Easter Term
[2010] UKSC 23
On appeal from: [2007] EWCA Civ 939

JUDGMENT

OB (by his mother and litigation friend) (FC) (Respondent) *v* Aventis Pasteur SA (Appellants)

before

Lord Hope, Deputy President
Lord Saville
Lord Rodger
Lord Walker
Lady Hale

JUDGMENT GIVEN ON

26 May 2010

Heard on 15 April 2010

Appellant
George Leggatt QC
Prashant Popat QC
(Instructed by Arnold & Porter LLP)

Respondent
Simeon Maskrey QC
Hugh Preston
(Instructed by Freeth Cartwright LLP)

LORD RODGER (delivering the judgment of the court)

1. The claimant, Declan O'Byrne, was vaccinated on 3 November 1992 with an HIB vaccine ("the Product"). He alleges that the Product was defective and that it caused him brain damage.

2. The vaccine in question was manufactured in France by a French company, now known as Aventis Pasteur SA ("APSA"). On 18 September 1992 APSA sent a consignment of the vaccine, including the Product, to a company, now known as Aventis Pasteur MSD Ltd ("APMSD"), in England. At all relevant times in 1992 APMSD was a wholly owned subsidiary of APSA and acted as a United Kingdom distributor for APSA's products. APMSD received the consignment on 22 September. On an unknown date, probably in late September or early October, APMSD sold part of the consignment, including the Product, to the Department of Health, which in turn supplied it to the medical practice which used it to vaccinate the claimant.

3. On 1 August 2001 the claimant began proceedings for damages against APMSD, alleging that he had suffered damage caused by a defect in the Product which APMSD had manufactured and/or produced and so it was liable under section 2 of the Consumer Protection Act 1987. In its defence, served in November 2001, APMSD pointed out that it was not the manufacturer, but merely the distributor, of the Product. In response to a further request, in April 2002 APMSD identified APSA as the manufacturer of the Product.

4. On 16 October 2002 the claimant issued separate proceedings against APSA, also under section 2 of the Consumer Protection Act, alleging that APSA was the producer of the Product and claiming damages against it. APSA defended the action on the basis, inter alia, that it had put the Product into circulation either on 18 September 1992, when it sent the Product to APMSD, or on 22 September 1992 when APMSD received it. APSA contended that, in these circumstances, the claimant's action against it was time-barred since it had been raised more than 10 years after APSA had put the Product into circulation. In advancing this defence, APSA relied on section 11A(3) of the Limitation Act 1980 and 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 L210, p 29) ("the Directive"), which 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 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."

5. Faced with this defence in his action against APSA, in his action against APMSD – with which this appeal is concerned – the claimant applied on 10 March 2003 for an order that APSA be substituted as defendant in place of APMSD. The application was based on section 35(5)(b) and (6)(a) of the Limitation Act 1980 and rule 19.5(3)(a) of the CPR.

6. It is, of course, common ground that the application was made after the expiry of the ten- year time-limit under Article 11 for initiating proceedings against the producer of the Product. In these circumstances APSA contended that, in so far as English law might permit APSA to be substituted after the expiry of the time-limit, it was inconsistent with Article 11. By contrast, the claimant contended that provisions of domestic law permitting this substitution would not be inconsistent with Article 11.

7. In November 2003, at the request of both parties, the High Court made a preliminary reference to the European Court of Justice. The European Court answered three questions: *O'Byrne v Sanofi Pasteur MSD Ltd (formerly Aventis Pasteur MSD Ltd) (Case C-127/04)* [2006] 1 WLR 1606. One of the questions concerned the point in time at which a product was put into circulation for purposes of Article 11 in a situation where the producer which manufactured it then transferred it to a distribution subsidiary. I quote and discuss the European Court's ruling on this point at paras 20-23 below.

8. So far as the power to substitute one producer for another as defendant was concerned, the European Court held, [2006] 1 WLR 1606, 1622:

> "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."

