OPINION OF ADVOCATE GENERAL MENGOZZI
delivered on 27 October 2011[1]

1. This reference for a preliminary ruling concerns the interpretation of Articles 3 and 13 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).

2. The reference was made in the course of a dispute concerning the liability of the Centre Hospitalier Universitaire de Besançon ('CHU Besançon') for the damage caused to a patient consequential on the use of a defective mattress heater.

1 — Original language: French.

I — Legal background

A — *Directive 85/374*

3. The 1st, 4th, 13th and 18th recitals in the preamble to Directive 85/374 state:

'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 protection of the consumer requires that all producers involved in the production process should be made liable, in so far as their finished product, component part or

any raw material supplied by them was defective; whereas, for the same reason, liability should extend to importers of products into the Community and to persons who present themselves as producers by affixing their name, trade mark or other distinguishing feature or who supply a product the producer of which cannot be identified;

…

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; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible;

…

Whereas the harmonisation resulting from this cannot be total at the present stage, but opens the way towards greater harmonisation; …'

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 the directive reads 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 13 of Directive 85/374 provides as follows:

'This directive 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.'

B — *National law*

7. Directive 85/374 was transposed into domestic law by Articles 1386-1 to 1386-18 of the Civil Code.

8. The Conseil d'État (Council of State) (France) explains that the liability of public healthcare establishments to their patients is part of a system of liability governed, inter alia, by principles laid down by decisions of the administrative courts.

9. Amongst those principles is one established by the Conseil d'État in a decision of 9 July 2003 [2], according to which a public healthcare establishment must provide compensation, even in the absence of fault on its part, for injury suffered by a patient owing to the failure of equipment or any product used in the context of care provision.

II — The dispute in the main proceedings and the questions referred for a preliminary ruling

10. A patient, then aged 13 years, suffered burns during surgery performed on 3 October 2000 in CHU Besançon. Those burns were caused by a heated mattress on which he had been placed and whose temperature control mechanism was defective.

11. By a judgment dated 27 March 2000, the Tribunal Administratif (Administrative Court), Besançon, ordered CHU Besançon to provide compensation for the damage caused. The appeal against this judgment was dismissed by the Cour administrative d'appel (Administrative Court of Appeal), Nancy, by a judgment of 26 February 2009. CHU Besançon then lodged an appeal on a point of law with the Conseil d'État.

12. In support of its appeal on a point of law, CHU Besançon argues that the decision of the Cour administrative d'appel is contrary to Directive 85/374. In fact, that directive, it submits, precludes a public hospital from incurring liability, in the absence of any fault

2 — Conseil d'État, 9 July 2003 Assistance Publique – Hôpitaux de Paris v Mrs Marzouk, No 220437.

on its part, where harmful consequences ensue solely as a result of the failure of healthcare equipment and appliances used by it. Only the manufacturer of the mattress, once duly identified, should be held liable.

13. The principle that a public hospital must make reparation, even where it is not at fault, for injury suffered by a patient due to the failure of an appliance or product used in the provision of care, is a principle laid down by the Conseil d'État on 9 July 2003. This particular system of liability derives from the specific relationship between public hospitals and the persons who are taken into their care. In the view of the Conseil d'État, it could thus be argued that this system of liability is founded on a specific basis, distinct from the system established by Directive 85/374. The system of liability governing public healthcare establishments could therefore continue to apply, under Article 13 of the directive.

14. If that is not the case, the Conseil d'État is of the view that the outcome of the dispute in the main proceedings then depends on whether the system of liability established by Directive 85/374 applies to damage which a user of a defective product may have caused to a third party in the course of providing services to that party.

15. In those circumstances the Conseil d'État decided to stay proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Having regard to the provisions of Article 13 thereof, does Directive [85/374] permit the implementation of a system of liability based on the special situation of patients in public healthcare establishments, in so far as it recognises, inter alia, that they have the right to obtain from such establishments, even when those establishments are not at fault, compensation for damage caused by the failure of products and equipment which they use, without prejudice to the possibility for the establishment to bring third-party proceedings against the producer?

