OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER

delivered on 14 December 2000 [1]

1. A reference has been made to the Court of Justice under Article 234 EC by the Højesteret (Danish Supreme Court) for a preliminary ruling on five questions regarding the interpretation of Directive 85/374/EEC [2] concerning liability for defective products ('Directive 85/374').

I — The facts of the main proceedings

2. According to the summary of the facts of the case set out in the order for reference, on 21 November 1990 a kidney transplant operation was to be performed at Skejby hospital. Mr Veedfald, the appellant in the main proceedings, was the intended recipient of the organ. The respondent is the Århus Amtskommune (the Århus Regional Authority) which owns and operates Skejby hospital and the hospital at Århus.

Following its removal from the living donor (Mr Veedfald's brother), flushing of the kidney's blood vessels was commenced by mean of a perfusion fluid in order to clean the kidney of blood and to cool and stabilise the organ. The fluid consisted of a basic fluid, produced in the dispensary of Århus hospital, to which the operating staff at Skejby hospital added a glucose solution, magnesium chloride, heparin and papaverine designed to increase the fluid's stabilising effect on the cell tissue while the kidney was without a blood supply. These substances were also prepared in the dispensary of Århus hospital.

After irrigation with one litre of fluid, it was observed that a small area of the kidney had not gone through the normal colour change and that there was a fall in the processing rate. An additional dose of perfusion fluid was therefore administered and the irrigation rate fell further, to the point that the flow through the kidney's blood vessels came almost to a standstill. A subsequent examination of the bottle containing the perfusion fluid showed a cloudy, heavy precipitation consisting of small crystals. An attempt was made to irrigate the kidney in the opposite direction using a clear fluid and, since the rate at which the fluid passed through the vascular system continued to be very slow, an examination of the kidney was undertaken during which

1 — Original language: Spanish.

2 — 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).

it was found that an arterial branch was obstructed by a substance resembling the crystalline precipitation found in the perfusion fluid. Consequently, the decision was taken not to transplant the kidney.

The surgeons taking part in the operation stated that over the course of twenty years the perfusion fluid had been used in approximately one thousand transplant operations, without complications having arisen. After the operation, a test was conducted, in which a fresh portion of perfusion fluid was prepared. Following mixing, the fluid was completely clear but after three or four minutes it also crystallised and a deposit formed. The laboratory of the Sundhedsstyrelse (Health Ministry) carried out an analysis of the preparations used to produce the perfusion fluid and an analysis of the mixed perfusion fluid containing the deposit but was unable to provide an unequivocal explanation as to why the precipitation had occurred in the fluid.

3. Mr Veedfald commenced proceedings before the Vestre Landsret (Western Regional Court), seeking a ruling that the Århus Regional Authority was liable for the failure of the transplant operation and an order that the authority should pay compensation for that failure. During the course of those proceedings, questions were addressed to the Retslægeråd (Medical Legal Council), but neither the answers provided nor the evidence adduced in support of Mr Veedfald's claim enabled the actual cause of the precipitation which occurred in the perfusion fluid to be explained.

In 1997, the Vestre Landsret delivered a judgment dismissing the claim on the ground that the Århus Regional Authority had not incurred any liability.

II — The questions referred for a preliminary ruling

4. The appellant appealed against that judgment to the Højesteret, which, prior to ruling on the substantive issue, decided to stay the proceedings and to refer five questions to the Court of Justice for a preliminary ruling, explaining that the matters it raised centred on whether the provisions of Lov No 371 om Produktansvar (Law on Product Liability), which transposed Directive 85/374 into Danish law, created an obligation to pay compensation.

5. The five questions are as follows:

'(1) Must Article 7(a) of Council Directive 85/374/EEC of 25 July 1985 be construed as meaning that a defective product is not put into circulation if the producer of the defective product, in the course of providing a specific medical service, produces and uses the product on a human organ which, at

the time when the damage occurred, had been removed from a donor's body in order to be prepared for transplant into another person's body, with resulting damage to the organ?

