ECLI:EU:C:2017:484

Provisional text

JUDGMENT OF THE COURT (Second Chamber)

21 June 2017 (*)

(Reference for a preliminary ruling — Directive 85/374/EEC — Liability for defective products — Article 4 — Pharmaceutical laboratories — Vaccination against hepatitis B — Multiple sclerosis — Proof of defect of vaccine and of causal link between the defect and the damage suffered — Burden of proof — Methods of proof — Lack of scientific consensus — Serious, specific and consistent evidence left to the discretion of the court ruling on the merits — Whether permissible — Conditions)

In Case C-621/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Cour de cassation (France) made by decision of 12 November 2015, received at the Court on 23 November 2015, in the proceedings

N.W,

L.W,

C.W

v

Sanofi Pasteur MSD SNC,

Caisse primaire d’assurance maladie des Hauts-de-Seine,

Carpimko,

THE COURT (Second Chamber),

composed of M. Ilešič, President of the Chamber, A. Prechal (Rapporteur), A. Rosas, C. Toader and E. Jarašiūnas, Judges,

Advocate General: M. Bobek,

Registrar: V. Giacobbo-Peyronnel, Administrator,

having regard to the written procedure and further to the hearing on 23 November 2016,

after considering the observations submitted on behalf of:

– N.W, L.W and C.W, by M. Jéhannin, avocate,

– Sanofi Pasteur MSD SNC, by J.-P. Chevallier and F. Monteret-Amar, avocats,

– the French Government, by D. Colas and J. Traband, and by A. Maitrepierre, acting as Agents,

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

– the German Government, by M. Hellmann and T. Henze, acting as Agents,

– the European Commission, by O. Beynet and G. Braga da Cruz, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 7 March 2017,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 4 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 request has been made in proceedings between N., L. and C.W ('W and Others'), acting in both their own names and in their capacity as heirs to J.W, and Sanofi Pasteur MSD SNC ('Sanofi Pasteur') and the Caisse primaire d'assurance maladie des Hauts-de-Seine and Carpimko, an independent pension and insurance fund, concerning Sanofi Pasteur's potential liability for an allegedly defective vaccination manufactured by it.

Legal framework

EU law

3 The 1st, 2nd, 6th, 7th and 18th recitals of Directive 85/374 read as follows:

‘[w]hereas 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;

[w]hereas 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;

...

[w]hereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances;

[w]hereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances;

...

[w]hereas 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:

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

5 Article 4 of that directive provides:

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

6 Article 6(1) of that directive provides:

‘A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

(a) the presentation of the product;

(b) the use to which it could reasonably be expected that the product would be put;

(c) the time when the product was put into circulation.'

French law

7 Article 1386-1 of the Civil Code provides:

'The producer shall be liable for the damage caused by a defect in his product, whether or not he is bound to the victim by contract.'

8 Article 1386-9 of the Civil Code provides:

'The plaintiff is required to prove the damage, the defect and the causal relationship between defect and damage.'

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

9 Mr W was vaccinated against hepatitis B through three injections, administered on 26 December 1998, 29 January 1999 and 8 July 1999, of a vaccine produced by Sanofi Pasteur. From August 1999, Mr W began to present with various troubles, which led to a diagnosis of multiple sclerosis in November 2000.

10 On 1 March 2005, legal experts concluded that, as from 20 January 2001, due to his multiple sclerosis Mr W was no longer fit to work. Mr W's state of health continued to decline progressively until it reached a functional disability of 90% requiring round-the-clock care until the time of his death on 30 October 2011.

11 In 2006, Mr W and W and Others, being three members of his family, brought proceedings on the basis of Article 1386-1 et seq. of the Civil Code, seeking to have Sanofi Pasteur ordered to pay compensation for the damage they claim to have suffered due to Mr W's having been administered the vaccine in question. In support of their claim, they pleaded that the short period between the vaccination and the appearance of the first symptoms of multiple sclerosis, in conjunction with the lack of any personal or family history of the disease, are such as to give rise to serious, specific and consistent presumptions as to the existence of a defect in the vaccine and as to there being a causal link between the injection of the vaccine and the occurrence of the multiple sclerosis.