(2) Does Directive [85/374] limit the ability of the Member States to define the liability of persons who use defective equipment or products while providing services and, in so doing, cause damage to the recipient of those services?'

III — Proceedings before the Court

16. This reference for a preliminary ruling made by the Conseil d'État by decision of 4 October 2010 was received at the Court on 15 October 2010.

17. CHU Besançon, the French, German and Greek Governments and the European Commission, lodged written observations with the Court.

18. Those interested parties, with the exception of the German Government, presented oral argument at the hearing which was held on 20 September 2011.

IV — Legal analysis

19. As all the parties present at the hearing rightly acknowledged, the Court should first of all address the second question, because it seeks to determine whether or not a system of liability such as that at issue in the main proceedings comes within the scope of Directive 85/374. A negative reply to that question would render devoid of purpose examination of the first question referred, which relates to Article 13 of Directive 85/374, and would give the national court sufficient information to resolve the dispute in the main proceedings.

A — *Second question*

20. The second question raised by the referring court concerns the determination of the scope of Directive 85/374. In particular, the Court of Justice must determine whether the directive limits the possibility of applying a national system of liability for public hospitals which use defective equipment or products in the course of providing services.

21. In more general terms, the question arises as to the application of Directive 85/374 to the system of liability applicable to a service provider in respect of damage caused by a defective product used by it in providing services. There are two hypothetical cases in which the directive could apply to the service provider, thereby precluding the implementation of a national system of liability.

22. In the first, Directive 85/374 would apply to the system of liability governing the service provider because he is deemed to be the 'supplier' of a defective product, within the meaning of Article 3(3) of Directive 85/374. Article 3(3) provides that, 'where the producer of a product cannot be identified, each supplier of the product is to 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 legislature does not define the term 'supplier', which could thus include the service provider. Under Article 3(3) of

Directive 85/374, the provider would then be deemed to be a 'producer' of the defective product used in the course of providing services, unless he informed the injured person, within a reasonable time, of the identity of the producer or of his own 'supplier'.

23. In the second hypothetical case, Directive 85/374 would apply to the system of liability governing the service provider because it excludes him from an exhaustive list of persons liable for defective products, which expressly includes only the 'producer' and 'supplier'. Unlike in the first case, the provider of services would not be regarded as a 'producer' of a defective product if he cannot be deemed to be a 'supplier' of the product. He would not therefore incur liability for damage caused by the defective product, even if he does not identify the 'producer' or person who supplied him with the product used in the provision of services.

24. I shall consider these two hypothetical cases in turn, that is to say, firstly, the inclusion of the service provider in the term 'supplier' within the meaning of Article 3(3) of Directive 85/374 (1), and, secondly, the exhaustive determination in Directive 85/374 of the class of persons liable (2).

1. Deeming the service provider to be a 'supplier' within the meaning of Article 3(3) of Directive 85/374

25. Directive 85/374 does not define a 'supplier' of a defective product, within the meaning of Article 3(3).

26. According to the Greek Government, the 'supplier' for the purposes of Article 3(3) of Directive 85/374 means the person who operates in the chain of distribution [3]. In the main proceedings, the last link in the chain of distribution is therefore the delivery of the defective mattress to CHU Besançon. The subsequent use of the mattress by CHU in the context of care provided to patients does not form part of that chain of distribution. The French Government, for its part, considers that the 'supplier' must be a person acting in a professional capacity in the marketing chain for the product [4]. At the hearing, the Commission agreed with both parties.

27. In the light of the Court's case-law on the interpretation of Directive 85/374, the concept of a 'supplier', within the meaning

3 — The Greek Government bases its argument on the Council Resolution of 19 December 2002 on amendment of the liability for defective products Directive (OJ 2003, C 26, p. 2), of which paragraph 4 states that 'The Council notes that the word "supplier" within the meaning of Article 3(3) means the person who operates in the chain of distribution.'

