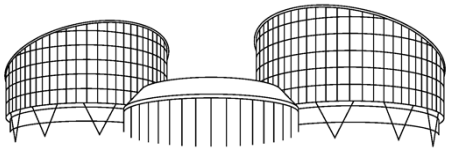

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FIFTH SECTION

CASE OF SANOFI PASTEUR v. FRANCE

(Application no. 25137/16)

JUDGMENT

Art 6 (civil) • Fair trial • Starting-point of limitation period for an action for damages as from the stabilisation of the disease • Evolutive disease not susceptible to stabilisation • Domestic law attaching greater weight to the right to a court of victims of physical damage than to the right to legal certainty of the parties responsible for that damage • Choice not challenged as such in the light of the broad margin of appreciation granted to States • No exemption from statutory limitation

STRASBOURG

13 February 2020

FINAL

13/06/2020

This judgment will become final in the circumstances set out in Article 44 § 2 of the Convention. It may be subject to editorial revision.

In the case of Sanofi Pasteur v. France,

The European Court of Human Rights (Fifth Section), sitting as a Chamber composed of:

Síofra O'Leary, *President,*
Gabriele Kucsko-Stadlmayer,
Ganna Yudkivska,
André Potocki,
Yonko Grozev,
Lətif Hüseynov,
Anja Seibert-Fohr, *judges,*
and Claudia Westerdiek, *Section Registrar,*

Having deliberated in private on 21 January 2020,

Delivers the following judgment, which was adopted on that date:

PROCEDURE

1. The case originated in an application (no. 25137/16) against the French Republic lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by a legal entity established under French law and based in Lyon, the limited liability company Sanofi Pasteur ("the applicant company") on 28 April 2016.

2. The applicant company is represented by Mr E. Baraduc, a lawyer practising in Paris. The French Government ("the Government") are represented by their agent, Mr F. Alabrune, Director of Legal Affairs in the Ministry for Europe and Foreign Affairs.

3. The applicant company complained in particular that, contrary to Article 6 § 1 of the Convention, the procedure for establishing the starting point of the limitation period for an action for damages against it had had the effect of exempting the action from statutory limitation, and that the Court of Cassation had rejected its request for a preliminary ruling from the Court of Justice of the European Union ("CJEU") without providing reasons.

4. On 11 September 2017 the Government were given notice of the application.

FACTS

I. THE CIRCUMSTANCES OF THE CASE

5. In her capacity as a trainee nurse, X, who was born in 1972, had been subject to compulsory vaccination against hepatitis B. Between 1992 and 1994 she had therefore received several injections of a vaccine manufactured by the applicant company. The latter did not specify the date

on which that vaccine had been launched on to the market. The Toulouse Court of Appeal (judgment of 10 February 2014; see paragraphs 9-11 below) noted that the product had been launched on to the market before 30 July 1988, the deadline for transposing Directive no. 85/374/EEC of the Council of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (see paragraphs 28-33 below).

6. She had been diagnosed with multiple sclerosis in 1993, with Crohn's disease in 1999, and with polymyositis in 2004.

A. Administrative court decisions

7. In 2002, attributing those diseases to her hepatitis B vaccination, X filed an action for damages against the State under Article L. 3111-9 of the Public Health Code. Her action was successful: the State was ordered to pay her 656,803.83 euros (EUR) in compensation for the damage to her health and to award her an annual pension of EUR 10,950 (Toulouse Administrative Court judgment of 5 July 2007; judgment of the administrative court of appeal of 10 December 2009).

B. Judicial court decisions

1. *Judgment of the Toulouse* tribunal de grande instance *of 3 September 2012 and judgment of the Toulouse Court of Appeal of 10 February 2014*

8. In 2005 X brought civil proceedings against the applicant company seeking compensation for the worsening of the damage to her health for which she had obtained compensation from the administrative court. She submitted that the applicant company had failed in its duty of protection or care under Articles 1135 and 1147 of the Civil Code as interpreted in the light of Directive no. 85/374.

9. The Toulouse *tribunal de grande instance*, by judgment of 3 September 2012, and then the Toulouse Court of Appeal, by judgment of 10 February 2014, declared the action admissible, and stated that the ten-year limitation period would start running on the date of stabilisation of the damage. On the latter point, the 10 February 2014 judgment reads as follows:

> "... in cases of physical damage, the ten-year limitation period for the action for damages ... does not start running until the date of stabilisation of the damage. In the instant case, the experts who examined [X] in the framework of the administrative proceedings did not establish any de date of stabilisation, and it is undisputed that X's condition is evolutive. The limitation period of the action filed by X against the manufacturer of the vaccine to which she attributes the worsening of her health damage has therefore not been running, and her action has not become statute-barred...".

