OPINION OF ADVOCATE GENERAL GEELHOED

delivered on 2 June 2005 [1]

I — Introduction

1. This reference by the High Court of Justice, Queen's Bench Division (United Kingdom) 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 [2] (hereinafter: the Directive).

2. In particular the referring court wishes to know at what time a product may be considered to be put into circulation. On that moment depends whether a claim against the producer has been lodged in time, that is to say within the 10-year time-limit after the product has been put into circulation laid down by Article 11 of the Directive. An additional factor is that the first transfer of the allegedly defective product took place between two companies in the same group of companies. Does a transfer within a group amount to putting a product into circulation?

3. Furthermore, it seems that a first action was brought within the time period of 10 years, but against the wrong person, namely a supplier (the defendant in the first action), in the mistaken belief that the supplier was the producer. Consequently, it seems, a subsequent action against the actual producer (the defendant in the second action) was brought just before or just after the expiry of the period. The next question is thus whether it is permitted in such situations to treat the proceedings instituted against the defendant in the first action as proceedings against the producer (the defendant in the second action, the proposed defendant in the first action), or, if the second action against the producer was brought out of time, whether it is possible for the national court to substitute the second defendant for the first.

1 — Original language: English.

2 — OJ 1985 L 210, p. 29.

II — Legal framework

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

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. 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 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.'

7. In the *Veedfald* case, [3] the Court held that Article 7(a) of the Directive is to be interpreted as meaning that a defective product is put into circulation when it is used during the provision of a specific medical service, consisting in preparing a human organ for transplantation, and the damage caused to the organ results from that preparatory treatment.

8. The United Kingdom implemented the Directive by means of Part I of the Consumer Protection Act 1987, which came into force on 1 March 1988. Section 4 of the Act is worded 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

...

3 — Case C-203/99 [2001] ECR I-3569.

(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;

...'

9. In addition, the Consumer Protection Act 1987 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 ten 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 ten years.'

III — Facts, procedure and preliminary questions

10. On 3 November 1992 the young child Declan O'Byrne, the claimant in the main proceedings, was vaccinated with a dose of antihaemophilus vaccine in the MacDonald Road Medical Centre surgery.

11. Following that vaccination, the claimant became severely brain damaged. He claims that his injury was caused by the vaccine which was defective.

12. The producer of the vaccine was Pasteur Mérieux Sérums et Vaccins SA, a French company, which subsequently changed its name to Aventis Pasteur SA (hereinafter: APSA).

13. Mérieux UK Limited, an English company, was a wholly-owned subsidiairy of APSA and acted as a distributor in the United Kingdom of products manufactured by APSA. Mérieux UK Limited subsequently changed its name to Aventis Pasteur MSD (hereinafter: APMSD).

14. On 18 September 1992 APSA had sent a consignment of units of the vaccine, including that which was administered to the victim, to APMSD, which received the consignment on 22 September 1992. APSA sent an invoice to APMSD for the consignment, which was duly paid by APMSD.

15. On a date unknown, before or after 7 October 1992, part of the consignment appears to have been 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 in question where the claimant was vaccinated on 3 November 1992.

16. On 2 November 2000 the claimant brought proceedings for compensation against APMSD, claiming that the latter was the producer of the product.

17. On 7 October 2002 a second action was brought against APSA. The claimants' advisers stated to the national court that it was only 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.

18. In those proceedings, APSA contends that, since it had placed the product on the market by the consignment to its subsidiary on 18 September 1992, which received it on 22 September 1992, the action brought on 7 October 2002 was commenced after the expiry of the period for bringing an action of 10 years from the date on which the product was put into circulation provided for by section 11A(3) of the Limitation Act, which transposed Article 11 of the Directive into national law. The action is therefore statute-barred.

19. The claimant claims however that the product was not put into circulation until it was supplied by APMSD to the hospital nominated by the Department of Health and that this did not occur until after 7 October 1992, less than 10 years prior to the bringing of the second action. The action is therefore not statute-barred.

