Case C-338/24

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

7 May 2024

Referring court:

Cour d'appel de Rouen (France)

Date of the decision to refer:

25 April 2024

Appellant:

LF

Respondent:

SANOFI PASTEUR S.A.

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1. Subject matter of the main proceedings:

1 LF, who was born on 7 January 1980, was vaccinated on 20 March 2003 against diphtheria, tetanus and poliomyelitis with the Revaxis vaccine, manufactured by the Sanofi Pasteur laboratory.

2 LF claims that, from 2004 onwards, she suffered various symptoms, infections and pain (affecting her digestive system, throat, shoulder, arm, hands, neck and causing urinary infections, lower back pain and hair loss) and, from December 2005 onwards, took repeated periods of sick leave from work.

3 Various medical examinations were carried out, including a muscle biopsy of her left deltoid on 31 March 2008 which revealed macrophagic myofasciitis, indicating the residual presence of aluminium hydroxide, an adjuvant used in certain vaccines. This macrophagic myofasciitis caused her to be admitted to hospital from 2 to 5 April 2013.

4 On 2 June 2015, LF referred her case to the Commission de Conciliation et d'Indemnisation des Accidents Médicaux (Conciliation and Compensation Board for Medical Accidents), which ordered an expert report to be drawn up.

5 The expert report found that LF's condition had stabilised on 20 September 2016 and that it could not be concluded that her illness was caused by the Revaxis vaccination. The Board dismissed her case on 11 January 2017.

6 By documents dated 17 and 23 June 2020, LF initiated proceedings against Sanofi Pasteur, inter alia, before the Tribunal Judiciaire d'Alençon (Court of Alençon, France), seeking compensation for the injuries suffered following her vaccination. Her claims relied on liability for defective products and also on fault-based liability.

7 By order of 10 June 2021, the judge preparing the case for trial at the Court of Alençon found that LF's action against Sanofi was time-barred and dismissed her claims.

8 On 30 June 2021, LF brought an appeal against that order. By judgment of 31 May 2022, the Cour d'appel de Caen (Court of Appeal, Caen, France) largely upheld the contested order, and declared LF's claims relying on liability for defective products and fault-based liability to be inadmissible.

9 By judgment of 5 July 2023, the Cour de cassation (Court of Cassation, France) essentially set aside the judgment of the Court of Appeal of Caen and remitted the case to the Cour d'appel de Rouen (Court of Appeal, Rouen, France).

10 On 18 September 2023, LF brought proceedings before the referring court.

11 This case raises several questions of interpretation 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.

12 First of all, a question arises as to the exclusive nature of the system of rules governing liability for defective products. In other words, can this system of rules be applied concurrently with another system, such as that pertaining to fault-based liability, and is it therefore possible to bring an action relying on both of those systems, as LF has done? Next, as regards the rules governing liability for defective products, the question arises as to whether the 10-year limitation period for bringing an action provided for in Article 11 of Directive 85/374 infringes the right of access to a court. Lastly, there is a question of interpretation of the three-year limitation period for bringing a civil liability action for defective products, laid down by Article 10 of the directive, and more particularly of the date on which that period starts to run, particularly in the case of a complex progressive medical condition such as that of LF.

2. Legal framework:

European Union law

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

13 Article 10 provides as follows:

'1. Member States shall provide in their legislation that a limitation period of three years shall apply to proceedings for the recovery of damages as provided for in this Directive. The limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.

…'

14 Article 11 provides as follows:

'Member States shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.'

15 Article 13 provides as follows:

'This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.'

Charter of Fundamental Rights of the European Union

16 Article 52 of the Charter of Fundamental Rights provides as follows:

'1. Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

2. Rights recognised by this Charter for which provision is made in the Treaties shall be exercised under the conditions and within the limits defined by those Treaties.

3. In so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and

Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. This provision shall not prevent Union law providing more extensive protection.'

17 Article 47 of the Charter provides as follows:

'Right to an effective remedy and to a fair trial

Everyone whose rights and freedoms guaranteed by the law of the Union are violated has the right to an effective remedy before a tribunal in compliance with the conditions laid down in this Article.

Everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal previously established by law.

…'

French law

Code civil (Civil Code)

18 Article 1245-16 of the Civil Code, which transposes Article 10 of Directive 85/374, provides as follows:

'A limitation period of three years shall apply to proceedings for the recovery of damages as provided for under this Title. The limitation period shall begin to run from the day on which the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.'