(2) Must Article 7(c) of Council Directive 85/374/EEC of 25 July 1985 be construed as meaning that a publicly owned hospital is free from liability under the directive for products produced and used by that hospital in the course of providing a specific publicly financed service to the person suffering injury and in respect of which that person has not paid any consideration?

(3) Does Community law impose requirements as to how Member States should define the expressions "damage caused by death or by personal injuries" and "damage to, or destruction of, any item of property" in Article 9 of Council Directive 85/374/EEC of 25 July 1985, or are individual Member States free to decide what meaning is to be attached to those expressions?

(4) Must Article 9(a) of Council Directive 85/374/EEC of 25 July 1985 be construed as meaning that damage to a human organ which, at the time when the damage occurred, had been removed from a donor's body for immediate transplant into a certain other person's body is covered by the expression "damage caused by personal injuries" in relation to the intended recipient of the organ?

(5) Must Article 9(b) of Council Directive 85/374/EEC of 25 July 1985 be construed as meaning that damage to a human organ which, at the time when the damage occurred, had been removed from a donor's body for immediate transplant into a certain other person's body is covered by the expression "damage to, or destruction of, any item of property" in relation to the intended recipient of the organ?'

III — Procedure before the Court of Justice

6. The appellant and the respondent in the main proceedings, the Danish, French, Irish, Austrian and United Kingdom Governments and the Commission have submitted written observations in these pro-

ceedings within the period prescribed for that purpose by Article 20 of the EC Statute of the Court of Justice.

At the hearing, which took place on 16 November 2000, oral argument was presented by the representatives of Mr Veedfald, the Århus Amtskommune, the French Government, the Irish Government and the Commission.

IV — The applicability of Directive 85/374 to a product prepared by a professional operator for use in the course of his business

7. Before considering the questions referred and suggesting a reply, I should like to make some observations regarding the applicability of Directive 85/374 on liability for defective products to a situation in which a fluid which caused damage was prepared by qualified hospital staff, with the sole aim of its being used in a specific surgical operation, from constituent substances supplied by the dispensary of another hospital.

8. The first three recitals in the preamble to Directive 85/374 state that the aim of the directive is to approximate the laws of the Member States concerning the liability of a producer for damage caused by the defectiveness of his products, since the existing divergences may distort competition, affect the free movement of goods within the common market and entail a differing degree of protection of consumers against damage caused by a defective product to their health or property; that liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production; and that liability without fault should only apply to movables which have been industrially produced.

9. Under Article 1 of Directive 85/374, a producer is liable for damage caused by a defect in his product. Article 2 defines as a 'product' all movables, even though incorporated into another movable or into an immovable. [3] Article 3(1) defines a 'producer' as 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.

10. For the purposes of Directive 85/374, Article 9 provides that 'damage' means

3 — Primary agricultural products, which were excluded from the scope of Directive 85/374, have since been included by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC (OJ 1999 L 141, p. 20).

damage caused by death or by personal injuries and damage to, or destruction of, any item of property other than the defective product itself. Under Article 7(a) and (c), a producer will not be liable if he proves that he did not put the product into circulation, or that the product was not manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business.

11. At the hearing, I asked the parties to comment on the applicability of Directive 85/374 to the circumstances giving rise to the main proceedings and it emerged that views differed. While the appellant, the French Government and the Commission were unreservedly of the view that the directive does apply, the respondent regional authority and the Irish Government expressed the opposite view.

12. In view of the aim of Directive 85/374 and of the matters it governs, I myself consider that the directive is not applicable to a case such as the one before the Højesteret. My conviction is based on a number of reasons.

13. First, Directive 85/374, which provides that a producer is to be liable without fault for defects in his products, only applies to movables which have been manufactured industrially. However, I deduce from the summary of the facts set out in the order for reference that the perfusion fluid used on the kidney, consisting of a base fluid prepared in the dispensary of Århus hospital and of other substances which were added by the operating staff at Skejby hospital, is a single preparation which is specially made up each time it is required for use in a transplant operation. In those circumstances, I must conclude that this was not an industrially produced product.