20. On 10 March 2003 the claimant applied to the national court for an order in the first action, brought in 2000, that APSA be substituted for all legal purposes for APMSD.

The preliminary questions

21. The High Court of Justice, Queen's Bench Division, decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling.

'1. On a true interpretation of Article 11 of the Council 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 Council 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 Council Directive?

3. Does Article 11 of the Council 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?'

IV — Assessment

22. By the first question, the referring court seeks to know what is to be understood by 'put into circulation' in Article 11 of the Directive. It identifies four possible dates, the first two relating to an intra-group transaction, the last two to a transaction further down in the distribution chain.

23. The liability of a producer expires 10 years from the date on which the product was put into circulation. The notion 'put into circulation' is therefore important for determining precisely when the strict liability of the producer ends. This notion is to be found not only in Article 11, but also in Articles 6, 7 and 17. [4]

24. Despite the importance of this phrase, it is not defined in the Directive. At the time of the drafting it was considered unnecessary to define the phrase 'put into circulation' since, as we can read in the Commission's Explanatory Memorandum, 'it was considered self-explanatory in the ordinary meaning of the words'. According to this Memorandum, normally a product has been put into circulation where it has been started off on the chain of distribution. [5] Another reason for not defining this phrase could be the existence of the European Convention on products liability in regard to death and personal injury of 27 January 1977 (the 1977 Convention). [6] The scheme of the 1977 Convention and the Directive are more or less the same. According to Article 2(d) of the Convention a product has been put into circulation when the producer has delivered it to another person.

4 — Article 6(1)(c) reads: 'A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the time when the product was put into circulation.'
Article 7 stipulates that a producer shall not be liable as a result of the Directive if he proves:
(a) that he did not put the product into circulation; or
(b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards, or ...
(e) that the state of scientific and technological knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered, or ... .
Article 17 provides that the Directive does not apply to products put into circulation before the date when the provisions of national legislation by which the Member States gives effect to the Directive enter into force.

5 — [1976] II E.C. Bull. Supp. L11/15.

6 — http://conventions.coe.int/Treaty/en/Treaties/Html/091.htm

25. This case demonstrates that the concept of 'put into circulation' requires, contrary to the Commission's Explanatory Memorandum, a definition as to the moment when the period of 10 years starts. The Court has not yet had to define the phrase 'put into circulation'. It was considered in the *Veedfald* case, [7] but it was in the context of Article 7(a) of the Directive, the facts of the case were specific and the Court did not have to give a general definition of the phrase.

26. In the *Veedfald* case the defendant claimed that he had never put the product into circulation. The defendant was the producer of a defective fluid designed for flushing kidneys prior to transplantation. The fluid was produced by hospital A and used in hospital B, both owned by the defendant. The argument used by the defendant was that the product was used in the course of providing a service (which is not covered by the Directive) and not in the course of a kind of selling arrangement. According to the defendant in that case the product had never left the sphere of control of the dispensary of the hospital which made the fluid and the hospital where it was used, and therefore it was never put into circulation within the meaning of Article 7(a) of the Directive.

7 — Cited in footnote 3.

27. The Court did not accept that argument. The Court stated that 'such circumstances are not decisive where, as in the present case, the use of the product is characterised by the fact that the person for whom it is intended must bring himself within that sphere of control' (paragraph 17) and answered the question posed to the effect that 'Article 7(a) ... is to be interpreted as meaning that a defective product is put into circulation when it is used during the provision of a specific medical service, consisting in preparing a human organ for transplantation, and the damage caused to the organ results from the preparatory treatment.'

28. In the present case the issue is not *whether* the product has been put into circulation but *when* it was put into circulation. The question as to which 'action' counts is relevant for the start and thus the final date of the 10-year liability period.