4 — The French Government refers to Case C-402/03 *Skov and Bilka* [2006] ECR I-199, paragraph 28.

of Article 3(3) of Directive 85/374, may be clarified with greater precision. In *Skov and Bilka* [5], the Court stated that 'Articles 1and 3 of the directive … determine which of the operators who have taken part in the manufacture and marketing processes will have to assume the liability established by the directive' [6]. In a subsequent judgment it criticised Danish provisions which made 'intermediaries in the distribution chain' liable under the same conditions as the manufacturer [7]. In addition, the Court stated as follows, in regard to the 'putting into circulation' of a defective product: '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 [Directive 85/374]' [8].

28. Furthermore, the Court took the view that the 'producer... is defined, in particular, as the manufacturer of a finished product. It is only in the cases exhaustively listed that other persons can be considered to be a producer, namely, any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer (Article 3(1) of the directive), any person who imports a product into the Community (Article 3(2) of the directive) and the supplier who, where the producer of the product cannot be identified, does not inform the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product (Article 3(3) of the directive)' [9]. Adopting a particularly wide definition of the concept of 'supplier' would run counter to that intention to draw up an exhaustive list of 'producers'.

29. The Court has never directly defined the concept of 'supplier' within the meaning of Article 3(3) of Directive 85/374. Nevertheless, it is clear from the judgments mentioned above that the supplier of a defective product must be regarded as an intermediary involved in the marketing or distribution chain of the defective product. Such a definition should be restrictive in nature.

30. In order to ascertain what is meant by 'supplier', as referred to in Article 3(3) of Directive 85/374, in the context of the marketing or distribution chain of a defective product,

5 — Judgment cited above.

6 — Ibid., paragraph 30.

7 — Case C-327/05 *Commission v Denmark* [2007] ECR I-93, paragraph 18.

8 — Case C-127/04 *O'Byrne* [2006] ECR I-1313, paragraph 28.

9 — Ibid., paragraphs 36 and 37.

it is helpful to refer to Directive 2001/95/EC [10]. In fact, as pointed out by the French Government, the delimitation of the scope of that directive necessarily reflects the delimitation of the scope of Directive 85/374 [11].

31. Directive 2001/95 states, in recital 9 in its preamble, that '[t]he safety of the equipment used by service providers themselves to supply a service to consumers... has to be dealt with in conjunction with the safety of the service provided...'. Given the link between the two directives, it may also be considered in parallel, in the light of Directive 85/374, that the use of the defective product by a service provider has to be dealt with in conjunction with the service for which it is used. Accordingly, the provider of services is distinct from the 'supplier' of a defective product, within the meaning of Article 3(3) of Directive 85/374, because he provided not a product but services in the provision of which the defective product was used [12].

32. In the main proceedings, the defective mattress was plainly used in the course of care provision by CHU Besançon. As noted by the Commission at the hearing, this case did not involve a consumer looking to purchase a mattress, but a patient who came into hospital. The safety of the defective mattress must therefore be dealt with in conjunction with the care provision itself. Accordingly, the CHU Besançon cannot be deemed to be the distributor of the defective mattress and cannot be equated with a 'supplier' under Article 3(3) of Directive 85/374, contrary to the first hypothesis advanced at point 22 of this Opinion.

10 — Directive 2001/95/EC of the European Parliament and of the Council, of 3 December 2001, on general product safety (OJ 2001 L 11, p. 4).

11 — The French Government invokes Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, which amended Directive 85/374 (OJ 1999 L 141, p. 20) – that directive brought primary agricultural products within the scope of Directive 85/374. Directive 1999/34 provides, in its first recital, that 'whereas product safety and compensation for damage caused by defective products are social imperatives which must be met within the internal market; whereas the Community has responded to those requirements by means of Directive [85/374] and Directive 92/59/EEC [which was replaced by Directive 2001/95] ...'.