12 They relied in that regard on the case-law of the Cour de cassation (Court of Cassation, France), according to which, as stated by that court in its order for reference, in the area of liability of pharmaceutical laboratories for the vaccines they produce, proof of a causal link between the defect in the product and the damage suffered by the person injured can be derived from serious, specific and consistent presumptions, which falls within the remit of the court ruling on the merits in the exercise of its exclusive jurisdiction to appraise the facts.

13 In particular, that case-law is very clear on the point that the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant, such as the time lapse between the administering of the vaccine and the occurrence of a disease and the patient's lack of any personal or family history of the disease in question, constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease in question, notwithstanding the finding that medical research does not establish a relationship between the vaccine and the occurrence of the disease.

14 The action brought by the family members of Mr W was upheld at first instance by the tribunal de grande instance de Nanterre (Regional Court, Nanterre, France) in a judgment of 4 September 2009. It was subsequently overturned on appeal by the cour d'appel de Versailles (Court of Appeal, Versailles, France) in a judgment of 10 February 2011. The latter court held that the evidence relied on by W and Others was sufficient to establish serious, specific and consistent presumptions capable of proving a causal relationship between the injection of the vaccine and the occurrence of the disease but were insufficient to establish a defect in the vaccine.

15 An appeal against that judgment was brought before the Cour de cassation (Court of Cassation), which quashed it by judgment of 26 September 2012. In its judgment, the Cour de Cassation (Court of Cassation) held that, in ruling on the basis of general considerations relating to the cost/benefit ratio of the vaccination, after having acknowledged, given Mr W's previous excellent state of health, the lack of family antecedents and the close temporal connection between the vaccination and the appearance of the disease, that there were serious, specific and consistent presumptions supporting the conclusion that the causal link between the disease and the administering of the vaccine had been sufficiently established, without examining whether or not the particular circumstances recognised by it also constituted serious, specific and consistent presumptions establishing that the vaccine was defective, the cour d'appel de Versailles (Court of Appeal, Versailles) had failed to provide a legal basis for its decision.

16 The case was sent before the cour d'appel de Paris (Court of Appeal, Paris, France), which again overturned the first instance judgment of the tribunal de grande instance de Nanterre (Regional Court, Nanterre). The cour d'appel de Paris (Court of Appeal, Paris) observed, firstly, that there was no scientific consensus supporting a causal relationship between the vaccination against hepatitis B and multiple sclerosis and that all the national and international health authorities had rejected the association between a likelihood of being affected by central or peripheral demyelinating disease (characteristic of multiple sclerosis) and the vaccination against hepatitis B. It considered, secondly, that according to multiple medical studies the aetiology of multiple sclerosis is currently unknown. Thirdly, a recent medical publication concluded that, at the time when the first symptoms of multiple sclerosis appear, the pathophysiological process probably commenced many months, or many years earlier. Fourthly and lastly, that court noted that epidemiological studies show that 92 to 95% of persons with multiple sclerosis had no antecedent of the disease in their family. In the light of those various elements, the cour

d'appel de Paris (Court of Appeal, Paris) concluded that the criteria relating to temporal proximity between the vaccination and the first symptoms and the lack of personal and family antecedents relied on by W and Others could not, together or separately, establish serious, specific and consistent presumptions supporting the conclusion of there being a causal link between the vaccination and the disease in question.

17 In those circumstances, dealing with a new appeal on a point of law brought by W and Others against that judgment, the Cour de cassation decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Must Article 4 of [Directive 85/374] be interpreted as precluding, in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method of proof by which the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease, notwithstanding the finding that medical research does not establish a relationship between the vaccine and the occurrence of the disease?

(2) If the answer to Question 1 is in the negative, does Article 4 of Directive 85/374 … preclude a system of presumptions by which the existence of a causal relationship between the defect attributed to a vaccine and the damage suffered by the injured person will always be considered to be established where certain indications of causation are found?

(3) If the answer to Question 1 is in the affirmative, must Article 4 of Directive 85/374 … be interpreted as meaning that proof, the burden of which rests on the person injured, of the existence of a causal relationship between the defect attributed to a vaccine and the damage suffered by that person cannot be considered to have been adduced unless the causal relationship is established scientifically?'

The questions referred for a preliminary ruling

Consideration of the first question

18 By its first question, the referring court asks, in essence, whether Article 4 of Directive 85/374 must be interpreted as precluding national evidentiary rules such as those at issue in the main proceedings under which, when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease.

