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Judgment of the Court (Fifth Chamber) of 10 May 2001. - Henning Veedfald v Århus Amtskommune. - Reference for a preliminary ruling: Højesteret - Denmark. - Approximation of laws - Directive 85/374/EEC - Liability for defective products - Exemption from liability - Conditions. - Case C-203/99.

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Keywords

1. Approximation of laws - Liability for defective products - Directive 85/374 - Exemption from liability - Condition - Not put into circulation - Use of a product during the provision of a medical service

(Council Directive 85/374, Art. 7(a))

2. Approximation of laws - Liability for defective products - Directive 85/374 - Exemption from liability - Condition - Activity having no economic or business purpose - Product manufactured and used in the course of a medical service financed from public funds

(Council Directive 85/374, Art. 7(c))

3. Approximation of laws - Liability for defective products - Directive 85/374 - Damage to be taken into account - Material damage

(Council Directive 85/374, Art.9)

4. Approximation of laws - Liability for defective products - Directive 85/374 - Damage to be taken into account - Obligation of the national court to determine under which head the damage was incurred

(Council Directive 85/374, Art. 9)

Summary

1. Article 7(a) of Directive 85/374 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, which provides that the producer is not to be liable if he proves that he did not put the product into circulation, 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.

(see para. 18, and operative part 1)

2. Article 7(c) of Directive 85/374 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 the exemption from liability where an activity has no economic or business purpose does not extend to the case of a defective product which has been manufactured and used in the course of a specific medical service which is financed entirely from public funds and for which the patient is not required to pay any consideration.

(see para. 22, and operative part 2)

3. Article 9 of Directive 85/374 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, save for non-material damage whose reparation is governed solely by national law and the exclusions detailed in that article as regards damage to an item of property, a Member State may not restrict the types of material

damage, resulting from death or from personal injury, or from damage to or destruction of an item of property, which are to be made good.

(see para. 29, and operative part 3)

4. The national court is required, under Directive 85/374 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, to examine under which head the circumstances of the case are to be categorised, namely whether the case concerns damage covered either by point (a) or by point (b) of the first paragraph of Article 9 or non-material damage which may possibly be covered by national law. The national court may not, however, decline to award any damages at all under the Directive on the ground that, where the other conditions of liability are fulfilled, the damage incurred is not such as to fall under any of the foregoing heads.

(see para. 33, and operative part 4)

Parties

In Case C-203/99,

REFERENCE to the Court under Article 234 EC by the Højesteret, Denmark, for a preliminary ruling in the proceedings pending before that court between

Henning Veedfald

and

Århus Amtskommune,

on the interpretation of Article 7(a) and (c) and points (a) and (b) of the first paragraph of Article 9 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),

THE COURT (Fifth Chamber),

composed of: A. La Pergola, President of the Chamber, M. Wathelet, D.A.O. Edward, P. Jann (Rapporteur) and L. Sevón, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,

Registrar: H. von Holstein, Deputy Registrar,

after considering the written observations submitted on behalf of:

- Mr Veedfald, by T. Rørdam, advokat,

- Århus Amtskommune, by J. Andersen-Møller, advokat,

- the Danish Government, by J. Molde, acting as Agent,

- the French Government, by K. Rispal-Bellanger and R. Loosli-Surrans, acting as Agents,

- the Irish Government, by M.A. Buckley, acting as Agent, assisted by D. Barniville, BL,

- the Austrian Government, by C. Pesendorfer, acting as Agent,

- the United Kingdom Government, by R. Magrill, acting as Agent, assisted by M. Hoskins, Barrister,

- the Commission of the European Communities, by M. Patakia and H. Støvlbæk, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Mr Veedfald, represented by K. Andreasen, advokat, of Århus Amtskommune, of the French Government, of the Irish Government and of the Commission at the hearing on 16 November 2000,

after hearing the Opinion of the Advocate General at the sitting on 14 December 2000,

gives the following

Judgment

Grounds

1 By judgment of 21 May 1999, received at the Court on 26 May 1999, the Højesteret (Supreme Court), Denmark, referred to the Court for a preliminary ruling under Article 234 EC five questions on the interpretation of Article 7(a) and (c) and points (a) and (b) of the first paragraph of Article 9 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, hereinafter the Directive).