29. Before dealing with this question I recall that the Directive seeks to create a balance between the interests of consumers and those of producers. This balance should be taken into account in interpreting the phrase 'put into circulation'. On the one hand the Directive aims to protect the consumer by providing for liability without fault of the producer where damage is caused by a defect in his product. On the other hand the

liability of the producer is limited in time and extinguished upon the expiry of 10 years from the date on which the product was put into circulation. Thus, Article 11 is written in the interest of producers. The limitation period is justified mainly by the fact that strict liability puts a higher burden on producers than liability under the traditional systems of contractual or extra-contractual liability. In order not to discourage technological innovation and to allow insurance cover, it was thought to be necessary to limit the strict liability rule in time.

30. Secondly, as I already mentioned, the phrase 'put into circulation' appears several times in the Directive. It is clear that it should have the same meaning wherever it appears in the Directive.

31. At what time is a product put into circulation?

32. Various points of view have been expressed on this matter. The claimant, the Italian Government and the Commission take the view that the time at which a product is put into circulation is when the producer ceases to have control over that product or it is transferred to a person over whom the producer has no control. It is the entry into the chain of distribution by delivery to a third party (in this case the hospital to which APMSD supplied the vaccine) which is important.

33. APSA and APMSD take a different view. They maintain that the decisive factor is the moment the product leaves the entity where it has been manufactured and that the identity of the purchaser, who is a subsidiary, is irrelevant.

34. Evidently the determination of the moment at which the period of strict liability starts should be as clear and objective as possible. It cannot be too early (the manufacturing process may not be complete), or too late (the product may be somewhere in the chain of distribution).

35. It would be contrary to the wording of the Directive for the relevant 10-year period to start at the moment the retail supplier puts the product on sale, since Article 11 of the Directive refers clearly to the producer.

36. It would be too early if a product is considered to be put into circulation by any genuine act of supply by the producer to a receiving entity. Such situations would also cover the supply to testing institutions. That would be in contrast to the explanatory documents to the 1977 Convention and the Directive, which documents clearly indicate that such institutions are not meant to be included in the concept of putting a product into circulation: quality control of the product will not have been completed, and it is not ready to be exposed to potential customers and therefore potential victims.

37. Normally the launching of a product in the chain of distribution will coincide with putting it into circulation. This will not always be the case, however, as we know from the *Veedfald* case. In that case there was no chain of distribution at all, nevertheless at a certain point in time the product was put into circulation. The most suitable approach is a definition linked to loss of control. In this approach the producer voluntarily relinquishes control over the product by transferring it, in a commercial transaction, to a separate entity.

38. Thus far all intervening parties agree with this approach; opinions start to diverge with regard to intra-group transactions.

39. The claimant, the Commission and the Italian Government take the view that as long as a product is within the group control over the product remains with the producer.

40. The defendants in the main proceedings, however, take the view that it is of no importance whether the product is delivered to a wholly-owned subsidiary, to a company connected with the producer in some other way or to an independent third party. In their view, the only question to be asked is whether the producing entity has voluntarily relinquished control over the product. They claim that in the present case the manufacturing process was complete and that the product left APSA's sphere of control when it was sent by APSA to APMSD. After the product was sold and sent to APMSD, APSA was no longer able to alter or modify it without calling the product back. Thus, in their opinion no specific criteria should be applied to intra-group transactions.

41. They add that control over a product should not be confused with control over a company. They are different concepts. The first relates to possession, in the legal sense,

the latter to voting rights. They stress that although a subsidiary is part of the same group of companies as the parent company, it has a legal personality distinct from that of its parent company, with separate rights and liabilities.

42. I recall, as set out above, that Article 11 of the Directive is written mainly in the interest of the producers. However consumers have an interest too, which is that a producer should not be able to manipulate the length of the liability period by way of its internal organisation. Therefore, I do not agree with the argument that a transaction within a group should be treated simply the same as a transaction with a third party.

43. First, it is clear that the point of reference should be control or surrender of control over the product.

44. Second, it is important not to lose sight of the economic reality. In fact there is great variety in the way companies may organise their respective production, sale and marketing activities. This is especially the case where the company's organisation extends to the territory of more Member States. In such circumstances there will be an even greater degree of diversity.