14. Second, even if the preparation in question is a movable, in other words a 'product', and each of the hospitals could be deemed to be the 'producer', given the such broad definitions of these terms in Directive 85/374, regard must always be had to the fact that underlying the entire scheme of the directive is the idea of a product being 'put into circulation' by the producer, an activity which the directive does not define.

Thus, under Article 6, the time when the product *was put into circulation* may be taken into account in order to decide whether the product provided the safety which a person is entitled to expect. Article 7 provides that a producer is not to be liable if he proves that *he did not put the product into circulation*, or that *he did not manufacture the product for sale or distribution* for an economic purpose and that *he did not manufacture or distribute the product* in the course of his business, or that, at the time when the product was *put into circulation*, the state of scientific and

technical knowledge was not such as to enable the existence of the defect to be discovered. Lastly, under Article 11, the limitation period within which an injured person is entitled to commence proceedings claiming liability on the part of the producer is ten years from the date on which the product was *put into circulation.*

The perfusion fluid in this case was prepared for use in the course of a specific hospital procedure but it was not put into circulation on the market, it was not manufactured to be sold or distributed, it was not at any time available to consumers or intended for their use and, although it could be argued that it was manufactured in the course of a business, the preparation of a fluid of this type is, in fact, merely an activity [4] incidental to a hospital's primary mission of taking care of the sick, which includes the performance of operations.

15. There is also a third reason for my view, which reinforces the arguments advanced above. It is common knowledge that in November 1990 the Commission submitted a Proposal for a Directive to the Council, the aim of which was to harmonise the laws of the Member States relating to the liability of suppliers of services. [5] The Directive was to be governed by the principle of liability on the part of the supplier of a service in the case of a fault committed by him, making no distinction as to the supplier's public or private status, provided that it was rendered by a professional operator. It should be pointed out that the services covered by this proposal did not coincide with those envisaged by Articles 49 EC and 50 EC, since it included any transaction carried out in an independent manner, whether or not in return for payment, *which did not have as its direct and exclusive object the manufacture of movable property* or the transfer of rights *in rem* or intellectual property rights. For reasons I am not aware of, the Commission withdrew this proposal in June 1994. [6]

It can be inferred from this initiative that, in the view of the Commission, Directive 85/374 was not intended to apply to services. [7] It is my belief that, had the Proposal for a Directive become law, the liability of a supplier of services for personal injuries and for damage to property would have extended to damage caused by use of a product manufactured by the said

4 — Apparently, perfusion fluid is produced and marketed in some Member States by specialised laboratories. Hospitals can, therefore, either purchase the fluid or prepare it themselves using the basic constituents.

5 — Proposal for a Council Directive on the liability of suppliers of services, COM(90) 482 final; OJ 1991 C 12, p. 8.

6 — Izquierdo Peris, J.J., in '1995-1999: L'évolution de la directive 85/374/CEE relative à la responsabilité du fait des produits défectueux. Le Livre vert de la Commission européenne,' *Revue européenne de droit de la consommation*, 1999, pp. 241 et seq. points out the existence of Community initiatives relating to civil liability. Apparently, the Commission announced an initiative aimed at governing liability for defective services in its Communication of 1 December 1998, entitled 'Consumer Policy Action Plan 1999-2001' (COM(98) 696).

7 — At p. 6 of the Green Paper on Liability for Defective Products, the Commission itself actually states: 'Defective services are not covered by Directive 85/374/EEC. As indicated in its Consumer Policy Action Plan for 1999-2001, the Commission intends to examine the need to reinforce the safety of services. On the basis of this analysis, the Commission will propose initiatives that will address both service safety and the liability of service providers'.

supplier with the aim of using it exclusively in the course of his business.