2 The five questions have been raised in proceedings between Henning Veedfald and Århus Amtskommune (District of Århus, hereinafter the Amtskommune) concerning the latter's refusal to meet his claim for damages following an unsuccessful kidney transplant operation performed in a hospital belonging to the Amtskommune.

Community rules

3 Article 1 of the Directive lays down the principle that the producer is to be liable for damage caused by a defect in his product. Exemptions from liability are provided for in Article 7 of the Directive, worded as follows:

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; or

(b) ...

(c) that the product was neither 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;

...

4 Article 9 of the Directive provides:

For the purpose of Article 1, "damage" means:

(a) damage caused by death or by personal injuries;

(b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of [EUR] 500, provided that the item of property:

(i) is of a type ordinarily intended for private use or consumption, and

(ii) was used by the injured person mainly for his own private use or consumption.

This Article shall be without prejudice to national provisions relating to non-material damage.

Danish law

5 The Directive was transposed into Danish law by Law No 371 on Product Liability of 7 June 1989. Article 2 of that Law provides:

1. This Law covers compensation by way of damages for loss due to personal injury and loss of family support provided by the breadwinner. The Law also covers compensation for damage to material goods in the cases mentioned in subparagraph 2.

2. Damage to material goods is covered by the Law if the object in question is, given its nature, normally intended for non-commercial use and is primarily used by the injured person in accordance with that purpose. The Law does not cover damage to the defective product itself.

6 Article 7 of Law No 371 provides:

The producer shall not be liable is he establishes:

(1) that he did not put the product into circulation;

(2) that he did not manufacture, produce, collect or put the product into circulation in the course of his business;

...

The main proceedings and the questions referred for a preliminary ruling

7 According to the order for reference, on 21 November 1990, Mr Veedfald was due to undergo a kidney transplant operation at Skejby hospital. After a kidney had been removed

from the donor, in this case Mr Veedfald's brother, the kidney was prepared for transplantation through flushing with a perfusion fluid designed for that purpose.

8 This fluid proved to be defective and a kidney artery became blocked during the flushing process, making the kidney unusable for any transplant. The fluid had been manufactured in the laboratories of the dispensary of another hospital, the Århus District Hospital, and prepared with a view to its use in the Skejby hospital. The Amtskommune is the owner and manager of both hospitals.

9 Relying on Law No 371, Mr Veedfald claimed damages from the Amtskommune. The latter denied liability on the ground that it had not put the product into circulation and that the product had not been manufactured for an economic purpose, since the two hospitals concerned were funded entirely from public funds. Mr Veedfald then brought an action before the Vestre Landsret (Western Regional Court), Denmark, against that decision refusing to grant compensation. When his action was dismissed by judgment of 29 September 1997, he appealed to the Højesteret.

10 Being unsure as to the proper interpretation of Danish law in the light of the provisions of the Directive, the Højesteret decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

(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 [other] item of property" in relation to the intended recipient of the organ?

The first question

11 By its first question, the national court asks essentially whether Article 7(a) of the Directive is to be interpreted as meaning that a defective product is not put into circulation when the manufacturer of the product makes it and uses it in the course of providing a specific medical service, consisting in preparing a human organ for transplantation, and when the damage caused to the organ results from that preparatory treatment.

12 First, as regards the argument raised by the Amtskommune and the Danish Government that use of a product in the course of providing a service cannot in principle be covered by the Directive in the absence of any Community legislation on services, it is sufficient to observe that the present case involves the defectiveness of a product used in the course of providing a service and not any defect in the service as such.

13 According to the Amtskommune, in a situation such as the present, no product has been put into circulation within the meaning of Article 7(a) of the Directive. In the present situation, the patient had no intention to buy the product, and that product, intended for strictly internal use by the manufacturer himself, never left the sphere of control of the unit consisting of the hospital dispensary and the doctors undertaking the treatment.