10. On the merits, the Toulouse *tribunal de grande instance* declared the applicant company responsible for the damage to X's health, having specified the following:

> "Prior to the transposition into the Civil Code in 1998 of the 25 July 1985 European Directive on liability for defective products, it followed from Articles 1135 and 1147 of the Civil Code as interpreted in the light of that directive that the manufacturer of the vaccine, being bound by a duty of safety, was liable for any damage caused by the lack of safety of the vaccine, unless the manufacturer could establish the existence of a wholly unforeseeable and irresistible ground of exemption ...".

11. Upholding the impugned judgment, the Toulouse Court of Appeal held as follows:

> "... The vaccine administered to X was launched on to the market prior to 30 July 1988, the deadline for transposing the 25 July 1985 Directive. Therefore, the action is based on the provisions of Articles 1135 and 1147 of the Civil Code, which, with regard to defective products, impose on vaccine manufacturers a duty of safety: the manufacturer is required to provide a product free of any defect likely to create a danger for individuals, that is, a product which affords the safety which everyone can legitimately expect to enjoy. Such manufacturers are therefore liable for any damage caused by a dangerous defect in their vaccine, unless they can put forward a wholly unforeseeable and irresistible ground of exemption.
>
> In the present case, on 19 February 1992, 19 May 1992 and 20 June 1992 [X], who was 19 years old and a trainee nurse in perfect health, received injections of the vaccine Hevac B against hepatitis B, and on 19 September 1994 was administered a GenHevac booster. Following each of these injections she developed disorders which led to her diagnosis with a multiple-sclerosis-type demyelinating disease in February 1996.
>
> The first judge, precisely, concluded as follows on grounds adopted by the court: given the state of scientific knowledge, the cause of the disease is unknown, and the most likely explanation for its onset is the occurrence of an immunological disruption; the illness is caused by a set of genetic and environmental factors; a vaccine specifically acts on the immune system; consequently, science cannot rule out the possibility that vaccinating individuals against hepatitis B is a factor triggering multiple sclerosis, most likely in specific genetic contexts conducive to its development; X carries a DOCTEUR 15 blood marker, which scientific research has highlighted as a risk factor.
>
> As a result, the appearance of characteristic symptoms of incipient multiple sclerosis within day of the vaccinations, which greatly stimulate the immune system, whereby the subject had not presented any sign of an incipient neurological disease and the vaccine revealed the presence of a risk factor not mentioned by the manufacturer on the product injected in 1992 and 1994, constitutes sufficiently serious, precise and concurring presumptions for the purposes of Article 1353 of the Civil Code, to accept the existence of a causal link between the impugned vaccination and X's multiple sclerosis.
>
> The first judge, precisely, concluded that the multiple sclerosis and auto-immune diseases developed by X, Crohn's disease and polymyositis, stem from the same disruption of the immune system and the related intensive therapy, such that there is no need to differentiate the consequences of those various illnesses.

> The presumed causal link between the disease and the vaccination, together with the lack of certainty as to the safety of the vaccine, lead to a presumption of defectiveness of the vaccine administered to X between February and June 1992 and in September 1994 which could only be gainsaid by the provision of scientific proof that it was not the vaccine which triggered the disease under normal conditions of use. The fact is that the [applicant company] has not demonstrated that the disease stemmed solely from factors unconnected with the vaccine. ...".

12. Noting that the administrative court had ordered the State to pay compensation for the damage in question, the civil court, "before determining any compensation for a worsening of the damage", commissioned an expert assessment to ascertain whether the victim's current condition pointed to a worsening of the damage already redressed.

1. Court of Cassation's judgment of 12 November 2015

13. The applicant company appealed on points of law against the judgment of 10 February 2014. X lodged a cross-appeal.

14. In its first ground of appeal, relying, in particular, on the principle of certainty of the law and Article 1 of Protocol No. 1, the company complained that the court of appeal had declared that the limitation period would start running on the date of the stabilisation of the damage, whereas X's disease was by nature not open to such stabilisation, which meant that action was not subject to statutory limitation.