12 — In Case C-203/99 *Veedfald* [2001] ECR I-3569, the Court considered that the use of a defective product in the context of a provision of services fell within the scope of the directive, drawing a distinction between the defectiveness of the product used and the defectiveness of the provision of services as such (paragraph 12); however, the issue of regarding the provider of services as a 'supplier,' for the purposes of Article 3(3) of Directive 85/374, was not raised. That case concerned the liability of the municipal administration, both care provider and manufacturer of the defective product. Directive 85/374 therefore applied to its liability as a 'producer' of the defective product, within the meaning of Article 3(1) of that directive. Consequently, the judgment does not constitute a precedent precluding the exclusion of the service provider from the concept of 'supplier' of a defective product, for the purposes of Article 3(3) of Directive 85/374.

2. Exhaustive determination in Directive 85/374 of the persons liable for defective products

33. The system of liability for public hospitals applicable to CHU Besançon based on the judgment of the Conseil d'État of 9 July 2003 might fall within Directive 85/374, even if the hospital cannot be deemed a supplier within the meaning of Article 3(3) of the directive, under the second hypothesis advanced at point 23 of this Opinion. The view could be taken that the system established by the directive determines that all liability for defective products lies solely with the persons expressly mentioned in Directive 85/374. Accordingly, if CHU Besançon were held not to belong to the class of persons liable set out in Article 3 of Directive 85/374, it could not incur liability for using a defective mattress. Only the 'producer' and, where appropriate, the 'supplier' of the defective mattress would be liable for damage caused by the defective product when used in the provision of services.

34. In a series of judgments, the Court appears to rule to this effect in holding that the 'determination in Articles 1 and 3 [of Directive 85/374] of the class of persons liable must be regarded as exhaustive' [13].

35. However, a careful examination of the case-law on the interpretation of Directive 85/374 reveals that the assertion that the provider of services cannot be liable since there is no provision for such liability in Directive 85/374 is not supported by the case-law of the Court (a). In addition, a recent judgment demonstrates that, on the contrary, the directive should not be regarded as applicable beyond the matters in respect of which it makes express provision (b).

(a) The fact that the case-law has not extended Directive 85/374 to the system of liability applicable to service providers

36. One cannot disregard the context in which the Court's finding cited at point 34 of this Opinion was made. Consideration of the context reveals that the Court did not on that occasion expressly rule on the possible extension of the scope of Directive 85/374

13 — See *Skov and Bilka* (paragraph 33) and *O'Byrne* (paragraph 35); for a similar formula, see Case C-358/08 *Aventis Pasteur* [2009] ECR I-11305, paragraph 36, according to which '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'.

to the system of liability applicable to service providers.

37. The Court has made reference to the exhaustive definition of the class of persons liable in two separate situations. Firstly, in order to assess the extent of the liability of a 'supplier' within the meaning of Article 3(3) of Directive 85/374, in which context it has reaffirmed the subsidiary nature of the supplier's liability as compared with that of the 'producer' [14]. The designation of the 'supplier' did not give rise to difficulties, since in that case it was the owner of the shop in which the defective product was bought. Secondly, the Court again took up the notion that the class of persons liable has been exhaustively defined when the question arose as to the possible substitution of one party for another, in a case where an action was brought against a company which was erroneously taken to be the 'producer' of a defective product [15]. Plainly those cases related to the system of liability applicable to the 'producer' or 'supplier', within the meaning of Article 3 of Directive 85/374.

38. Other than in those cases, the Court has never directly ruled on the extension of the scope of Directive 85/374 to the liability of the service provider for a defective product. In particular, in *Veedfald*, concerning the implementation of Directive 85/374 when a defective product is used in the context of the provision of services, the Court ruled only on the liability of the 'producer' of the defective product, within the meaning of Article 3(1) of Directive 85/374 [16].

39. It should further be noted in this respect that the circumstances of one case in particular could have enabled the Court to rule on the matter. In that case, the Court was concerned with the situation of Ms Gonzalez Sanchez, who claimed to have been infected by the Hepatitis C virus by a transfusion in a medical establishment. [17] The Court could haven take that opportunity to clarify whether the medical establishment in question was considered a 'supplier' of the defective product, within the meaning of Article 3(3) of Directive 85/374. Without deeming the medical institution to be a 'supplier', it could have established that the scope of Directive 85/374 also extended to the system of liability applicable to the medical establishment. The Court did not provide such clarification, because the only question before it was whether 'Article 13 of [Directive 85/374] must be interpreted as precluding the restriction or

14 — See *Skov and Bilka*, paragraph 37.