19 Article 1245-15, which transposes Article 11 of Directive 85/374, provides as follows:

'Except where the producer is at fault, the producer's liability pursuant to the provisions of this Chapter shall be extinguished 10 years from the date on which the actual product which caused the damage was put into circulation, unless the injured person has in the meantime instituted proceedings.'

20 Article 1245-17, which transposes Article 13 of Directive 85/374, provides as follows:

'The provisions of this Chapter 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.

The producer shall remain liable for the consequences of its own fault and that of persons for whom it is responsible.'

21 Article 1240 of the Civil Code provides as follows:

'Any act whatsoever of a person which causes harm to another person obliges the person through whose fault it occurred to make reparation for it.'

3. The essential arguments of the parties:

The appellant

The exclusive nature of the system of rules governing liability for defective products

22 LF submits that she has a cause of action against Sanofi Pasteur both on the basis of liability for defective products pursuant to Article 1245 et seq. of the Civil Code and on the basis of fault-based liability pursuant to Articles 1240 and 1241 of that code. Despite numerous warnings about the effects of its aluminium-containing vaccine, Sanofi Pasteur took no action and failed to carry out any research or monitoring following the launch of Revaxis which would have enabled her to make an informed decision whether to have the vaccination, bearing in mind that the vaccination in question was not compulsory.

23 Sanofi Pasteur therefore committed a fault, which is a separate issue from any safety defect affecting the product.

The expiry of the limitation period for LF's action based on liability for defective products

24 LF submits that the 10-year limitation period for bringing an action provided for in Article 1245-15 of the Civil Code conflicts with the provisions of Article 6(1) of the European Convention for the Protection of Human Rights and Fundamental Freedoms by depriving her of her right of access to a court in view of the fact that her medical condition is a complex and progressive one.

25 Directive 85/374, which was transposed into French law by Article 1245 et seq. of the Civil Code, is not suited to matters of health or compensation for physical injury. The period of 10 years can only start to run on the day when LF had objective knowledge of her rights, which in the present case was on 17 October 2016, being the date on which the expert report was submitted.

The limitation period governing LF's action

26 LF submits that the three-year limitation period laid down in Article 1245-16 of the Civil Code only started to run on the date of knowledge of the damage and, given that she suffered physical injury resulting from a progressive medical condition, that date was the date of stabilisation of her condition.

The respondent

The exclusive nature of the system of rules governing liability for defective products

27 Sanofi Pasteur maintains that myofasciitis is a localised inflammatory reaction of muscle tissue at the site of a vaccine injection and that the experts never established any link between the complaints allegedly suffered by LF and her Revaxis vaccination. The opinions relied on by LF in support of her claims to the contrary represent a minority view.

28 The fault which LF alleges against Sanofi Pasteur, amounting to a lack of vigilance or failure to monitor its product after launch, is not a separate issue from the alleged safety defect raised under the system of liability for defective products, the only type of liability relevant to the present case; LF's claim founded on fault-based liability is thus inadmissible.

29 Sanofi Pasteur maintains that, according to the case-law of the Court of Justice of the European Union, only the rules governing liability for defective products are applicable because the action being pursued is for a breach of safety obligations, that system of rules being a matter of public policy.

30 The Court of Cassation's case-law in this area, arising in particular from various judgments of 15 November 2023, requires a reference for a preliminary ruling on this point.

The expiry of the limitation period for LF's action based on liability for defective products

31 Any liability on the part of Sanofi Pasteur has been extinguished because more than 10 years have passed since its vaccine was first marketed. LF was vaccinated on 20 March 2003 and the medical complaints which she relies on appeared within the 10-year period for bringing an action. That provision derives from Article 11 of Directive 85/374, which is compatible with the European Convention for the Protection of Human Rights and Fundamental Freedoms; it was transposed by Article 1245-15 of the Civil Code, and it applies to vaccines and healthcare products.

The limitation period governing LF's action

32 Sanofi Pasteur argues that LF's action is time-barred pursuant to Article 1245-16 of the Civil Code which refers not to the date of stabilisation but to the date on which the victim became aware of the damage. It notes that LF does not have a progressive medical condition according to the experts who examined her, that those experts determined a stabilisation date of 20 September 2016 and that LF does not dispute that stabilisation date.