14 In response to that argument it is to be observed that the Directive provides no definition of the expression put into circulation. This concept must therefore be interpreted in accordance with the purpose and aim pursued by the Directive.

15 Article 1 of the Directive, read in the light of the second recital to its preamble, lays down the principle that a producer is to be liable without fault for a defect in his product where it causes damage. However, according to Article 7 of the Directive, a producer may be exempt from liability in a certain number of cases, exhaustively listed by that provision, if he proves that the circumstances of his case fall within their ambit. In those circumstances, such cases must, in accordance with established case-law, be interpreted strictly.

16 As Mr Veedfald, the Austrian, French and United Kingdom Governments and the Commission have rightly pointed out, the exemption from liability provided for in Article 7(a) of the Directive where the product has not been put into circulation is intended primarily to cover cases in which a person other than the producer has caused the product to leave the process of manufacture. Moreover, as the Austrian and French Governments and the Commission point out, uses of the product contrary to the producer's intention, for example where the manufacturing process is not yet complete, and use for private purposes or in similar situations are excluded from the scope of the Directive. However, the facts of the case as presented to this Court do not appear to fall within one of those situations.

17 As regards the Amtskommune's argument that the product was never put into circulation since it never left the medical sphere of control of the dispensary which made the fluid and the hospital where it was used, 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. Where a patient is admitted to hospital, it cannot matter whether the product used in the course of medical treatment was made in the hospital establishment or was acquired from a third party, as it might have been in this instance, as the United Kingdom Government has pointed out. Whether a product used in the provision of a service was made by a third party, by the service provider himself or by an entity linked to the service provider cannot of itself alter the fact that the product was put into circulation.

18 The answer to be given to the first question must accordingly be 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.

The second question

19 By its second question, the national court asks essentially whether Article 7(c) of the Directive is to be interpreted as meaning that the exemption from liability where a product was not manufactured by the producer for an economic purpose or in the course of his business extends to the case of a defective product which has been manufactured and used in the course of providing a specific medical service, financed entirely from public funds, for which the patient is not required to pay any consideration.

20 The Amtskommune submits that, since the costs of medical care come from public funds, which is a special feature of the Danish medical system, there is no direct economic link between the hospital and the patient so that a hospital which makes a defective product is not acting for an economic purpose or in the course of business within the meaning of Article 7(c) of the Directive. The Danish and Irish Governments also submit that application of the Directive's system of liability to public hospitals would have harmful

consequences for the entire structure of health schemes thereby placing them at a disadvantage in relation to private schemes.

21 As to that point, the fact that products are manufactured for a specific medical service for which the patient does not pay directly but which is financed from public funds maintained out of taxpayers' contributions cannot detract from the economic and business character of that manufacture. The activity in question is not a charitable one which could therefore be covered by the exemption from liability provided for in Article 7(c) of the Directive. Besides, the Amtskommune itself admitted at the hearing that, in similar circumstances, a private hospital would undoubtedly be liable for the defectiveness of the product pursuant to the provisions of the Directive.

22 The answer to be given to the second question must therefore be that Article 7(c) of the Directive is to be interpreted as meaning that the exemption from liability where an activity has no economic or business purpose does not extend to the case of a defective product which has been manufactured and used in the course of a specific medical service which is financed entirely from public funds and for which the patient is not required to pay any consideration.

The third question

23 By its third question, the national court asks whether Community law imposes any 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 other than the defective product itself in Article 9 of the Directive.

24 Mr Veedfald, the Irish Government, the United Kingdom Government and the Commission consider that those expressions must be defined by Community law so that they are applied uniformly throughout the Community. The Amtskommune, on the other hand, submits that it is for the Member States to define the meaning of those expressions.

25 It is to be noted at the outset that, unlike the terms product, producer and defective product, for which the Directive provides express definitions in Articles 2, 3 and 6 respectively, the term damage is not defined in the Directive. Neither Article 9 nor Article 1 of the Directive, to which Article 9 refers, contains any explicit definition of the term damage.