15. In the fifth limb of its second ground of appeal, the applicant company criticised the trial court for having adopted a presumption of the defectiveness of the vaccine administered, which presumption could only be gainsaid with scientific proof that the vaccine had not triggered the disease, and for having based its finding on the view that the company had not demonstrated that the disease had stemmed solely from factors unconnected with the vaccine. Emphasising that a manufacturer's liability for a defective product was subject to proving that the product was unsafe, and that the mere fact that a product was involved in the materialisation of the damage was insufficient to establish its defectiveness, it complained of a reversal of the burden of proof, in breach of Article 1315 of the Civil Code (former Article 1353 of the Civil Code), stating that "anyone requesting the enforcement of an obligation must provide proof[;] likewise, anyone claiming to be released (from the obligation) must provide evidence of payment or of the act extinguishing his or her obligation" (see paragraph 24 below).

16. In the sixth limb of the second ground of appeal, the applicant company submitted that a medicine could become unsafe owing to a lack of information for the patient concerning the known side-effects at the time of its launch on the market. It therefore complained that the trial judge had concluded that the vaccine was presumed dangerous. The company considered that he should have verified whether the alleged unsafeness of

the product could have stemmed from lack of information on any undesirable effects of the vaccine known at the time of the vaccination. The company submitted that by failing so to verify, the trial court had deprived its decision of a legal basis in Article 1382 (later Article 1240) of the Civil Code), which provided that "any act that causes damage to another shall render the person through whose fault the damage was caused liable to make reparation for it".

17. In the context of the fifth and sixth limbs of its second ground of its cassation appeal, the applicant company invited the Court of Cassation, in the alternative, to forward to the CJEU requests for preliminary rulings on the interpretation of Directive 85/374.

18. The first two requests for opinions concerned Article 4 of the Directive, which requires the victim to prove the damage, the defect and the causal link between the defect and the damage. The requests were intended to invite the CJEU to specify whether that provision prevented proof of the safety issue with the product consisting exclusively of proof of the causal connection between the product and the damage, or of the mere existence of a presumed causal link between the product and the damage. The third request for a preliminary ruling concerned Article 6 of the Directive, which provides that a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the use to which it could reasonably be expected that the product would be put and the time when the product was put into circulation. The applicant company had hoped that the CJEU would be invited to explain whether the article in question meant that the dangerousness of a vaccine could not stem from an undesirable effect unknown to the manufacturer at the time when the product was put into circulation, where such undesirable effect did not call into question the use to which it could reasonably be expected that the product would be put.

19. In his report, the rapporteur stressed the following:

> "... As regards the legal basis of the action
>
> ... The court ruled that the dispute should be subject to the provisions of Articles 1135 and 1147 of the Civil Code as interpreted in the light of the Directive, such that the manufacturer of the vaccine was bound by a duty of safety, unless he could put forward a wholly unforeseeable cause for exemption .... That legal basis was upheld by the court of appeal, which pointed out that the vaccine administered to X had been launched on to the market before 13 July 1988, the deadline for transposing the Directive.
>
> In that regard, it should be remembered that under Article 19 of the Directive the deadline for transposing this instrument was 30 July 1988, and that Article 17 stated that it did not apply to products put into circulation before the date on which the provisions referred to in Article 19 entered into force.
>
> In principle, the 'ordinary meaning' interpretation rule only applies to the provisions of a directive which has not been transposed within the time-limit or has been

improperly transposed and whose direct effect cannot be relied on (1ère civ, 24 January 2006, B. 34).

In the aforementioned judgment of 24 January 2006 we ruled that 'the court of appeal which noted that the impugned products had been put into circulation in February 1985 rightly deduced, pursuant to Article 17 of Directive No. 85/374 of 25 July 1985, and since the subject matter had been a limitation period, that there was no need to interpret national law in the light of that directive.'

If, therefore, the 'ordinary meaning' interpretation rule is not justified, the choice of either Article 1147 or Article 1382 of the Civil Code would appear to provide the appropriate legal basis. Indeed, according to the same 2006 judgment, the 1st Civil Law Division considered that 'the court of appeal called upon to determine liability under Articles 1147 and 1382 of the Civil Code did not have to refer to the Directive, whose provisions had no impact on its appraisal' and 'that it primarily, and rightly, concluded that any producer was liable for damage caused by its product in respect of both the direct and indirect victims, without the need to differentiate them according to their status as contracting or third parties' (see to similar effect, albeit on the basis of Articles 1147 and 1384, para. 1, 1ère civ, 28 April 1998, B. 158) ...".