19 It must be borne in mind as a preliminary point that whilst Article 1 of Directive 85/374 lays down the principle that producers are to be held liable for damage caused by a defect in their product, Article 4 of that directive clarifies that the injured person will be required to prove the damage, the defect and the causal relationship between the defect and the damage.

20 Similarly, it must be remembered that, according to settled case-law, 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 of 20 November 2014, *Novo Nordisk Pharma*, C-310/13, EU:C:2014:2385, paragraph 23 and the case-law cited).

21 However, as can be seen from the 18th recital thereof, Directive 85/374 does not seek exhaustively to harmonise the sphere of liability for defective products beyond the matters regulated by it (judgment of 20 November 2014, *Novo Nordisk Pharma*, C-310/13, EU:C:2014:2385, paragraph 24 and the case-law cited).

22 In that regard it should be noted at the outset that Directive 85/374 does not contain any definition of the concept of 'causal relationship' within the meaning of Articles 1 and 4 thereof. By contrast, the concept of 'defect' within the meaning of those articles is indeed defined in Article 6 thereof.

23 As is apparent from Article 6(1) of that directive, a product is defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that it would be put and the time when the product was put into circulation. Moreover, according to the sixth recital of that directive, that assessment must be carried out having regard to the reasonable expectations of the public at large (judgment of 5 March 2015, *Boston Scientific Medizintechnik*, C-503/13 and C-504/13, EU:C:2015:148, paragraph 37).

24 Moreover, as regards proof, it must be emphasised that although, as observed in paragraph 19 of this judgment, Article 4 of Directive 85/374 provides that the victim has the burden of proof, neither Article 4 nor any other provision of that directive addresses the other aspects relating to how that proof is to be made out (see, to that effect, judgment of 20 November 2014, *Novo Nordisk Pharma*, C-310/13, EU:C:2014:2385, paragraphs 25 to 29)**.**

25 In those circumstances, under the principle of procedural autonomy and subject to the principles of equivalency and effectiveness, it is for the national legal order of each Member State to establish the ways in which evidence is to be elicited, what evidence is to be admissible before the appropriate national court, or the principles governing that court's assessment of the probative value of the evidence adduced before it and also the level of proof required (see, by analogy, judgments of 15 October 2015, *Nike European Operations Netherlands*, C-310/14, EU:C:2015:690, paragraphs 27 and 28, and of 21 January 2016, *Eturas and Others*, C-74/14, EU:C:2016:42, paragraphs 30 and 32).

26 Regarding more specifically the principle of effectiveness, it requires, in terms of the detailed procedural rules governing actions for safeguarding rights which individuals derive directly from EU law, that those rules do not render practically impossible or excessively difficult the exercise of rights conferred by EU law (see, to that effect, inter alia, judgment of 10 April 2003, *Steffensen*, C-276/01, EU:C:2003:228, paragraph 60 and the case-law cited).

27 As regards, more specifically, Directive 85/374, it follows from the Court of Justice's case-law that the national rules governing how evidence is to be adduced and appraised must not be such as to undermine either the apportionment of the burden of proof as provided for under Article 4 of that directive nor, more generally, 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 of 20 November 2014, *Novo Nordisk Pharma*, C-310/13, EU:C:2014:2385, paragraphs 26 and 30 and the case-law cited).

28 In that regard, it is true that national evidentiary rules such as those contemplated in the first question may make it easier for the victim to produce the requisite evidence enabling him to establish liability on the part of the producer. The statements in the order for reference state, in essence, that such rules do not require the victim to produce, in all circumstances, certain and irrefutable evidence of a defect in the product and of a causal link between the defect and the damage suffered, but authorises the court, where applicable, to conclude that such a defect has been proven to exist, on the basis of a set of evidence the seriousness, specificity and consistency of which allows it to consider, with a sufficiently high degree of probability, that such a conclusion corresponds to the reality of the situation.

29 However, such evidentiary rules do not bring about a reversal of the burden of proof which, as provided for in Article 4 of Directive 85/374, it is for the victim to discharge, since that system places the burden on the victim to prove the various elements of his case which, where applicable, taken together will provide the court hearing the case with a basis for its conclusion as to the existence of a defect in the vaccine and a causal link between that defect and the damage suffered (see, by analogy, judgment of 20 November 2014, *Novo Nordisk Pharma*, C-310/13, EU:C:2014:2385, paragraphs 26 to 28).