15 — See the judgments cited above *O'Byrne,* paragraph 39, and *Aventis Pasteur,* paragraphs 62 to 64.

16 — Judgment cited above.

17 — Case C-183/00 *Gonzalez Sanchez* [2002] ECR I-3901.

limitation, as a result of transposition of the directive, of rights granted to consumers under the legislation of the Member State' [18].

40. The Court gave a specific reply to that question, finding as follows: 'Article 13 of the directive must be interpreted as meaning that the rights conferred under the legislation of a Member State on the victims of damage caused by a defective product under a general system of liability having the same basis as that put in place by the directive may be limited or restricted as a result of the directive's transposition into the domestic law of that State' [19]. Any rights conferred by the legislation of a Member State on the victims of damage caused by a defective product may be limited or restricted as a result of the transposition of the directive. Indeed, if national law provides for other conditions under which the 'producer' or the 'supplier' incurs liability on the same basis of a defect in the product, those conditions cannot subsist once the directive is transposed. In that judgment, the Court did not therefore rule on the question of the scope of Directive 85/374 or its extension to service providers.

(b) Non-applicability of Directive 85/374 other than to the matters expressly regulated by it

41. The Court recently affirmed the non-applicability of Directive 85/374 beyond the matters expressly regulated by it when it was addressing a question concerning liability for a defective product. The case was the one which gave rise to the judgment in *Moteurs Leroy Somer* [20]. In that case, a hospital generator caught fire because an alternator overheated. The defective alternator thus caused damage to an item of property *intended for professional use* and employed for that purpose. The Court found that the harmonisation effected by Directive 85/374 did not cover compensation for this type of damage. Accordingly, the directive did not preclude a Member State from providing for a system of liability beyond that introduced by the directive.

42. The position thus adopted by the Court is consistent with the fact that Directive 85/374, in the 18th recital in its preamble, expressly states that 'the harmonisation resulting from this [directive] cannot be total at the present stage, but opens the way towards greater harmonisation' [21]. Directive 85/374 is not intended to govern exhaustively the field of liability for defective products.

18 — Ibid., paragraph 13.
19 — Ibid., paragraph 34.
20 — Case C-285/08 [2009] ECR I-4733.
21 — See the 18th recital in the preamble to Directive 85/374.

43. The Court adopted that position even though it had previously indicated that 'Articles 1 and 9... set out exhaustively the heads of damage that may be possible' [22]. In its judgment in *Moteurs Leroy Somer*, it stated that '[a]lthough Directive 85/374 … seeks to achieve, in the matters regulated by it, complete harmonisation of the laws, regulations and administrative provisions of the Member States [[23]], it does not, however, as is apparent from the 18th recital in the preamble thereto, seek exhaustively to harmonise the field of liability for defective products beyond those matters' [24]. The Court held that '[i]t is apparent both from the wording and from the structure of Directive 85/374... that compensation for damage to an item of property intended for professional use and employed for that purpose is not one of the matters regulated by that directive' [25]. Accordingly, the scope of Directive 85/374 does not extend to damage caused by a defective product to an item of property intended for professional use and employed for that purpose.

44. The position taken by the Court in *Moteurs Leroy Somer* is of particular significance for the purposes of the answer to be given to the referring court; this is because in *Veedfald*, the Court had confirmed the absence of rules relating to the liability of the provider of services for damage caused by defective products [26]. The Court thereby acknowledged that the legislature had not planned to introduce a system of liability applicable to the provision of services by means of Directive 85/374. If those two judgments are read together, the necessary conclusion is that the scope of Directive 85/374 extends only to the liability of the 'producer' or, where appropriate, the 'supplier' of a defective product, within the meaning of Article 3 of the directive, even when the product has caused damage while being used in the course of a provision of services. Therefore, the harmonisation of Directive 85/374 does not extend to the system of liability applicable to the service provider, contrary to the second hypothesis considered in point 23 of this Opinion.