26 However, Article 9 of the Directive indicates that damage must cover both damage resulting from death or from personal injuries and damage to, or destruction of, an item of property. In the latter case, the damage must be of an amount exceeding EUR 500 whilst the item damaged must be of a type ordinarily intended for private use or consumption and must have been used as such by the injured person.

27 Although it is left to national legislatures to determine the precise content of those two heads of damage, nevertheless, save for non-material damage whose reparation is governed solely by national law, full and proper compensation for persons injured by a defective product must be available in the case of those two heads of damage. Application of national rules may not impair the effectiveness of the Directive (see, to this effect, the judgment in Case C-365/88 Hagen [1990] ECR I-1845, paragraph 20) and the national court must interpret its national law in the light of the wording and the purpose of the Directive (see, in particular, the judgment in Case 14/83 Von Colson and Kamann [1984] ECR 891, paragraph 26).

28 A Member State cannot therefore restrict the types of material damage, resulting from death or personal injury, or from damage to or destruction of an item of property, which are to be made good.

29 The answer to the given to the third question must therefore be that Article 9 of the Directive is to be interpreted as meaning that, save for non-material damage whose reparation is governed solely by national law and the exclusions detailed in that article as regards damage to an item of property, a Member State may not restrict the types of material damage, resulting from death or from personal injury, or from damage to or destruction of an item of property, which are to be made good.

The fourth and fifth questions

30 By its fourth and fifth questions, the national court asks for guidance on the application of the term damage to the circumstances of the case before it.

31 It must be borne in mind at the outset that under Article 234 EC the Court has no power to apply rules of Community law to a particular case, but only to rule on the interpretation of the Treaty and of acts adopted by Community institutions (see, in particular, the judgment in Joined Cases C-9/97 and C-118/97 Jokela and Pitkäranta [1998] ECR I-6267, paragraph 30).

32 As regards the aspects of the Directive which call for an interpretation by the Court, it should be observed that Article 1 of the Directive provides that the producer is to be liable for damage caused by a defect in his product. Article 9 indicates the various heads of damage covered by the Directive, namely damage caused by death or personal injuries and damage to, or destruction of, an item of property, other than that caused to the defective product itself, whilst leaving it to the Member States applying their own national laws to provide for compensation for non-material damage. Articles 1 and 9 therefore set out exhaustively the heads of damage that may be possible.

33 It follows that the national court is required, under the Directive, to examine under which head the circumstances of the case are to be categorised, namely whether the case concerns damage covered either by point (a) or by point (b) of the first paragraph of Article 9 or non-material damage which may possibly be covered by national law. The national court may, however, not decline to award any damages at all under the Directive on the ground that, where the other conditions of liability are fulfilled, the damage incurred is not such as to fall under any of the foregoing heads.

Decision on costs

Costs

34 The costs incurred by the Danish, French, Irish, Austrian, and United Kingdom Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

Operative part

On those grounds,

THE COURT (Fifth Chamber),

in answer to the questions referred to it by the Højesteret by judgment of 21 May 1999, hereby rules:

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 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.

2. Article 7(c) of Directive 85/374 is to be interpreted as meaning that the exemption from liability where an activity has no economic or business purpose does not extend to the case of a defective product which has been manufactured and used in the course of a specific medical service which is financed entirely from public funds and for which the patient is not required to pay any consideration.

3. Article 9 of Directive 85/374 is to be interpreted as meaning that, save for non-material damage whose reparation is governed solely by national law and the exclusions detailed in that article as regards damage to an item of property, a Member State may not restrict the

types of material damage, resulting from death or from personal injury, or from damage to or destruction of an item of property, which are to be made good.

4. The national court is required, under Directive 85/374, to examine under which head the circumstances of the case are to be categorised, namely whether the case concerns damage covered either by point (a) or by point (b) of the first paragraph of Article 9 or non-material damage which may possibly be covered by national law. The national court may, however, not decline to award any damages at all under the Directive on the ground that, where the other conditions of liability are fulfilled, the damage incurred is not such as to fall under any of the foregoing heads.