30 It should also be stated, particularly since, as mentioned by the referring court, medical research neither confirms nor rules out a link between the administering of the vaccine and the occurrence of multiple sclerosis, that evidentiary rules that rule out any recourse to circumstantial methods and provide that, in order to meet the burden of proof provided for in Article 4 of that directive, the victim is required to produce certain proof based on medical research of the existence of a causal link between the defect attributed to the vaccine and the appearance of the disease, disregards the requirements resulting from that directive.

31 As observed by the Advocate General in point 45 of his Opinion, such a high evidentiary standard, which amounts to excluding any method of proof other than certain proof based on medical research, could make it excessively difficult in many situations or, as in the present case, where it is common ground that medical research neither confirms nor rules out the existence of such a causal link, impossible to establish producer liability, thereby undermining the effectiveness of Article 1 of Directive 85/374 (see, by analogy, judgment of 9 November 1983, *San Giorgio*, 199/82, EU:C:1983:318, paragraph 14).

32 Such a limitation as to the types of admissible evidence would also be inconsistent with the objectives pursued by Directive 85/374, seeking to ensure, in particular, as is apparent from the second and seventh recitals thereof, a fair apportionment of the risks inherent in modern technological production between the injured person and the producer (see, to that effect, judgment of 5 March 2015, *Boston Scientific Medizintechnik*, C-503/13 and C-504/13, EU:C:2015:148, paragraph 42) and, as evidenced by the first and sixth recitals thereof, that of protecting consumer health and safety (see, to that effect, judgment of 5 March 2015, *Boston ScientificMedizintechnik*, C-503/13 and C-504/13, EU:C:2015:148, paragraph 47).

33 Although, as shown by the discussion in paragraphs 28 to 32 of this judgment, national evidentiary rules such as those described in paragraph 28 above, which are ostensibly neutral as to the burden of proof referred to in Article 4 of Directive 85/374 and, in principle, capable of preserving the effectiveness of the system of liability provided for by that directive whilst ensuring compliance with the objectives pursued by it, the fact remains that the actual scope of such rules must be determined in the light of the interpretation and application given to them by national courts (see, by analogy, judgment of 9 December 2003, *Commission* v *Italy*, C-129/00, EU:C:2003:656, paragraph 31).

34 In that regard, the principles characterising that system of rules must not be applied by the national courts in such a way that in practice they introduce, to the detriment of the producer, unjustified presumptions liable to infringe Article 4 of Directive 85/374 or even undermine the very effectiveness of the substantive rules laid down in that directive.

35 As observed by the Advocate General in points 54, 60 and 75 of his Opinion, that could arise firstly in a situation where national courts apply those evidentiary rules in an overly rigorous manner by accepting irrelevant or insufficient evidence (see, by analogy, judgment of 15 October 2015, Nike *European Operations Netherlands*, C-310/14, EU:C:2015:690, paragraphs 29 and 43). In such a situation, there would be disregard not only of the rule on burden of proof laid down in Article 4 of Directive 85/374 but also, more generally, the effectiveness of the system of liability introduced by Article 1 of that directive, since the issue whether two of the three conditions on which producer's liability under that directive is contingent, namely the existence of a defect in the product and a causal link between that defect and the damage suffered by the victim, were met would not be sufficiently examined by the national court.

36 Secondly, disregard of the burden of proof could also result if the national courts were to apply the evidentiary rules described in paragraph 28 of this judgment in such a way that, where one or more types of factual evidence were presented together, an immediate and automatic presumption would operate of there being a defect in the product and/or a causal link between that defect and the occurrence of the damage. In such circumstances, the producer could then find itself, even before the courts ruling on the merits of the case had the opportunity to familiarise themselves with the producer's evidence and arguments, in the position of having to rebut that presumption in order to defend itself successfully against the claim (see, by analogy, judgments of 9 November 1983, *San Giorgio*, 199/82, EU:C:1983:318, paragraph 14, and of 9 February 1999, *Dilexport*, C-343/96, EU:C:1999:59, paragraph 52).