20. In his opinion, the Advocate-General stated, in particular, the following:

"... 1. The applicable regulations on liability

The court of appeal, like the *tribunal de grande instance*, considering that the vaccine administered to X in 1992 had been launched on to the market prior to 30 July 1988, the deadline for transposing Directive No. 85-374 of 25 July 1985, held that national law, on the basis of Articles 1135 and 1147 of the Civil Code, was applicable in the light of and in line with the objectives of that Directive.

The rapporteur rightly pointed out that the relationship between X and the laboratory is not contractual, observing that the grounds are based on Article 1382 of the Civil Code and that the questions raised should be examined.

Does this, however, mean that domestic law must be interpreted in the light and in line with the aims of the Directive, as submitted by the appellant?

The Sanofi company affirmed, albeit without providing any specific date or mentioning such date in the case file, that the vaccine administered had been put into circulation 'shortly' before the vaccination in 1992, that is to say after 30 July 1988 but before the Law of 10 May 1998 transposing the Directive into domestic law.

The impugned judgment ... considered that 'the vaccine administered to X had been launched on to the market before 30 July 1988', which fact was assessed with the court's unfettered discretion and has little impact on the limitation period.

In a similar case of a hepatitis B vaccination in 1994, followed by the development of multiple sclerosis in the patient, you ruled that the applicable provisions, that is to say Articles 1147 and 1382 of the Civil Code, should be interpreted in the light of EEC Directive no. 85-374 of 25 July 1985, which ought to have been transposed into domestic law by 30 July 1988 (Civ 1ère, 23 September 2003, no. 1-13.063, Bull no. 188).

... 3. Liability for defective products

The producer's liability is subject to the condition that the applicant must prove, in addition to the damage sustained, the defect in the product and the causal link between

the defect and the damage (Article 4 of the Directive of 25 July 1985 as reprised verbatim in Article 1386-9 of the Civil Code).

It should be remembered that X's vaccination dates back to 1992, followed by a booster injection in 1994, which rules out the application of Articles 1386-1 et seq., which stem from the Law of 19 May 1998 transposing the Directive of 25 July 1985 concerning liability for defective products.

We saw above that in such cases, leaving aside the question of the statutory limitation on the claim, case-law applies domestic law in the light of the Directive (civ 1ère, 23 September 2003, Bull. no. 188).

In the case at hand, the court of appeal, having pointed out that the producer is bound by an obligation of safety unless he can put forward a wholly unforeseeable and irresistible ground of exemption, set out the factors constituting serious, specific and concurring presumptions of a causal link between the vaccination and the illness suffered by X. The causal link thus established, combined with the uncertainty as to the safety of the vaccine, reveals the defect in the product.

... Assuming that the causal link can be established, the defect in the product has nevertheless to be demonstrated.

According to Article 6 of the Directive as reprised in Article 1386-4 of the Civil Code: 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.

Recital no. 6 of the Directive clearly states that: "... 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".

The defect in the product, which must be established and over which the Court of Cassation exercises its supervision, should therefore be appraised in accordance with the public's legitimate expectations *vis-à-vis* the product, which places the users in danger regardless of the use for which it is intended. The mere involvement of the product in the damage is insufficient to establish its defectiveness.

The lack of safety of the product, based on the risk/benefit test, must be very serious, exceeding the legitimate expectations of consumers liable to use it, having regard to the circumstances of its launch on to the market and the information provided on the risks linked to its use, which must be appraised at the time when it is put into circulation (Civ 1ère, 24 January 2006 no. 03-19.534, rapport Gallet p.11; Civ 1ère 3 March 1998 Bull. no. 95). ...".

21. On 12 November 2015, the first civil-law division of the Court of Cassation dismissed the appeals on points of law by a judgment based on the following reasons:

"... Regarding the first ground of the main appeal: ... whereas, having rightly stated that in the presence of physical damage the limitation period for the action for damages in respect of the administration of a vaccine in 1992, which is ten years pursuant to Article 2270-1 of the Civil Code and Article L. 110-4 of the Commercial Code as worded following the enactment of Law No. 2008-561 of 17 June 2008, relied on by the parties, only starts running on the date of stabilisation of the damage, the court of appeal, which noted that no date had been established for the stabilisation of Ms X's state of health, which was continuing to evolve, deduced, precisely, that the

limitation period for the action lodged by Ms X had not run and that her action had not become time-barred; ...