45. Furthermore, in *Moteurs Leroy Somer*, the Court held that the damage at issue 'is not covered by the term "damage" for the purposes of Directive 85/374' [27], rather than finding that the damage was covered by the directive and did not confer a right to compensation because the directive provided only for compensation for damage to items intended for private use and employed by the

22 — *Veedfald*, paragraph 32.

23 — The assertion derives from three judgments of 25 April 2002: C-52/00 *Commission v France* [2002] ECR I-3827, paragraphs 14 to 24; C-154/00 *Commission v Greece* [2002] ECR I-3879, paragraphs 10 to 20, and *González Sánchez*, paragraphs 23 to 32.

24 — *Moteurs Leroy Somer,* paragraph 25.

25 — Ibid., paragraph 27.

26 — In *Veedfald*, the Court thus stated: 'in the absence of any Community legislation on services' (paragraph 12).

27 — *Moteurs Leroy Somer*, paragraph 17.

injured person for that purpose. The Court's approach left open the possibility of assuring better compensation for victims of damage caused by defective products.

46. The main proceedings likewise concern liability incurred by a person not referred to in Directive 85/374. The national system of liability leaves intact the system of liability applicable to the 'producer' and, where appropriate, the 'supplier' of a defective product harmonised by the directive. As noted by the German Government, the national system of liability applicable to the service provider applies in addition to any liability incurred by the 'producer' and 'supplier' under Directive 85/374. That extension of the category of persons accountable to the patient of a public healthcare establishment thus reinforces the patient's rights. It may be noted in this regard that such an extension is in keeping with the spirit and purpose of the objective of effective consumer protection pursued by Directive 85/374 [28].

47. It is interesting to note in this regard that, contrary to its submissions in its written observations, at the hearing the Commission took the view that Directive 85/374 does not limit the Member States' ability to determine the liability of persons who use defective equipment or products in the course of providing services. In the main proceedings, as it rightly pointed out, only the application of a national system of liability to the service provider gives the patient a right to compensation for the burns caused by the defective mattress. In fact, as the damage occurred during an operation performed on 3 October 2000, any action against the 'producer' of the defective mattress, within the meaning of Article 3(1) of the directive, would be time-barred [29].

48. Consistently with its judgment in *Moteurs Leroy Somer*, the Court should therefore conclude that compensation by a service provider for damage caused by a defective product used in the course of the provision of services by it is not among the matters regulated by Directive 85/374. As a result, that directive does not preclude a Member State from providing for a system of liability beyond the one established by the directive, enabling CHU Besançon to be held liable as the provider of care in the course of which a defective mattress was used.

28 — See, in particular, the 13th recital in its preamble which states that 'under the legal systems of the Member States, an injured party may have a claim for damages based on grounds of non-contractual liability other than that provided for in this directive; in so far as these measures also serve to attain the objective of effective protection of consumers, they should remain unaffected by this directive'.

29 — Article 11 of Directive 85/374 thus provides that '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... product [...]'.

3. Interim conclusion

49. For all these reasons, I suggest that the Court's reply to the second question posed by the referring court should be that Directive 85/374 permits the Member States to determine the liability of persons who use defective equipment or products in the course of providing services and, in so doing, cause damage to the recipient of those services, without prejudice to the possibility of applying the rules provided for on the basis of Directive 85/374 as against the producer.

50. In the event that the Court does not share this view and is of the opinion that the scope of Directive 85/374 does extend to the system of liability governing the service provider in connection with the use by it of a defective product in the course of providing services, I shall in the alternative examine the first question referred, which concerns the interpretation of Article 13 of Directive 85/374, so as to give the Court as much assistance as possible.

B — *In the alternative, first question*

51. The first question asked by the referring court concerns the interpretation of Article 13 of Directive 85/374, which provides as follows: 'This directive 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'. In this case, the question is whether Directive 85/374 permits the implementation of a system of liability based on the specific situation of the patients of public healthcare establishments in respect of the failure of products and equipment used by such establishments.