16. My conviction in this regard is bolstered still further by the fact that products used exclusively in the course of a trade or business were excluded from the scope of Directive 92/59/EEC on general product safety. [8] Moreover, the Proposal for a Directive amending Directive 92/59, recently drafted by the Commission, [9] the aim of which is to establish within the framework of the Community a general obligation of safety for all products placed on the market or made available to consumers by other means, [10] is not intended to cover services. The ninth recital in the preamble to the proposed directive states that the directive does not govern services but that, in order to ensure that the consumer protection aims in question are achieved, the provisions of the directive also cover products supplied to or made available to consumers for their use in the context of the provision of a service. The safety of the equipment used by the suppliers of services themselves in the course of their business is not covered by the proposed directive since this is to be examined in relation to the safety of the service rendered.

With regard to the last point, it could be counter-argued that the national court has not requested an interpretation of Directive 92/59 and that the proposal for the amendment of the directive has not yet been adopted. However, both examples appear to indicate that, in the Commission's mind, products which are manufactured by a professional for use in the course of his business and which are not intended to be made available to the public are incidental to the supply of services and that, as such, any damage which they might cause must be dealt with in conjunction with the provision of the service.

17. It is therefore my opinion that Directive 85/374 is not applicable to a situation such as the one at issue in the proceedings before the national court which had referred these questions.

18. It follows from this conclusion that, in the absence of a directive governing liability for defective services, there is no Community legislation on which consumers may rely where they suffer damage caused by a product produced by a professional operator for use in the course of his business, a situation which is to be lamented.

Any solution cannot, however, lie in holding that Directive 85/374, the provisions of which are intended to establish the producer's strict liability for damage caused by defective products which have been indust-

8 — Fifth recital in the preamble to Council Directive 92/59/EEC of 29 June 1992 on general product safety (OJ 1992 L 228, p. 24).

9 — COM(2000) 139 final/2, which was tabled for discussion by the Council on 30 November 2000.

10 — Sixth recital in the preamble to the proposed directive.

rially manufactured and which, in general, are intended for circulation in the market, applies to such cases.

19. I am also aware of the case-law of the Court, according to which it is, by virtue of the division of functions provided for by Article 234 EC, for the national court, whose responsibility it is to rule on the substantive issue, to apply the rules of Community law to a specific case. [11] The Court has also held that, where a reference for a preliminary ruling concerns the interpretation of a provision of Community law, the Court delivers its ruling without, in principle, having to look into the circumstances in which a national court was prompted to submit the questions and envisages applying the provision of Community law which it has asked the Court to interpret. [12]

Nevertheless, the task of interpretation assigned to the Court by Article 234 EC is designed to ensure a uniform application of Community law throughout the Member States and to prevent the erroneous application of Community law provisions to matters that they are not intended to govern.

11 — Judgment in Joined Cases C-175/98 and C-177/98 *Lirussi and Bizarro* [1999] ECR I-6881, paragraph 38, and in Case C-107/98 *Teckal* [1999] ECR I-8121, paragraph 31.

12 — Judgment in Case C-67/91 *Asociación Española de Banca Privada and others* [1992] ECR I-4785, paragraphs 25 and 26; Case C-62/93 *BP Supergas* [1995] ECR I-1883, paragraph 10; and Case C-85/95 *Reisdorf* [1996] ECR I-6257, paragraph 15.

20. I therefore propose that the Court reply to the Højesteret that, as Community law stands at present, Directive 85/374 does not apply to cases of liability for defective services, which include damage caused by a professional operator as a result of his using, in the course of his business, a product which he himself prepared and which is intended for use solely within his organisation, since this liability has not yet been regulated by the Community legislature.

However, in the event that the Court does not share my view, I shall now examine the questions referred for a preliminary ruling.

V — Examination of the questions referred for a preliminary ruling

A — *The first question*

21. By its first question, the Højesteret wishes to know whether Article 7(a) of Directive 85/374 must be construed as meaning that, where a product which has caused damage was produced and used in

the course of providing a specific medical service, such as the kidney transplantation referred to in the order for reference, no product was put into circulation, so that the producer is exempt from liability.

22. The parties which have submitted observations in these proceedings differ as to the reply to be given to this question. The appellant in the main proceedings, together with the French, Austrian and United Kingdom governments and the Commission, take the view that the perfusion fluid is a product which was put into circulation because the person who made the product also used it. By contrast, the respondent Danish authority and the Danish and Irish Governments argue that use of a fluid prepared by medical staff employed at a publicly funded hospital and intended for use as an accessary element in a surgical operation, cannot be regarded as putting a product into circulation within the meaning of Article 7(a) of Directive 85/374.