4. Assessment by the Court of Appeal of Rouen

The exclusive nature of the system of rules governing liability for defective products

33 By judgment of 25 April 2002, *González Sánchez* (C-183/00, EU:C:2002:255), the Court of Justice held as follows:

'25 Accordingly, the margin of discretion available to the Member States in order to make provision for product liability is entirely determined by the Directive itself and must be inferred from its wording, purpose and structure.

26 In that connection it should be pointed out first that, as is clear from the first recital thereto, the purpose of the Directive in establishing a harmonised system of civil liability on the part of producers in respect of damage caused by defective products is to ensure undistorted competition between traders, to facilitate the free movement of goods and to avoid differences in levels of consumer protection.

27 Secondly, it is important to note that unlike, for example, Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ 1993 L 95, p. 29), the Directive contains no provision expressly authorising the Member States to adopt or to maintain more stringent provisions in matters in respect of which it makes provision, in order to secure a higher level of consumer protection.

28 Thirdly, the fact that the Directive provides for certain derogations or refers in certain cases to national law does not mean that in regard to the matters which it regulates harmonisation is not complete.

29 Although Articles 15(1)(a) and (b) and 16 of the Directive permit the Member States to depart from the rules laid down therein, the possibility of derogation applies only in regard to the matters exhaustively specified and it is narrowly defined. Moreover, it is subject inter alia to conditions as to assessment with a view to further harmonisation, to which the penultimate recital in the preamble expressly refers. An illustration of progressive harmonisation of that kind is afforded 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), which by bringing agricultural products within the scope of the Directive removes the option afforded by Article 15(1)(a) thereof.

30 In those circumstances Article 13 of the Directive cannot be interpreted as giving the Member States the possibility of maintaining a general system of product liability different from that provided for in the Directive.

31 The reference in Article 13 of the Directive to the rights which an injured person may rely on under the rules of the law of contractual or non-contractual liability must be interpreted as meaning that the system of rules put in place by the

Directive, which in Article 4 enables the victim to seek compensation where he proves damage, the defect in the product and the causal link between that defect and the damage, does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects.

32 Likewise the reference in Article 13 to the rights which an injured person may rely on under a special liability system existing at the time when the Directive was notified must be construed, as is clear from the third clause of the 13th recital thereto, as referring to a specific scheme limited to a given sector of production (see judgments of today in Case C-52/00 Commission v France [2002] ECR I-0000, paragraphs 13 to 23, and Case C-154/00 Commission v Greece [2002] ECR I-0000, paragraphs 9 to 19).

33 Conversely, a system of producer liability founded on the same basis as that put in place by the Directive and not limited to a given sector of production does not come within any of the systems of liability referred to in Article 13 of the Directive. That provision cannot therefore be relied on in such a case in order to justify the maintenance in force of national provisions affording greater protection than those of the Directive.

34 The reply to the question raised must therefore be that Article 13 of the Directive must be interpreted as meaning that the rights conferred under the legislation of a Member State on the victims of damage caused by a defective product under a general system of liability having the same basis as that put in place by the Directive may be limited or restricted as a result of the Directive's transposition into the domestic law of that State.'

34 Up until 15 November 2023, the Court of Cassation's position was that, although the system of rules governing liability for defective products that are neither intended for, nor put to, professional use did not preclude the application of other systems of contractual or non-contractual liability, that was conditional on those systems being based on grounds other than that of a safety defect in the product at issue, such as fault or a warranty in respect of latent defects.

35 By several judgments of 15 November 2023 (22-21.174, 178, 179, 180), the Court of Cassation held that *'the victim of damage attributed to a defective product may bring a liability action against the producer on the basis of the second of those provisions [Article 1240 of the Civil Code] if he or she can establish that the damage resulted from a fault committed by the producer, such as allowing the product to remain in circulation despite knowing that it was defective or failing in its duty to exercise vigilance with respect to the risks associated with the product.'*

36 The question therefore arises as to how the rule established by Article 13 of Directive 85/374 should be interpreted. That is the subject of the first question referred by the Court of Appeal for a preliminary ruling.

The expiry of the limitation period for LF's action based on liability for defective products

37 The ground put forward by LF seeks to challenge the compatibility of Article 1245-15 of the Civil Code, which transposes a European directive, with the European Convention for the Protection of Human Rights and Fundamental Freedoms. A national court is thus being tasked with assessing the compatibility of a European directive, which has supranational normative value under Article 288 of the Treaty on the Functioning of the European Union, with Article 47 of the Charter of Fundamental Rights.

