Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

20 November 2014*

(Reference for a preliminary ruling — Directive 85/374/EEC — Consumer protection — Liability for defective products — Material scope of the directive — Special liability system existing on the date of notification of that directive — Permissibility of a national liability system enabling information on the adverse effects of pharmaceutical products to be obtained)

In Case C-310/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Germany), made by decision of 6 May 2013, received at the Court on 6 June 2013, in the proceedings

Novo Nordisk Pharma GmbH

F

S.,

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, J. Malenovský, M. Safjan (Rapporteur), A. Prechal and K. Jürimäe, Judges,

Advocate General: M. Szpunar,

Registrar: M. Aleksejev, Administrator,

having regard to the written procedure and further to the hearing on 26 March 2014,

after considering the observations submitted on behalf of:

— Ms S., by J. Heynemann, Rechtsanwalt,

— the German Government, by T. Henze and J. Kemper, acting as Agents,

— the Czech Government, by M. Smolek and J. Vláčil, acting as Agents,

— the European Commission, by M. Šimerdová and G. Wilms, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 11 June 2014,

gives the following

* Language of the case: German.

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 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), as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 (OJ 1999 L 141, p. 20), ('Directive 85/374').

2 The request has been made in proceedings between Novo Nordisk Pharma GmbH and Ms S. concerning her request for information on the adverse and other effects of a medicinal product manufactured by that company.

Legal context

EU law

3 The thirteenth and the eighteenth recitals in the preamble to Directive 85/374 state:

'… [U]nder 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; …, 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;

…

… the harmonisation resulting from this cannot be total at the present stage, but opens the way towards greater harmonisation; … it is therefore necessary that the Council receive at regular intervals, reports from the Commission on the application of this Directive, accompanied, as the case may be, by appropriate proposals'.

4 Article 1 of Directive 85/374 provides:

'The producer shall be liable for damage caused by a defect in his product.'

5 Article 3(1) of that directive is worded as follows:

'"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.'

6 Article 4 of Directive 85/374 provides:

'The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.'

7 Under Article 7 of Directive 85/374, the producer is not to be treated as liable for the defective product if he proves that one of the conditions referred to in that provision is met.

8 Article 13 of that directive provides:

‘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.’

German law

9 Paragraph 15 of the Law on product liability (Gesetz über die Haftung für fehlerhafte Produkte) of 15 December 1989 provides:

‘1. If, as a result of having been administered a medicinal product intended for human use, a person dies or the body or health of a person is adversely affected, the present Law shall not apply where the product at issue has been supplied to the consumer under the Law on medicinal products [Arzneimittelgesetz of 24 August 1976; “the AMG”] and is subject to compulsory marketing authorisation or has been exempted by regulation from that requirement.

2. The provision made under subparagraph 1 shall be without prejudice to liability on the basis of other provisions.’

10 Under Paragraph 84(1) and (2) of the AMG:

‘1. If, as a result of having been administered a medicinal product intended for human use, a person dies or the body or health of a person is adversely affected to a substantial degree, the pharmaceutical undertaking which placed the medicinal product on the market under the present Law shall be required to compensate the injured party for the resulting damage, where the product at issue has been supplied to the consumer under the present Law and is subject to compulsory marketing authorisation or has been exempted by regulation from that requirement. Liability to provide compensation shall apply only where:

(1) when used as intended, the medicinal product has harmful effects in excess of what is considered acceptable in the light of current medical knowledge; or

(2) the damage has occurred as a result of labelling, or specialist information or instructions for use which do not reflect current medical knowledge.

2. If, in the circumstances of an individual case, the medicinal product administered is capable of causing the damage, a presumption shall arise to the effect that the damage was caused by that medicinal product. In each case, the question whether the medicinal product is capable of causing the damage shall be determined in the light of the product’s composition and the dosage administered, the intended manner and duration of use, the relationship in time between the dose administered and the damage, the nature of the damage and the state of health of the person adversely affected at the time when the product was administered and all other circumstances which, in the individual case, suggest that the product did, or did not, cause the damage. …’

11 Paragraph 84a of the AMG provides:

‘1. Where the facts suggest that a medicinal product has caused the damage, the injured party may require the pharmaceutical undertaking to provide him with information unless such information is unnecessary for the purposes of establishing whether damages may be claimed under Paragraph 84. That request for information may relate to the effects, adverse effects and interactions known to the pharmaceutical undertaking, to suspected cases of adverse effects and interactions brought to its attention and to any other factor which may be of significance for the purposes of assessing whether

the adverse effects are acceptable. … There shall be no right to obtain disclosure where statutory provisions require that the information remain confidential or where non-disclosure is justified by an overriding interest of the pharmaceutical undertaking or of a third party.

2. In the circumstances specified in subparagraph 1, the injured party may also require information to be disclosed by the authorities responsible for the authorisation and supervision of medicinal products. Those authorities shall be under no obligation to disclose the information where statutory provisions require that the information remain confidential or where non-disclosure is justified by an overriding interest of the pharmaceutical undertaking or of a third party.'

12 In Germany, the liability system under the AMG was the only special liability system that existed at the time of the notification of Directive 85/374 on 30 July 1985.

13 The presumption of a causal link referred to in Paragraph 84(2) of the AMG and the right to information under Paragraph 84a of the AMG were inserted in the AMG by the Law amending the legislation on compensation for damage (Zweites Schadensersatzrechtsänderungsgesetz) of 19 July 2002 (BGBl. 2002, p. 2674), which entered into force on 1 August 2002.

The order for reference and the question referred for a preliminary ruling

14 During the period from 2004 to June 2006, Ms S., who suffers from diabetes, was prescribed and administered Levemir, a medicinal product manufactured by Novo Nordisk Pharma, which caused her to suffer lipoatrophy, which is the loss of subcutaneous fat tissue at the injection sites.