45. The same or comparable activities can be organised in different ways, depending, for example, on the fiscal and other legal consequences of the different types of organisation. Whereas some companies distribute their product through branches, others do so through subsidiaries and sometimes the producer delivers directly to third parties. Hybrid constructions are also used.

46. Third, the more organisational diversity there exists, the greater the need will be for a clear criterion for determining the moment at which the product is put into circulation. That moment coincides with the surrender of control, the moment at which the product is transferred for the first time to a person or company outside the group, an independent third party. If not, the starting point of the period would differ, depending on whether a producer made use of a subsidiary or a branch for distribution, while the issue of control in both alternatives is the same. For the purposes of the application of the Directive it is immaterial which legal form of organisation a producer has chosen.

47. Therefore, as long as a product has not been transferred to a party which is not subject to the control of the group, it may be presumed that the product is still under the control of the group to which the actual producer belongs.

48. Indeed, as the Commission pointed out, the date of the first transfer within a group of companies as the starting point of the period may be premature, because it is very likely that in most cases the chances that a product could come into contact with persons outside the group will be small until the product leaves the control of a member of a group. Considering the first move within a group as putting the product into circulation could easily reduce the period of strict liability. That is for example the case where a product is kept by a subsidiary or another plant belonging to the producer without being used for a couple of years and then sold or hired out to a person outside the group.

49. As long as the product remains within the group, the producer may still ensure that the product does not come into the hands of a group of potential victims. That means that his period of strict liability has not started yet. He might be liable under other systems, but not under the Directive.

50. In addition, outsiders may not know when the product was first transferred by the producer to a subsidiary. It might be quite complicated in the event of multiple intra-group transactions to establish where and when the first delivery took place. Both the victim and the other interested parties (any supplier within the meaning of Article 3(3) of the Directive) require a clear point of reference for determining the time at which a product is put into circulation. Intra-group relations are often too opaque to be useful in this respect.

51. By way of analogy I would like to remark that the argument that a subsidiary is legally distinct from the parent company (and thus that the transfer from one legal entity to another within the same group of companies coincides with putting the product into circulation) does not convince me. The use of different legal persons is common practice

for all sorts of reasons. Also, as is the case for example in the field of competition law, legally distinct persons may well be treated as a single unit for the purposes of Article 81 EC. [8] That so because of the close economic links between them. That means that arrangements between them must be seen as internal allocation of functions and roles within that economic unit. For that reason agreements between the group members fall outside the scope of the said article. Likewise, one cannot accept that a product has been put into circulation when it has been transferred to one of the distribution units of the parent company, be it a branch or subsidiary. The fact that that distribution unit will be invoiced is not decisive as internal transfer pricing is a common practice in intra-corporate relations.

52. Thus, the period of strict liability should start at the moment at which the producer voluntarily relinquishes control over the product by transferring it for commercial reasons to someone unrelated to the group to which the producer belongs.

8 — See for example Case 22/71 *Béguelin Import* [1971] ECR 949.

The second and third questions

53. By the second question the referring court asks whether Article 11 of the Directive permits the laws of the court seised by a plaintiff to treat the proceedings instituted against company A as '*proceedings against the producer*' when the proceedings were commenced against A in the mistaken belief that A was the producer of the product and the real producer was another company, company B. The third question deals with the issue of substitution. The referring courts asks whether it is permissible to substitute B (the producer) for A (the actual defendant) when the proceedings against B have been brought outside the 10-year period laid down in Article 11 of the Directive.

54. In dealing with these questions I will read APMSD for A and APSA for B. I will also disregard the fact that there is some lack of information in the order for reference. It is not clear, for example, why it took a while (from November 2000 to October 2002) before the claimant started an action against APSA. It is also not clear how APMSD reacted when it was served with the claim

and whether and when this company informed the claimant about the identity of the actual producer. This is a question of fact for the referring court to deal with.