As regards the second ground of the main appeal: ... whereas ... the court of appeal ... highlighted the existence of serious, specific and concurring presumptions of a defect in the impugned vaccination resulting in the multiple sclerosis as contracted by Ms X; ...

For those reasons, and whereas there is no need to request a preliminary ruling from the Court of Justice of the European Union:

Rejects the appeals on points of law ...".

2. *17 November 2015 judgment of the Toulouse* tribunal de grande instance

22. By judgment du 17 November 2015, in the light of the expert report, the Toulouse *tribunal de grande instance* ordered the applicant company to pay X: EUR 8,050 in respect of her permanent functional impairment; EUR 1,500 in respect of the suffering and disfigurement endured; an annual allowance of EUR 5,475 for assistance from a third person; and EUR 2,000 in respect of procedural costs. Since no appeal was lodged against this judgment, it became final.

RELEVANT DOMESTIC LAW

A. Public Health Code

23. At the material time Article L. 3111-9 of the Public Health Code provided:

"Without prejudice to possible actions exercised under ordinary law, compensation for damage directly attributable to a compulsory vaccination administered under the conditions mentioned in this chapter shall be payable by the State.

The State shall be subrogated, for an amount no higher than the sums paid out, to the victim's rights against the person liable for the damage."

B. Civil Code

24. The relevant provisions of the Civil Code are set out below (version in force at the material time):

Article 1135

"Conventions bind the parties not only to their express provisions, but also to all the consequences of the binding provisions in terms of fairness, usage or law in accordance with their nature."

Article 1147

"Debtors shall, as appropriate, be ordered to pay damages either for failure to execute the obligation or for delays in such execution, unless they can provide evidence that the failure to execute originated in an external cause which cannot be attributed to them, even where they have acted in good faith."

Article 1315

"The party demanding execution of an obligation must provide proof of the latter.

Reciprocally, the party claiming to be released from the obligation must provide evidence of payment or of the act which extinguished his or her obligation."

Article 1353

"Presumptions which have not been established by law shall be left to the discretion of the judge, who must only accept serious, specific and concurring presumptions, and only in cases where the law permits testimonial evidence, unless the act has been challenged on grounds of fraud or malice."

Article 1382

"Any act committed by a person that causes damage to another renders the person through whose fault the damage was caused liable to make reparation for it."

Article 2270-1

"Civil actions concerning non-contractual liability shall become statute-barred within ten years from the emergence or exacerbation of the damage. ..."

25. The Court of Cassation has stated that in the event of an action for damages seeking compensation for bodily injury, the limitation period can only start running on the date of stabilisation, since only then can the claimant gauge the full extent of his or her injury (Cass 1ère civ. 1 June 1999, B. 178; Cass. 2ème civ., 4 May 2000, no. 97-21.731; Cass 2ème civ. 11 July 2002, no. 01-02.182).

26. Article 1386-1 of the Civil Code read as follows (wording established by Law no. 98-389 of 19 May 1998; see paragraph 28 below; it is currently Article 1245 of the Civil Code):

"The producer is liable for damage caused by any defect in his product, whether or not he is bound by a contract with the victim."

C. The Commercial Code

27. At the material time, Article L. 110-4 of the Commercial Code read as follows:

"Obligations created at the time of transactions in respect thereof between traders or between traders and non-traders shall become time-barred after ten years unless they are subject to special limitation periods of shorter duration. ..."

III. RELEVANT EUROPEAN UNION LAW

A. Directive 85/374

28. Directive 85/374 establishes a no-fault liability regime incumbent on a producer where damage has been caused by a defect in his product. The Directive was belatedly transposed into French law under Law No. 98-389 of 19 May 1998, after an infringement judgment of the CJEU of 12 January 1993 (C-293/91; EU:C:1993:4).

29. Article 1 of the Directive provides:

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

30. Article 3 § 1 of the Directive specifies that the word "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.

31. Articles 4 and 6 of the Directive provide:

Article 4

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

Article 6

> "1. 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.
>
> 2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."

32. Articles 10, 11, 17 and 19 of the Directive read as follows:

Article 10

> "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. ..."