52. The Court has interpreted Article 13 of Directive 85/374 to mean that 'the system of rules put in place by the directive, which in Article 4 enables the victim to seek compensation where he proves damage, the defect in the product and the causal link between that defect and the damage, does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects' [30].

53. Accordingly, Directive 85/374 permits the application of a special liability system which was in place at the time of notification of the directive and of a system of contractual or non-contractual liability having a different basis.

30 — *Commission v France,* paragraph 22; *Commission v Greece,* paragraph 18; *González Sánchez,,* paragraph 31; *Skov and Bilka*, paragraph 47, and *Moteurs Leroy Somer,* paragraph 23.

54. As regards, first, the special liability system in place at the time of notification of Directive 85/374, the directive was notified to the Member States on 30 July 1985. However, it must be observed in this regard, as pointed out by the referring court, that the system of liability in question in the main proceedings is based on a principle originally laid down by the Conseil d'État in a judgment of 9 July 2003. According to the written observations of the French Government, prior to that judgment, the case-law of the Conseil d'État required that there be fault in order for a public healthcare establishment to incur liability [31]. It was therefore only from the judgment of 9 July 2003 that public hospitals could be held liable, even in the absence of fault on their part, for the harmful consequences to users of the failure of healthcare products and equipment used in the provision of care. Accordingly, that system of liability cannot be regarded as having been in place at the time of notification of Directive 85/374.

55. As regards, next, a system of contractual liability or non-contractual liability having a different basis, it is necessary to determine whether the system of liability applicable to a public healthcare establishment has a different basis than the system established by Directive 85/374.

56. According to the Court, unlike the regimes applicable to warranties for latent defects or fault-based liability, Directive 85/374 establishes a system of liability based solely on the defectiveness of the product. Directive 85/374 defines what it means by defective, namely a product which 'does not provide the safety which a person is entitled to expect' [32]. For the Court, the concept of basis relates solely to the defectiveness of the product.

57. In finding that a system of liability has a different basis, the Court did not refer more generally to the conditions or effects of a system of liability and did not consider the context of such liability. Accordingly, Directive 85/374 must be interpreted as excluding the application of a system having the same subject-matter, namely liability, and the same basis, namely a defective product which does not offer the safety which a person is entitled to expect.

58. In the referring court's view, it may be argued that the system of liability in question has a different basis because it is founded on the specific relationship which is established between public hospital and the persons whom it takes into its care. In the view of the German Government, the basis is different because a category of persons liable is established which departs from Directive 85/374. The concept of basis it puts forward in its submissions seems to be different from that

31 — Conseil d'État, 1 March 1989, Époux Peyre, n° 67255.

32 — Article 6(1) of Directive 85/374.

advanced by the Court in its line of case-law on the interpretation of Directive 85/374. It is significant in this respect that the French Government does not regard it as decisive whether or not the system at issue has the same basis of no-fault liability.

59. The system at issue in the main proceedings is a system of liability based on the failure of healthcare products and equipment. However, basing a system of liability on product failure is the same as basing such a system on a defect in a product which does not offer the safety a person is entitled to expect. That system of liability cannot therefore be regarded as having a different basis than that on which the system established by Directive 85/374 is based.

60. Accordingly, if the Court were to consider that the scope of Directive 85/374 extends to the system of liability applicable to public healthcare establishments for the failure of products and equipment they use, the Court would then have to accept that Directive 85/374, in the light of the interpretation of Article 13 thereof, does not permit the implementation of a system of liability based solely on the failure of those products and that equipment.

V — Conclusion

61. In the light of the considerations set out by way of principal argument, I suggest that the Court reply to the Conseil d'État as follows:

Council Directive 85/374/EEC of July 25 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for

defective products permits the Member States to determine the liability of persons who use defective equipment or products in the course of the provision of services and, in so doing, cause damage to the recipient of those services, without prejudice to the possibility of applying the rules provided for on the basis of Directive 85/374 as against the producer.