15 Ms S. brought proceedings before the Landgericht Berlin (Regional Court, Berlin) seeking the disclosure by Novo Nordisk Pharma, pursuant to Paragraph 84a of the AMG, of information on the adverse and other effects of Levemir inasmuch as they relate to lipoatrophy.

16 The Landgericht Berlin upheld the claims made by Ms S. Novo Nordisk Pharma's appeal against that judgment was dismissed by the Kammergericht Berlin (Higher Regional Court, Berlin), whereupon that company lodged an appeal on a point of law before the Bundesgerichtshof (Federal Court of Justice; or 'the referring court').

17 The referring court states that the outcome of that appeal on a point of law, which relates to the right to information, referred to in Paragraph 84a of the AMG, depends on whether such a provision infringes Directive 85/374.

18 In those circumstances, the Bundesgerichtshof decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Article 13 of Directive 85/374 be interpreted as meaning that, as a "special liability system", the German system of liability for pharmaceutical products is not affected by that directive, with the result that the national system of liability for pharmaceutical products may be further developed

or

must that provision be interpreted as meaning that the situations covered by the liability system for pharmaceutical products existing at the time when the directive was notified (30 July 1985) may not be extended?'

Consideration of the question referred

19 By its question, the referring court essentially asks whether Directive 85/374 and, in particular, Article 13 of that directive must be interpreted as precluding national legislation — such as that at issue in the main proceedings, establishing a special liability system for the purposes of that provision — under which, in consequence of an amendment to that legislation made after the directive had been notified to the Member State concerned, the consumer has the right to require the manufacturer of the medicinal product to provide him with information on the adverse effects of that product.

20 As a preliminary point, it should be noted that, under Article 13 of Directive 85/374, that directive does not affect any rights which an injured person may have under a special liability system existing on the date when the directive was notified.

21 As the Advocate-General noted in point 34 of his Opinion, the German system of liability for pharmaceutical products, established under the AMG, constitutes such a special liability system for the purposes of Article 13 of Directive 85/374 in so far as it is limited to a specific manufacturing sector and it existed on 30 July 1985, the date on which the directive was notified to the Federal Republic of Germany.

22 In those circumstances, it is necessary to determine whether Directive 85/374 precludes rules forming part of such a national liability system, under which — in consequence of an amendment made after the date of the notification of that directive to the Member State concerned — the consumer has a right to information on the adverse effects of a product. However, it must first be determined whether such a right is governed by Directive 85/374.

23 In that regard, the Court has consistently held that 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 (judgment in *Dutrueux and caisse primaire d'assurance maladie du Jura*, C-495/10, EU:C:2011:869, paragraph 20 and the case-law cited).

24 However, as can be seen from the eighteenth recital thereto, Directive 85/374 does not seek exhaustively to harmonise the sphere of liability for defective products beyond the matters regulated by it (judgment in *Dutrueux and caisse primaire d'assurance maladie du Jura*, EU:C:2011:869, paragraph 21 and the case-law cited).

25 As regards the consumer's right to obtain information on the adverse effects of a product, it should be noted that neither that right nor the scope of the information that the consumer could require the manufacturer of that product to provide are covered, as such, by Directive 85/374.

26 As regards the fact that, in accordance with Article 4 of Directive 85/374, it is for the injured person to prove 'the damage, the defect and the causal relationship between defect and damage', it must be ascertained whether a statutory right to information, provided for under the legislation of a Member State, is capable of undermining the allocation of the burden of proof as delimited in that provision by the EU legislature.

27 In that regard, it should be acknowledged that national legislation under which the victim has the right to obtain information on the adverse effects of the product concerned may make it easier for that person to produce the requisite evidence enabling him to establish liability on the part of the manufacturer.

28 However, such national legislation does not bring about a reversal of the burden of proof, which is for the victim to discharge, and does not introduce any change in the circumstances, listed in Article 7 of Directive 85/374, in which the manufacturer is to be exempt from liability.

29 That being so, it must be held that the consumer's right to require the manufacturer of a product to provide him with information on the adverse effects of that product is not among the matters governed by Directive 85/374 and that, accordingly, it falls outside the scope of that directive.

30 Moreover, national legislation establishing such a right must not undermine the effectiveness of the system of liability provided for under Directive 85/374 or the objectives pursued by the EU legislature by means of that system (see, to that effect, judgment in *Dutrueux and caisse primaire d'assurance maladie du Jura*, EU:C:2011:869, paragraph 29).

31 National legislation such as that at issue in the case before the referring court does not compromise the effectiveness of the system provided for under Directive 85/374 or the objectives pursued by that directive.

32 As the Advocate-General observed in substance in point 46 of his Opinion, such national legislation is only intended to eliminate the significant imbalance which exists between the manufacturer of the relevant product and the consumer — to the detriment of the latter — as regards access to information relating to that product, and does not change either the nature or the basic elements of the manufacturer liability system established by Directive 85/374.

33 Consequently, the answer to the question referred is that Directive 85/374 must be interpreted as not precluding national legislation — such as that at issue in the main proceedings, establishing a special liability system for the purposes of Article 13 of that directive — under which, in consequence of an amendment to that legislation made after the directive had been notified to the Member State concerned, the consumer has the right to require the manufacturer of the medicinal product to provide him with information on the adverse effects of that product.

Costs

34 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

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, as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, must be interpreted as not precluding national legislation — such as that at issue in the main proceedings, establishing a special liability system for the purposes of Article 13 of that directive — under which, in consequence of an amendment to that legislation made after the directive had been notified to the Member State concerned, the consumer has the right to require the manufacturer of the medicinal product to provide him with information on the adverse effects of that product.

[Signatures]