9. In the light of this answer, Teare J allowed the claimant's application for substitution of APSA in place of APSMD, pursuant to section 35(5)(b) and (6)(a) of the Limitation Act 1980 and rule 19.5(3)(a) of the CPR, on the ground that the claimant had named APMSD as the defendant in mistake for APSA: *O'Byrne v Aventis Pasteur MSD Ltd* [2007] 1 WLR 757. APSA appealed, but the Court of Appeal (Sir Anthony Clarke MR, Arden and Moore-Bick LJJ) [2008] 1 WLR 1188 dismissed its appeal. The House of Lords granted APSA leave to appeal. At the hearing of the appeal a majority of the appellate committee considered that it was clear that the European Court was saying that, in some circumstances, proceedings, which are obviously intended to be proceedings against the producer but which use the wrong name, can properly be treated by national procedural law as having been proceedings against the producer. The majority considered that this would have been the proper approach in the circumstances in the present case and so they would have dismissed APSA's appeal. But, because this was not the unanimous view of the appellate committee as to the effect of the judgment of the European Court, the House of Lords referred the case to Luxembourg for a second time: [2008] 4 All ER 881. The decision on this reference was given by the Grand Chamber: *Aventis Pasteur SA v OB (Case C-358/08*) (unreported) given 2 December 2009.

10. The answer returned by the European Court in response to the second reference is not in line with either of the interpretations of its judgment on the first reference which had been advanced before the appellate committee. Happily, however, this time the core answer could not be clearer:

> "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."

11. Putting the point shortly – and subject to the important qualification which I must address in a moment – the Court of Justice holds that, once ten years have passed since a producer put a product into circulation, that producer cannot be sued, unless proceedings have been taken against it within the ten-year period. As the Court explains, at para 38 of its judgment, Article 11:

> "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."

It follows, as the Court says at para 44, that "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."

12. As it explained in paras 41-43 of its judgment, the Court adopted this approach because, in its view, it gave effect to the balance which the Community legislator had intended to achieve between the interests of consumers and producers:

> "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.
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> 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 progress 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).
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> 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."

13. The European Court also went out of its way, at para 48, to emphasise that it made no difference if the failure to sue a particular producer within the relevant ten-year period had been due to some mistake on the claimant's part. Even in that event what mattered was that the ten years had expired without that producer having been sued. So it could not be substituted as defendant after the ten years were up:

> "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)."

14. In these circumstances the claimant now accepts that he cannot use section 35 of the Limitation Act 1980 as a basis for substituting APSA for APMSD as the defendant in the present proceedings.

15. The claimant submits, however, that, even though he cannot make the substitution on the basis of his mistake, the European Court indicated in its judgment a different basis on which he can actually make the desired substitution. For this purpose he relies on the second answer which the Court of Justice gave on the second reference:

> "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."

In short, the claimant submits that the position falls within the terms of this qualification to the European Court's core answer on the effect of Article 11 and so there is nothing to prevent him from substituting APSA for APMSD on this basis. APSA contends, however, that this passage in the Court's judgment has to be interpreted in the context of the judgment as a whole and in the light of the Opinion of Advocate General Trstenjak, 8 September 2009, unreported, which preceded it. When that is done, APSA says, it can be seen that the qualification should be given a narrower interpretation, which would not allow substitution in this case. As will become apparent, in a case like the present, the possibility of substitution depends, to some extent, on various matters of fact concerning the relationship between the two entities. At the hearing before this Court, however, on the basis of what he now knows about the facts, the claimant's counsel, Mr Maskrey QC, accepted that, if the Court were to conclude that APSA's interpretation of the European Court's judgment was correct, then its appeal against its substitution for APMSD should be allowed.

16. The dispute between the parties turns, therefore, on the interpretation of paras 49-53 of the judgment of the European Court on the second reference:

> "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.
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> 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-0000, paragraph 60).
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> 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).
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> 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.
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> 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."

17. Under reference to its reasoning in paras 34-48, in para 49 the European Court gave its core ruling on the construction of Article 11, which I have already discussed. The Court then went on, in the subsequent paragraphs, to give some additional guidance which it considered might be helpful to any domestic judges who were going to be dealing with this particular case. There is nothing, however, to suggest that, in these paragraphs, the Court was intending to depart from the principled approach which it had just been at such pains to develop and finally to formulate in para 49. What the Court says in paras 50-54 must therefore be read in the light of that core decision. In other words, the Court is explaining how that decision may fall to be applied, depending on the domestic court's assessment of the practical relationship between the manufacturer, APSA, and the distributor, APMSD.

18. In venturing to give this additional assistance the European Court was following the lead of the Advocate General. Although the structure of her Opinion makes for repetition, it is clear that she, too, had concluded that only the bringing of proceedings against the particular producer could stop the Article 11 time-bar from taking effect ten years after the producer had put the relevant product into circulation. See, in particular, paras 61 and 69-78 of her Opinion. So, in reaching its conclusion in para 49 of its judgment, the Court was following this aspect of the Advocate General's reasoning. The Advocate General went on to hold, at para 68, that a substitution of the producer as a defendant when he has been released by the expiry of the ten-year limitation period is equally incompatible with the Directive. She gave her reasoning for this conclusion at para 79, where she said that to allow the substitution of a producer against which proceedings had not been taken within the ten-year period in place of a producer against which they had been taken would

> "de facto be capable of also interrupting the limitation period in relation to producers. The upper temporal limit of liability for producers in Article 11 would thereby be broken through, and that is excluded in the light of the complete harmonisation of the field which is the aim of Directive 85/374."