37 Therefore, national courts must first ensure that the evidence adduced is sufficiently serious, specific and consistent to warrant the conclusion that, notwithstanding the evidence produced and the arguments put forward by the producer, a defect in the product appears to be the most plausible explanation for the occurrence of the damage, with the result that the defect and the causal link may reasonably be considered to be established.

38 Secondly, those same courts must ensure that the principle that it is for the victim to prove, through all means of proof generally allowed under national law and, as in the present case, inter alia through the production of serious, specific and consistent evidence, that there is a defect in the vaccine and a causal link, remains intact. This requires the court to safeguard its own freedom of assessment in determining whether such proof has been made out to the requisite legal standard, until such time as, having examined all the evidence adduced by both parties and the arguments exchanged by them, it considers itself in a position to draw a definitive conclusion on the matter, having regard to all the relevant circumstances of the case before it (see, by analogy, judgment of 9 November 1983, *San Giorgio*, 199/82, EU:C:1983:318, paragraph 14).

39 Turning to the specific evidence in the case before the referring court in this instance, it must be borne in mind that Article 267 TFEU empowers the Court not to apply the rules of EU law to a specific case, but only to rule on the interpretation of the treaties and acts adopted by the EU institutions.

40 According to settled case-law, the Court may, however, in the framework of the judicial cooperation provided for by that article and on the basis of the material presented to it, provide the national court with an interpretation of EU law which may be useful to it in assessing the effects of such rules (see, inter alia, judgment of 28 September 2006, *Van Straaten*, C-150/05, EU:C:2006:614, paragraph 37 and the case-law cited).

41 In the present case, evidence such as that relied on in the main proceedings relating to the temporal proximity between the administering of a vaccine and the occurrence of a disease and the lack of personal and familial history of that disease, together with the existence of a significant number of reported cases of the disease occurring following such vaccines being administered, appears on the face of it to constitute evidence which,

taken together where applicable, may lead a national court to consider that a victim has discharged his burden of proof under Article 4 of Directive 85/374. That could be the case inter alia where that evidence leads the court to consider, first, that the administering of the vaccine is the most plausible explanation for the occurrence of the disease and, second, that the vaccine therefore does not offer the safety that one is entitled to expect, taking all circumstances into account, as provided for in Article 6 of that directive, because it causes abnormal and particularly serious damage to the patient who, in the light of the nature and function of the product, is entitled to expect a particularly high level of safety (see, to that effect, judgment of 5 March 2015, *Boston Scientific Medizintechnik*, C-503/13 and C-504/13, EU:C:2015:148, paragraph 39).

42 As stated above, however, any such conclusions can be drawn in a fully enlightened manner in each specific case by the court ruling on the merits of a given case only after that court has duly taken into consideration all the circumstances of the case before it, including in particular all the other explanatory evidence and arguments put forward by the producer challenging the relevance of the evidence relied on by the victim and questioning the plausibility, referred to in the preceding paragraph, of the explanation put forward by the victim.

43 In the light of all the foregoing considerations, the answer to the first question is that Article 4 of Directive 85/374 must be interpreted as not precluding national evidentiary rules such as those at issue in the main proceedings under which, when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease. National courts must, however, ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by Article 4 being disregarded or the effectiveness of the system of liability introduced by that directive being undermined.

Consideration of the second question

44 By its second question, the referring court asks whether Article 4 of Directive 85/374 must be interpreted as precluding evidentiary rules based on presumptions according to which, where medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented.

45 It is apparent from the case file as a whole in the Court's possession that, when ruling on disputes involving similar sets of facts, courts ruling on the merits of those

cases have repeatedly held, on the basis of similar evidence, that some cases involved the necessary seriousness, specificity and consistency to enable a presumption of there being a causal link between a defect attributed to a vaccine against hepatitis B and the occurrence of multiple sclerosis, whilst others did not. The mutually contradictory national decisions in the main proceedings outlined in paragraphs 14 to 16 above provide an illustration of this situation.

46 In its first question, moreover, the referring court emphasises the exclusive jurisdiction that the courts ruling on the merits of the case have in appraising the factual evidence submitted to them.

47 In that context, the referring court asks whether it or, as the case may be, the national legislature may list certain types of pre-determined relevant evidence which, taken together, will be capable of establishing an automatic presumption of a causal link between the defect attributed to the vaccine and the occurrence of the disease.