55. As a preliminary remark I would call to mind that Article 11 of the Directive refers to the producer. Who can be considered to be a producer is defined in Article 3 of the Directive: the actual producer and anyone who presents himself as the producer by putting his name, trade mark or other distinguishing feature on the product.

56. Next, an injured person may also sue any supplier of the product when the producer cannot be identified and the supplier fails to inform the victim within a reasonable time of the identity of the producer or of the person who supplied him with the product. In that case, under Article 3(3) of the Directive the supplier of the product is to be treated as the producer.

57. Article 11 of the Directive, as I said, aims to establish a clear final date after which the strict liability of the producer will be extinguished unless proceedings have been instituted against him before that date.

58. It is clear that if an injured person has mistakenly commenced proceedings against a person who is not the producer within the meaning of Article 3, the 10-year period is not interrupted. The error might well have as a consequence that in the meantime the time-limit of 10 years has elapsed, since the Directive does not permit national courts or national legal orders to disregard the time-limit where proceedings were instituted before the deadline against a company other than the producer, as that would undermine the balance struck by the Directive between the respective interest of users and producers.

59. This being so, I shall consider Questions 2 and 3 in the light of the factual situation at issue in the main proceedings.

60. It is a fact that the producer and the supplier in the present case belong to the same group of companies. As we know from the answer to the first question, APMSD is neither an independent third-party supplier, nor the actual producer. It is however the legal person which for the first time put the product into circulation by transferring it to

a party outside the group. For the purposes of Article 3(3) of the Directive, APMSD could be sued as the supplier.

61. In such a situation, characterised by the circumstance that the allegedly defective product is put into circulation by a company belonging to the same group as the company which produced it, there is a great likelihood that the interested party who suffered damage might be confused as to the correct identity of the producer.

62. If the supplier is erroneously sued as the producer, he should immediately inform the suing party as to the identity of the producer, particularly where the supplier is the subsidiary of the producer, as in the present case. If he were to fail to do so, by analogy with Article 3(3) of the Directive, he should/could be treated as the producer.

63. As I said before, if the identity of the producer is unknown to the injured person he may bring an action against the supplier, who to escape liability must disclose the identity of the producer. The same holds true if there was a mistaken belief that the supplier was the producer of the product. Indeed, following the logic of Article 3(3) of the Directive, denying being the producer entails the obligation to inform the claimant as to the identity of the producer if this is known to the supplier, which seems very likely to be the case here.

64. It would be unacceptable if the victim's claim were to be rejected because the limitation period had expired, which might be the case if the supplier, erroneously sued as the producer, neglected to provide the information known by it as to the identity of the producer within a reasonable time.

65. Therefore, in my opinion, it is not contrary to the Directive, in particular Articles 3(3) and 11, to permit the court seised of a claim brought by a plaintiff against a supplier to treat such proceedings as 'proceedings against the producer' when the supplier knew who was the producer and could have informed the plaintiff in due time for a claim to be lodged against the producer within the 10-year period laid down in Article 11.

66. In view of the answer proposed to the second question, there is no need to answer the third question.

V — Conclusion

67. I therefore conclude that the following answers should be given to the questions referred by the High Court of Justice, Queen's Bench Division.

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 from the moment at which it is transferred by a person or company over whom the producer exercises effective control to a person or company over whom the producer does not exercise such control.

Where proceedings asserting rights conferred on the claimant pursuant to Directive 85/374/EEC in respect of an allegedly defective product are instituted against a supplier within the 10-year period laid down in Article 11 of the Directive in the mistaken belief that the supplier was the producer of the product when in fact the producer was another company within the same group of companies to which both the supplier and the producer belong, the provisions of Directive 85/374/EEC, and in particular Articles 3(3) and 11, permit the court seised to treat such proceedings as proceedings against the producer within the meaning of Article 11 when the supplier knew the identity of the producer and was in a position to inform the plaintiff thereof in a reasonable time and in any event before the expiry of that 10-year period.