23. In the event that the Court should take the view that Directive 85/374 applies to products prepared by a professional operator for use exclusively in the course of his business, I would propose that it hold that the product's mere use must mean that it has been put into circulation. This is the only meaning that accords with the aim of the directive, since products prepared in these circumstances are naturally intended to be used within an organisation and, if a supplier of services were entitled to argue that he is not liable on the ground that he did not put a product into circulation, then a large number of consumers would be without protection.

It follows that Article 7(a) of Directive 85/374 must be construed as meaning that where a professional operator produces a preparation, for use in the course of his business and within his organisation (as may be the case with a shampoo used by a hairdresser or an oil used by a masseur), he cannot avoid liability if the preparation causes damage to his clients, by arguing that he did not put it into circulation.

B — *The second question*

24. By its next question, the Højesteret wishes to know whether, under Article 7(c) of Directive 85/374, a public hospital is exempt from liability for preparations which it produces and uses in the course

of providing a specific publicly funded service to the person suffering injury and in respect of which that person has not paid any consideration.

This provision exempts the producer from liability if he did not manufacture the product for sale or distribution for economic purposes and if he did not manufacture or distribute the product in the course of his business.

25. The appellant in the main proceedings argues that the product was prepared in the course of a business and that, in Denmark, although patients are not required to pay for medical treatment in hospitals, they do in fact finance hospitals through the payment of taxes. So, it is not to be concluded that a public hospital is free from liability on the ground that the injured person has not paid any consideration. The French, Austrian and United Kingdom Governments and the Commission hold the same view. The opposite view is held by the respondent in the main proceedings and by the Danish and Irish Governments.

26. I agree with the parties which argue that the fact that a hospital is publicly owned and its patients do not pay for treatment cannot exempt it from liability where it has used a defective product which was prepared by its own staff. As the Commission rightly indicates in its observations, the exemption from liability provided for by Article 7(c) of Directive 85/374 requires that two conditions be met, namely, that the product was not manufactured for economic purposes, in other words for financial gain, and that the product was not manufactured or distributed by the producer in the course of his business. Although it could be argued that the first condition has been met in the situation referred to by the national court in its question, it must be concluded that the second condition does not obtain since the perfusion fluid was prepared and used by the hospital in the course of its business.

27. The reply to the second question must therefore be that a public hospital is not exempt from liability under Directive 85/374 in respect of preparations which it produces and uses in the course of providing a specific publicly-financed service to the person suffering injury and in respect of which that person has not paid any consideration.

C — *The third question*

28. Thirdly, the national court asks whether Community law imposes requirements

as to how Member States should define the expressions 'damage caused by death or by personal injuries' and 'damage to, or destruction of, any item of property' in Article 9 of Directive 85/374 or whether, alternatively, Member States are free to decide what meaning is to attach to these expressions.

29. The appellant in the main proceedings, the Irish Government, the United Kingdom Government and the Commission are of the view that these terms should be defined according to Community law so that they are uniformly applied throughout the whole Community. The respondent regional authority, however, argues that it is for Member States to specify what is meant by these expressions.

30. I agree with the argument that the terms should be interpreted according to Community law. The aim of Directive 85/374 is to harmonise the laws of the Member States concerning the liability of producers for defective products and Article 9 thereof defines, in a quite detailed manner, what is meant by 'damage' for the purpose of Article 1, leaving aside from coordination only national provisions relating to non-material damage. Consequently, when transposing the provisions of Directive 85/374 into national law, Member States are bound by the definition of 'damage' contained therein and do not have any latitude to alter its meaning.

D — *The fourth and fifth questions*

31. By the last two questions, the Højesteret wishes to know whether the damage caused to the kidney, which made it unusable for a transplant, must be construed, in relation to the intended recipient of the organ, as personal injury or as damage to an item of property for the purposes of Article 9 of Directive 85/374.

