerly Mérieux UK), which in 1992 supplied the vaccine which was administered to OB to the United Kingdom Department of Health, was, at that time, a wholly-owned subsidiary of APSA (formerly Pasteur Mérieux).

52 In such a context, it is for the national court, in accordance with the applicable rules of national law on matters of proof, to assess whether the putting into circulation of the product in question was, in fact, determined by the parent company which manufactured it.

53 Where the national court notes that fact, Article 11 of Directive 85/374 does not preclude that court from holding that, in the proceedings instigated within the period prescribed by that article against the subsidiary under the system of liability laid down by that directive, the parent company, 'producer' within the meaning of Article 3(1) of that directive, can be substituted for that subsidiary.

54 Second, having regard to the fact, previously observed in paragraph 51 of this judgment, that APMSD is the supplier of the vaccine administered to OB, it should be noted that, under Article 3(3) of Directive 85/374, where the producer cannot be identified, the supplier of the product is to be treated as the producer, unless he informs the injured person, within a reasonable time, of the identity of the producer or of his own supplier.

55 As was pointed out by both the European Commission and by the Advocate General in point 97 of her Opinion, that provision should be understood as referring to the situation in which, taking into account the circumstances of the case, the person injured by the allegedly defective product could not reasonably have identified the producer of that product before exercising his rights against its supplier. In the present case, that will be for the national court, if appropriate, to determine.

56 In such a case, it follows from Article 3(3) of Directive 85/374 that the supplier is to be treated as a 'producer' if he has not informed the injured person, within a reasonable time, of the identity of the producer or his own supplier.

57 It is necessary, first of all, to state that the mere fact that the supplier of the product in question denies being its producer cannot, where that supplier has failed to couple that denial with information about the identity of the producer or its own supplier, suffice for that supplier to be treated as having informed the injured person of the facts referred

to in Article 3(3) of Directive 85/374 or, therefore, for it to be ruled out that it could be treated as a 'producer' under that provision.

58 Next, it should be noted that the condition relating to the supply of such information within 'a reasonable time', within the meaning of Article 3(3) of Directive 85/374, involves the requirement that the supplier, against whom proceedings are brought by an injured person, inform the latter, on its own initiative and promptly, of the identity of the producer or its own supplier.

59 In the present case, it is, where appropriate, for the national court to determine, in the light of the circumstances of the case, whether or not APMSD has fulfilled that requirement, taking account, in particular, of the specific fact that APMSD, having as subsidiary of APSA bought the vaccine at issue directly from the latter, clearly knew the identity of the producer of that vaccine at the time when OB brought proceedings against it.

60 If the national court's determination leads it to find that the conditions for the application of Article 3(3) of Directive 85/374 are satisfied, APMSD should therefore be treated as a 'producer' for the purposes of the application of that directive. Therefore, it could be held that the proceedings instituted, in November 2000, by OB against that company under the system of liability laid down by that directive interrupted the limitation period applicable to it, in accordance with Article 11 thereof.

61 On the other hand, for the reasons stated in paragraphs 37 to 47 of this judgment, such a finding, or indeed the contrary finding, would not, without infringing Directive 85/374, authorise upholding the application for substitution of APSA for APMSD in the said procedure, in the light of the fact that that application was made by OB after the expiry

of the period which the latter had, under Article 11 of Directive 85/374, to bring his claim against APSA in accordance with that directive, as was noted in paragraph 26 of this judgment.

62 Regard being had to all of the above considerations, the answer to the question referred is that Article 11 of Directive 85/374 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.

63 However, first, Article 11 must be interpreted as not precluding a national court from holding that, in the proceedings instituted within the period prescribed by that article against the wholly-owned subsidiary of the 'producer', within the meaning of Article 3(1) of Directive 85/374, that producer can be substituted for that subsidiary if that court finds that the putting into circulation of the product in question was, in fact, determined by that producer.

64 Second, Article 3(3) of Directive 85/374 must be interpreted as meaning that, where the person injured by an allegedly defective product was not reasonably able to identify the producer of that product before exercising his rights against the supplier of that product, that supplier must be treated as a 'producer' for the purposes, in particular, of the application of Article 11 of that directive, if it did not inform the injured person, on its own initiative and promptly, of the identity of the producer or its own supplier, which it is for the national court to determine in the light of the circumstances of the case.

Costs

65 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 (Grand Chamber) hereby rules:

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.

However, first, Article 11 must be interpreted as not precluding a national court from holding that, in the proceedings instituted within the period prescribed by that article against the wholly-owned subsidiary of the 'producer', within the meaning of Article 3(1) of Directive 85/374, that producer can be substituted for that subsidiary if that court finds that the putting into circulation of the product in question was, in fact, determined by that producer.

Second, Article 3(3) of Directive 85/374 must be interpreted as meaning that, where the person injured by an allegedly defective product was not reasonably able to identify the producer of that product before exercising his rights against the supplier of that product, that supplier must be treated as a 'producer' for the purposes, in particular, of the application of Article 11 of that directive, if it did not inform the injured person, on its own initiative and promptly, of the identity of the producer or its own supplier. That is for the national court to determine in the light of the circumstances of the case.

[Signatures]