Article 11

> "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."

Article 17

"This Directive shall not apply to products put into circulation before the date on which the provisions referred to in Article 19 enter into force."

Article 19

"1. Member States shall bring into force, not later than three years from the date of notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. ..."

33. Article 21 of Law No. 98-389 of 19 May 1998 (paragraph 28 above) states that the provisions transposed from the Directive are applicable to products which were put into circulation after the date of its entry into force (21 May 1998) even if they were the subject of a prior contract.

B. Article 267 of the Treaty on the Functioning of the European Union and related CJEU *Cilfit* case-law

34. Article 267 of the Treaty on the Functioning of the European Union ("TFEU"; former Article 234 of the Treaty establishing the European Community) lays down the following preliminary ruling procedure in respect of the CJEU:

"The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:

(a) the interpretation of the Treaties;

(b) the validity and interpretation of acts of the institutions ... of the Union;

Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon.

Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court.

..."

35. Interpreting that provision, the CJEU stated the following in the case of *S.r.l. CILFIT and Lanificio di Gavardo S.p.a. v. Ministry of Health* (C-283/81, judgment of 6 October 1982, ECLI:EU:C:1982:335, § 21):

"... a court or tribunal against whose decisions there is no judicial remedy under national law is required, where a question of [Union] law is raised before it, to comply with its obligation to bring the matter before the Court of Justice, unless it has established that the question raised is irrelevant or that the [Union] provision in question has already been interpreted by the Court or that the correct application of [Union] law is so obvious as to leave no scope for any reasonable doubt. The

> existence of such a possibility must be assessed in the light of the specific characteristics of [Union] law, the particular difficulties to which its interpretation gives rise and the risk of divergences in judicial decisions within the [Union]."

36. As regards the initiation of preliminary ruling procedures, the CJEU stated as follows in the case of *György Katz v. István Roland Sós* (C-404/07, 9 October 2008, ECLI:EU:C:2008:553, § 37):

> "... it is for the national court, not the parties to the main proceedings, to bring a matter before the Court of Justice. The right to determine the questions to be put to the Court thus devolves on the national court alone and the parties may not change their tenor ..."

37. In its judgment of 9 November 2010 in the case of *VB Pénzügyi Lízing Zrt. v. Ference Schneider* (C-137/08, ECLI:EU:C:2010:659, § 28), the CJEU specified the following:

> "...the system established by Article 267 TFEU with a view to ensuring that European Union law is interpreted uniformly throughout the Member States instituted direct cooperation between the Court of Justice and the national courts by means of a procedure which is completely independent of any initiative by the parties ...".

38. On 25 November 2016 the CJEU published an update of its "recommendations to national courts and tribunals in relation to the initiation of preliminary ruling procedures" (2016/C 439/01), the relevant section of which reads as follows:

> "3. The jurisdiction of the Court to give a preliminary ruling on the interpretation or validity of EU law is exercised exclusively on the initiative of the national courts and tribunals, whether or not the parties to the main proceedings have expressed the wish that a question be referred to the Court. In so far as it is called upon to assume responsibility for the subsequent judicial decision, it is for the national court or tribunal before which a dispute has been brought — and for that court or tribunal alone — to determine, in the light of the particular circumstances of each case, both the need for a request for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court."

THE LAW

I. ALLEGED VIOLATION OF ARTICLE 6 § 1 OF THE CONVENTION ON ACCOUNT OF THE METHOD OF ESTABLISHING THE STARTING POINT OF THE LIMITATION PERIOD

39. The applicant company complained that the establishment of the starting point for the limitation period of X's action as being the date of the stabilisation of the damage had meant that that action was *de facto* not subject to time limitation, given that the illness having caused the damage had not been susceptible of stabilisation. It considered that that had violated the legal certainty principle as secured under Article 6 § 1 of the Convention, and had infringed its right to the peaceful enjoyment of its possessions as guaranteed by Article 1 of Protocol No. 1.

40. The Court, being master of the characterisation to be given in law to the facts of a case (see, for example, *Fernandes de Oliveira v. Portugal* [GC], no. 78103/14, § 81, 31 January 2019), considers that this complaint should be examined solely under Article 6 § 1 of the Convention, the relevant parts of which provide:

> "In the determination of his civil rights and obligations ... everyone is entitled to a fair ... hearing ... by a ... tribunal ...".