32. Here again, there is disagreement among the parties which have submitted observations on these questions. The appellant in the main proceedings is of the opinion that, since he was the intended recipient of the organ, he had a property right at the time when it became unusable, with the result that the damage he suffered amounts to personal injury within the meaning of Article 9(a) of Directive 85/374. In the event that the Court does not agree with this argument, the appellant contends that the damage can be construed as being covered by the term 'damage to, or destruction of, any item of property other than the defective product itself' within the meaning of Article 9(b) of the directive.

The respondent holds the opposite view, arguing that Mr Veedfald is not covered by either of the definitions of 'damage' contained in Article 9 of Directive 85/374. The Irish and United Kingdom Governments are in agreement, pointing out that the intended recipient of the organ did not suffer any personal injuries by virtue of the fact that the kidney that was supposed to be transplanted into his body was rendered unusable and that it is not possible to construe the damage suffered as 'damage to, or destruction of, any item of property' since property rights cannot be exercised in relation to human organs, which are not items of property.

33. In my view, the correct approach is the one suggested by the Commission, which argues that damage caused to a human organ which has been removed from the body of the donor for immediate transplantation into the body of the recipient is 'damage caused by personal injuries'.

Article 9(a) and (b) effectively provides for two heads of damage, namely, damage caused by death or by personal injuries and damage to, or destruction of, any item of property other than the defective product itself. Having regard to the fact that a human organ does not fulfil the requirements laid down by Article 9(b)(i) and (ii) in order for there to be damage to an item of property, namely that the item must be of a type ordinarily intended for private use or consumption and that it must have been used by the injured person mainly for that purpose, the conclusion must be that, in a case such as the one before the Court, the damage can only be damage caused by personal injuries.

34. Directive 85/374 does not, however, resolve the question of how the victim of the damage is to be identified. It is therefore for the laws of each Member State to determine which persons have a right to compensation. This means that the Court, when interpreting Article 9 of Directive 85/374, can rule on the question whether the damage caused by non-use of a kidney in the circumstances described is damage caused by personal injuries or damage to an item of property, but it may not tell the national court which referred the question whether the damage was caused to the intended recipient of the organ, to the donor, or to both of them, and in what measure.

35. For the reasons I have given, I propose that the Court, in reply to the last two questions, should rule that Article 9 of Directive 85/374 must be construed as meaning that damage caused to a human organ at the time when it is removed from the body of a donor for immediate transplantation into another person's body is covered by the expression 'damage caused by personal injuries' but not by the expression 'damage to, or destruction of, any item of property'.

VI — Conclusion

36. In view of the foregoing considerations, I propose that the Court of Justice should reply as follows to the Højesteret:

As Community law stands at present, 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 does not apply to cases of liability for defective services, which include damage caused by a professional operator as a result of his using, in the course of his business, a product which he himself prepared and which is intended for use solely within his organisation.

37. In the event that the Court does not agree with that opinion, I propose that it should reply to the questions referred for a preliminary ruling as follows:

(1) Article 7(a) 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 construed as meaning that where a professional operator produces a preparation, for use in the course of his business and within his organisation, he cannot avoid liability if the preparation causes damage to his clients, by arguing that he did not put it into circulation.

(2) Article 7(c) of Directive 85/374 does not allow a public hospital to escape liability for preparations which it produces and uses in the course of providing a specific public-funded service to the person suffering injury in respect of which that person has not paid any consideration.

(3) Article 9 of Directive 85/374 defines the meaning of 'damage' for the purpose of Article 1 in a quite detailed manner and excludes from coordination national provisions relating to non-material damage. Consequently, when transposing the provisions of Directive 85/374 into national law, Member States are bound by the definition of 'damage' contained therein and do not have any latitude to alter its meaning.

(4) Under Article 9 of Directive 85/374, damage caused to a human organ at the time when it is removed from a donor's body for immediate transplantation into the body of another person is covered by the expression 'damage caused by personal injuries' and not by the expression 'damage to, or destruction of, any item of property'.