So, when reaching the comparable conclusion at paras 44-47 of its judgment, the European Court was, again, following the Advocate General's approach.

19. The Advocate General also gave some thought to how Article 11, thus interpreted, should be applied in a case, like the present, where the parent manufacturing producer (APSA) transferred the Product to a distributor (APMSD) which was its wholly owned subsidiary.

20. In this connexion the Advocate General referred back to the judgment of the European Court on the first reference: *O'Byrne v Sanofi Pasteur MSD Ltd (formerly Aventis Pasteur MSD Ltd)* [2006] 1 WLR 1606. The first ruling in that judgment, at p 1622, had been in these terms:

> "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."

This conclusion reflects what the Court says in para 27 of its judgment, which is, in turn, based on its reasoning in the preceding paras 20-26. Paragraphs 27-32, [2006] 1 WLR 1606, 1620-1621, are of importance in the present context:

> "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.
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> 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.
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> 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, ie 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.
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> 31. In any case, contrary to what is maintained by the defendants, 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.
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> 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."

21. As can be seen from para 31 of the European Court's judgment, in the first reference APSA – which naturally wanted to push the starting-date for the ten-year period back as far as possible – was arguing that it had put the Product into circulation when it transferred the consignment containing the Product to APMSD in the period of 18 to 22 September 1992. In support of that argument APSA was pointing to the fact that APMSD had been invoiced for the consignment and had paid for it. The claimant's counsel, who was, of course, contending for as late a date as possible for the Product being put into circulation, was contending that this had not happened until APMSD supplied it to the Department of Health.

22. The European Court rejected any approach that was based on the formal legal relationship between the parent manufacturing producer and the subsidiary distributor. In particular, the Court emphasised, at para 30, that the fact that the manufacturer and the distributor were distinct legal entities was irrelevant. The national court had to look at all the links between the two entities and decide on that basis whether they were so close that, for the purposes of Article 11, the concept of the manufacturing producer (which would apply to APSA) really included the distributor (in this case, APMSD). In that event, even if the Product

were transferred from one to the other, this would not mean that it had been taken out of the manufacturing process operated by the producer. So, applying the test in para 27 of that judgment, for the purposes of Article 11 the Product would not have been put into circulation by the manufacturing producer when it transferred it to the distributor. Obviously, the Court's concern was that, unless this were indeed the position, at least in the case of products with a long shelf-life, by the time they were eventually put on the market by the distributor, a significant part of the ten-year period for proceedings against the manufacturing producer might have elapsed. This would upset the balance which the Directive sought to maintain between the interests of the consumer and the producer.

23. In paras 83-90 of her Opinion on the second reference, the Advocate General did indeed make use of this part of the Court's analysis in the first reference when considering how the domestic court might determine the date at which the Product was put into circulation. But she also used it for the rather different purpose of showing when a distribution subsidiary could be so closely involved with the parent producer that they could, in effect, be regarded as one for the purposes of Article 11. In that event, suing the subsidiary would be tantamount to suing the parent. In concrete terms, if that were the position in this case, by suing APMSD within the ten-year period, the claimant would also have sued APSA within that period. So the Article 11 time-bar would not bite and the claimant could, if he wished, substitute APSA for APMSD as defendant in the present action – or, indeed, simply proceed with his (second) action against APSA.

24. The Advocate General's reasoning and conclusions on these matters are to be found in paras 109-113 of her Opinion:

> "109. If, by contrast, the national courts were to reach the conclusion in the main proceedings that a supplier such as APMSD was, because of its involvement in the manufacturing process operated by APSA, to be regarded together with APSA as a producer within the meaning of the first half of Article 3(1) of Directive 85/374, the bringing of proceedings in due time against APMSD would indeed have the effect of interrupting the limitation period in relation to APSA.
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> 110. The decisive point here is the fact that a supplier who is sufficiently closely involved in the manufacturing process operated by the producer is to be classified together with the producer as a producer within the meaning of the first half of Article 3(1) of the directive. Because those two entities are to be regarded, in the light of the functional interpretation of the concept of producer, as one