38 Since neither the Treaty on the Functioning of the European Union, nor the Charter of Fundamental Rights, nor the European Convention for the Protection of Human Rights and Fundamental Freedoms lays down any rules governing conflicts between the two legal systems, the Court of Justice must be consulted on this point. That is the subject of the second question referred by the Court of Appeal for a preliminary ruling.

The limitation period governing LF's action

39 In that regard, the Court of Appeal refers to Article 10 of Directive 85/374 and to Article 1245-16 of the Civil Code, which transposes Article 10.

40 The Court of Appeal recalls that the Court of Cassation, in its judgment remitting the case to the lower court, held that, under Article 1245-16 of the Civil Code, proceedings for the recovery of damages brought on the basis of Article 1245 et seq. of that code are subject to a limitation period of three years from the date on which the claimant became aware, or should have become aware, of the damage, the defect and the identity of the producer. In that regard, the Court of Cassation held that, in a case of physical injury, the date of becoming aware of the damage should be understood to mean the stabilisation date, as it is only then that the claimant can measure the extent of his or her damage. In the case of a progressive medical condition, which makes it impossible to determine a stabilisation date, the time limit laid down by the aforementioned provision cannot start to run.

41 In that regard, the Court of Cassation criticised the Court of Appeal of Caen for having declared LF's claims for defective product liability to be inadmissible on the grounds that, in 2013, LF had undergone many examinations and assessments in relation to her various medical complaints, most of which had appeared between 2004 and 2007, and that she therefore had detailed knowledge of the damage no later than 15 October 2013, the date of her last medical examination.

42 The Court of Cassation found that, in reaching that conclusion, without investigating whether LF's damage had stabilised and, if it had not, whether her condition was progressive, where stabilisation was impeded, the decision of the Court of Appeal Caen lacked any legal basis.

43 According to the Court of Appeal of Rouen, the interpretation given to Article 1245-16 of the Civil Code, which transposes Article 10 of Directive 85/374, means that the *'day on which the claimant became aware, or should have become aware, of the damage'* is the stabilisation date. Since stabilisation can be defined as the moment from which the condition of the victim of a physical injury is no longer progressive, it follows that, in the case of a progressive medical condition resulting from a defective product, the time limit laid down by those two provisions cannot start to run.

44 The question therefore arises as to how the rule established by Article 10 of Directive 85/374 is to be interpreted, which requires a reference to the Court of Justice on this point. This is the context for the third question referred by the Court of Appeal for a preliminary ruling.

5. Questions referred for a preliminary ruling:

45 The Court of Appeal refers the following questions to the Court of Justice for a preliminary ruling:

(1) Must Article 13 of Directive 85/374/EEC of 25 July 1985, as interpreted by the judgment of 25 April 2002 (*Maria Victoria Gonzalez Sanchez* v *Medicina Asturiana SA*. C-183/00), according to which an injured person may rely on systems of contractual or non-contractual liability having a different basis from that put in place by the directive, be interpreted to mean that the victim of a defective product may seek compensation for his or her injury from the producer under a general system of fault-based liability, relying in particular on the fact that the product has been allowed to remain in circulation, a failure to exercise vigilance with respect to the risks associated with the product or, more generally, a safety defect in that product.?

(2) Is Article 11 of Directive 85/374/EEC of 25 July 1985, under which the rights conferred on the victim by that directive are extinguished upon the expiry of a period of 10 years from the date on which the harmful product was put into circulation, incompatible with the provisions of Article 47 of the Charter of Fundamental Rights of the European Union in that it deprives a victim suffering from a progressive injury caused by a defective product from the right of access to a court?

(3) Can Article 10 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, which determines the date on which the three-year limitation period begins to run as 'the day on which the plaintiff became aware, or should reasonably have become aware, of the damage', be interpreted as meaning that the period starts to run only on the day on which the whole of the damage is known, in particular by the establishment of a stabilisation date, defined as the moment from which the condition of the victim of physical injury is no longer evolving – meaning that, where a medical condition

is progressive, the limitation period does not start to run – rather than as the day when the damage has clearly appeared and can be linked to the defective product, regardless of its subsequent development?