48 It should be borne in mind in that regard that the safeguarding of rights enjoyed by individuals by virtue of the relevant Treaty provisions depends, to a large extent, on successive legal categorisations of facts. Similarly, it should be noted that when a court, like the referring court in the present case, is called upon to rule at final instance, it is responsible inter alia for ensuring, on a nationwide scale, uniform interpretation of the legal rules (see, to that effect, judgment of 13 June 2006, *Traghetti del Mediterraneo*, C-173/03, EU:C:2006:391, paragraph 36).

49 The fact remains, however, that the Court does not have jurisdiction to interpret national law and that only the national courts may determine the exact scope of national legislative, statutory or administrative provisions. This holds true inter alia for national provisions on proof (see, to that effect, judgment of 9 February 1999, *Dilexport*, C-343/96, EU:C:1999:59, paragraph 51 and the case-law cited) and for rules demarcating the respective jurisdictions of national courts.

50 As regards national provisions on proof, covered by the first question, it must nevertheless be emphasised that the national courts called on to apply them must take account of both the principles referred to in paragraphs 37 and 38 of this judgment and of the principle of legal certainty, the corollary of which is the principle of the protection of legitimate expectations, which requires, in particular, that the application of rules of law must be foreseeable by those subject to them (judgment of 2 December 2009, *Aventis Pasteur*, C-358/08, EU:C:2009:744, paragraph 47 and the case-law cited).

51 As to the rules relating to the courts' jurisdiction, only national law and the referring court may determine, taking into account, inter alia, the principles referred to in paragraphs 37, 38 and 50 of this judgment, how the powers vested in that court enable it to supervise the assessments made by the courts ruling on the merits of the case of the seriousness, specificity and consistency of the evidence put before them, thereby helping to ensure the greatest possible degree of uniformity in the application of the EU rules in question.

52 By contrast, the use by the national legislature or, as the case may be, the supreme judicial body, of a method of proof such as that referred to in the second question, under which the existence of a causal link between the defect attributed to a vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented, would inter alia have the consequence of the burden of proof provided for in Article 4 of Directive 85/374 being undermined.

53 In stating in its question that once certain pre-determined facts are established, the existence of such a causal link will 'always be considered to be established', the referring court seems to refer to an irrefutable presumption. However, such a presumption would have the consequence that, even where the pre-identified facts are not, hypothetically, capable of establishing with certainty the existence of such a causal link, the producer would, in such a case, be deprived of all opportunity to adduce facts or put forward arguments, such as scientific arguments, in order to rebut that presumption, and the court would thus not have any opportunity to assess the facts in the light of that evidence or those arguments. In being so automatic, such a situation would not only undermine the principle set out in Article 4 of Directive 85/374 by which the victim has the burden of proof of the defect and the causal link, but would also risk compromising the very effectiveness of the system of liability introduced by that directive. The presence of one of the three conditions for engaging the liability of the producer under that directive would then be imposed on the court, without its even having the possibility of examining whether the other facts submitted to it for assessment in the case before it might not lead to the opposite conclusion.

54 Moreover, even if the presumption envisaged by the referring court were to be refutable, the fact remains that, since the facts pre-identified by the legislature or supreme judicial body would be proven, the existence of a causal link would be automatically presumed, with the result that the producer could then find itself, even before the courts ruling on the merits of the case had the opportunity to familiarise themselves with the producer's evidence and arguments, in the position of having to rebut that presumption in order to defend itself successfully against the claim. As observed in paragraph 36 above, such a situation would lead to the burden of proof provided for in Article 4 of Directive 85/374 being disregarded.

55 In the light of all the foregoing considerations, the answer to the second question is that Article 4 of Directive 85/374 must be interpreted as precluding evidentiary rules based on presumptions according to which, where medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented.

Consideration of the third question

56 In the light of the answer given to the first question, it is not necessary to answer the third question.

Costs

57 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 (Second Chamber) hereby rules:

1. **Article 4 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 interpreted as not precluding national evidentiary rules such as those at issue in the main proceedings under which, when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease. National courts must, however, ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by Article 4 being disregarded or the effectiveness of the system of liability introduced by that directive being undermined.**

2. **Article 4 of Directive 85/374 must be interpreted as precluding evidentiary rules based on presumptions according to which, where medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented.**

[Signatures]

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* Language of the case: French.