> producer within the meaning of the first half of Article 3(1), the limitation period must also run in the same way for both entities.
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> 111. In this connection the Court in *O'Byrne*, after carefully weighing up the interests of consumers and producers, synchronised the starting point of the 10-year limitation period under Article 11 of Directive 85/374 for the producer *stricto sensu* and the supplier who forms part of the manufacturing process by reference to the date on which the supplier puts the product into circulation. In the context of the same balancing of interests, the running of the limitation period must also be uniform.
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> 112. Since the running of the limitation period under Article 11 of the directive is interrupted only by the bringing of proceedings, a uniform limitation period for the producer and supplier who are to be regarded together as a producer within the meaning of the first half of Article 3(1) presupposes that the bringing of proceedings against the supplier interrupts the running of the 10-year limitation period not only in relation to that supplier but also in relation to the producer in whose manufacturing process the supplier is involved.
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> 113. Accordingly, my conclusion is that classification – to be assessed by the national courts – of the supplier of a product as its producer has the consequence that that supplier is liable under Article 1 of the directive for the damage caused by a defect in the product, regardless of whether he is classified as a producer within the meaning of Article 3(1) or a producer within the meaning of Article 3(3) of the directive. Classification of a supplier as a producer within the meaning of the first half of Article 3(1) of the directive has the further consequence that the 10-year limitation period for the producer in whose manufacturing process the supplier is involved does not start to run until the time when the supplier puts the product into circulation. At the same time, proceedings brought against that supplier will in that case interrupt the running of the limitation period under Article 11 of the directive in relation also to the producer in whose manufacturing process the supplier is involved.

In the summary which she gives in para 115, the Advocate General repeats the conclusion which she reaches in para 113.

25. Two points stand out. First, the Advocate General's conclusion in paras 113 and 115 involves no departure from the principle that the Article 11 time-bar can only be interrupted by bringing proceedings against the producer concerned. Secondly, when she contemplates the domestic court classifying a supplier as a producer within the meaning of Article 3(1), she

contemplates the domestic court applying the approach of the European Court in its judgment on the first reference: *O'Byrne v Sanofi Pasteur MSD Ltd (formerly Aventis Pasteur MSD Ltd)* [2006] 1 WLR 1606. And – as the Advocate General recalls at paras 111 and 113 – according to that judgment, where the supplier forms part of the manufacturing process, the starting point of the ten-year limitation period under Article 11 is fixed by reference to the date on which *the supplier* puts the product into circulation. Indeed, in the proceedings on the first reference, the claimant fought successfully to establish exactly that point.

26. With this background in mind, it is appropriate to return to paras 51 and 52 of the European Court's judgment on the second reference:

> "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).
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> 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."

27. It is correct to say that, unlike the Advocate General, the European Court does not actually refer to its answer to the first question on the first reference. But there is nothing whatever to suggest that it intended to depart in any way from that analysis. The assumption must therefore be that it falls to be applied where appropriate. Certainly, the Court supplies no alternative or additional theoretical analysis which could displace or supplement it.

28. The European Court is concerned to show how the principle which it has just laid down would apply in relation to the substitution of APSA for APMSD. Certainly, to judge by the Advocate General's analysis – and there is no rival – the only way in which that principle could be maintained and yet APSA could be substituted for APMSD, would be if, by suing APMSD, the claimant had, in effect, sued APSA. So the Court must be pointing the domestic court to the way in which it should approach that issue.

29. Mr Maskrey argued, however, that the position was really much simpler. As the European Court noted, at para 51, APMSD was a wholly owned subsidiary of APSA. Secondly, APSA had determined that the Product should be put into circulation by transferring it to its wholly owned subsidiary, APMSD, and it had then in fact transferred the product to the subsidiary. So the requirements of paras 51 and 52 were fulfilled and the substitution could be made.

30. I would reject that argument. As counsel freely admitted, this argument runs completely counter to the one which the claimant advanced on the first reference. That is, of course, merely a forensic point. More significantly, the argument is internally incoherent as well as being inconsistent with the reasoning of the Court of Justice. If, as counsel now contends, APSA put the Product into circulation when it supplied it to APMSD, then, consistently with the Court's ruling on the first reference, this can only be because the two companies are to be regarded as having operated quite distinctly – so that the Product was taken out of the manufacturing process operated by APSA when it was transferred to APMSD. But the fact that APMSD was a wholly owned subsidiary of APSA, which the Court began by noting in para 51, could not be a pointer towards that conclusion. If anything, it would point against it. So, on this interpretation, the European Court could have had no reason to draw attention to the status of APMSD. Yet it did.

31. Mr Maskrey criticised APSA's interpretation of para 52 on the specific ground that it involved reading in 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." Mr Leggatt QC accepted that this was, in effect, how he contended that the sentence should be interpreted. In my view, that is indeed the correct interpretation.

32. The European Court's reference to APMSD being a wholly owned subsidiary of APSA is only consistent with it directing attention to factors which may point to a close connexion between the two companies. Given the context of the discussion (seeing whether proceedings against APMSD count as proceedings against APSA), that is precisely what we would expect. For the reasons already given, we should also expect the focus to be on the time when the Product was supplied by APMSD to the Department of Health, since, if APMSD was, in effect, tied into the manufacturing process of APSA, the Product would only be put into circulation when it was supplied by APMSD. And that is what we find in para 51 where the European Court refers to APMSD's status as a wholly owned subsidiary at the time when it supplied the Product to the Department of Health. Therefore, in para 52 the Court must indeed be referring to the Product being put into circulation *by the supplier* at the behest of its parent. That interpretation is also consistent, of course, with what the Advocate General says in paras 111 and 113 of her Opinion on the second reference (quoted at para 24 above).

33. This interpretation of para 52 is also consistent with its language, both in the English version and in the original French ("si la mise en circulation du produit concerné a été déterminée en fait par la société mère qui l'a fabriqué"). The European Court is plainly contemplating a situation where, to all outward appearances, a supplier has decided to put a product into circulation. The domestic court must look at the circumstances to see whether, despite appearances, *in fact*, it was the manufacturing parent company which had determined that the product should be put into circulation. If, by contrast, the European Court had meant what Mr Maskrey suggested, it would have had no reason to use this language: all it would have required to say was that the national court was to assess whether the parent company, which manufactured the product, transferred it to its wholly owned subsidiary, the distributor. The further difficulty with that interpretation is, of course, that everyone agrees that APSA sent the consignment containing the Product to APMSD on 18 September and that APMSD received it on 22 September. There would therefore be nothing for the domestic court to assess.

34. The European Court was therefore indicating, in para 52, that the domestic court was to consider, in accordance with domestic rules of proof, whether the manufacturer, APSA, was in fact controlling APMSD and determining when it put the Product into circulation. There is nothing in the judgment of the European Court on either reference to suggest that the fact that APMSD was a wholly owned subsidiary of APSA could somehow, of itself, be a reason for allowing APSA to be substituted after the expiry of the ten-year period. Indeed, that would be inconsistent with the two companies being distinct entities. Rather, the fact that APMSD was a wholly owned subsidiary was simply one – by no means decisive – factor to be taken into account by the domestic court when assessing how closely the subsidiary was involved with its parent's business as an Article 3(1) producer. All the circumstances would have to be taken into account. If APSA was indeed in a position to decide when the Product was to be distributed, then APMSD would be integrated into the manufacturing process and so tightly controlled by APSA that proceedings against APMSD could properly be regarded as proceedings against the parent company, APSA. Hence, as the European Court goes on to hold in para 53, the manufacturing parent company could be substituted for the subsidiary – APSA for APMSD.

35. Mr Maskrey submitted that, if the European Court's judgment were interpreted in this way, then it would allow substitution of the parent producer only where the supplier could, in any event, itself be sued as a producer falling within the definition in Article 3(1). But that is, of course, precisely what the Advocate General does say in paras 113 and 115 of her Opinion. Moreover, the criticism seems a little ungenerous. It is, after all, the claimant who, for what must presumably appear to him to be good reasons, wishes to substitute APSA for APMSD as the defendant. The Advocate General and the Court are merely

responding to that situation by pointing to circumstances where it might indeed be possible for the claimant to do so. It is, of course, the case that, in any such circumstances, the claimant will also be able to sue the supplier as a producer within the terms of Article 3(1). But that is not a criticism of the approach taken by the Advocate General or the Court. If a claimant will gain nothing by suing the manufacturer in substitution for the supplier, he will presumably not try to do so. But such a course might have advantages if, say, the supplier were insolvent. The Advocate General and the European Court were entitled to assume that, in this case, the claimant had what he regarded as good reasons for wishing to make the substitution.

36. For these reasons, I would allow the appeal and set aside paragraph 1 of the order of Teare J dated 20 October 2006 substituting Aventis Pasteur SA for Aventis Pasteur MSD in the present action, HQ02X00848.