A. Admissibility

41. Noting that the complaint is not manifestly ill-founded within the meaning of Article 35 § 3 (a) of the Convention and that it is not inadmissible on any other grounds, the Court declares it admissible.

B. Merits

1. The parties' submissions

(a) The applicant company

42. The applicant company emphasised that if the claimant had to be able to initiate legal proceedings within an appropriate timeframe compatible with ascertaining the extent of the damage sustained, the respondent party must be granted entitlement to an effective starting point for the limitation period so as not to remain indefinitely exposed to an appeal: it must be able to avail itself of statutory limitation without any risk of the claimant opportunistically relying on the evolutive nature of his or her pathology and the lack of stabilisation of the condition. The company rejected the Government's submission that there was no question of non-applicability of statutory limitation in the present case since in any event the action would become time-barred ten years after the victim's death. It considered that the applicability of statutory limitation to an action had to be assessed in respect of the originator of the latter rather than of any of his or her heirs. Furthermore, the uncertainty about the date of death and the resultant "sliding deadline" precluded the setting of a firm date. At all events, using the date of stabilisation for an evolutive illness led to "excessive flexibility" and therefore posed a serious threat to legal certainty.

43. The applicant company conceded that there were late-onset evolutive diseases and injuries. However, it observed that that was not the case of multiple sclerosis where it was associated with hepatitis B vaccination, since the proximity between the vaccination and the emergence of the first symptoms was one of the factors taken into account by the courts in order to establish a causal link between the two events; where the diagnosis was made following the first symptoms, the patient knew that his or her illness was subject to deterioration. The claimant in the present case, X, was

apprised of her injury less than ten days after her vaccination, because she had brought proceedings against the State within that time.

44. The applicant company rejected the plea that the action had not been exempt from statutory limitation because the instant case had concerned not an initial injury but a deterioration of the latter, whereby each stage in the deterioration had created a separate right of action. The company submitted that statutory limitation no longer applied where stabilisation could never be established, as was the situation with multiple sclerosis. It also disagreed with the Government's contention that requiring the claimant to bring fresh proceedings every time her condition deteriorated would be contrary to Article 6 § 1 because very often, in the case of a degenerative disease which had to be assessed in the long term, the worsening of the injury could not be dated. It observed on that point that multiple sclerosis progressed in fits and starts, which usually corresponded to a period in hospital in tandem with a deterioration in the patient's condition and which could therefore be dated. The applicant company added that the fact that the victim might possibly be forced to use successive remedies in order to redress each deterioration of his or her injury stemmed from the fact that French law did not allow for claiming damages for future injuries, and observed that the claimant was in a position to bring proceedings as soon as the first symptoms of multiple sclerosis appeared, or at least as soon as the illness was diagnosed.

(a) The Government

45. The Government stated first of all that, contrary to the applicant company's submissions, the action brought against it had indeed been subject to statutory limitation. They emphasised that the Toulouse Court of Appeal had, under its right of unfettered discretion, held that the vaccine administered to the claimant had been put into circulation before the deadline for the transposition of Directive 85/374 (30 July 1988), such that that Directive had been inapplicable, and that the ordinary-law time-limit of ten years from the data of stabilisation of the injury had had to be respected. They added that while the starting-point of the time-limit was liable to be postponed when the victim's injury deteriorated, the limitation period began running, at the very latest, on the latter's death; thus, the victim's heirs' action became statute-barred ten years after his or her death at the very latest. The Government also pointed out that when legislation fixed the starting point of the limitation period on the date of stabilisation of the injury, it took the deterioration of the person's condition as a further injury; compensation for the initial injury was definitively established at the first trial, and neither the assessment of nor the decision on the original damage could be challenged during the proceedings concerning additional compensation. Given that there were then two separate actions which shared the same triggering event but related to differed injuries, the applicant

company could not claim that the failure of the claimant's disease to stabilise had exempted her action from statutory limitation.

46. The Government submitted that that by taking the date of stabilisation of the injury as the starting point of the limitation period the French courts had not shown excessive flexibility resulting in the elimination of the relevant procedural conditions prescribed by law. They emphasised that claimants could not know the extent of his or her injury until the date of stabilisation. They added that the aim was to give persons suffering from evolutive illnesses effective access to a tribunal. In fact, taking the date of sale of the vaccine as the starting point of the limitation period would have deprived such persons of any possible remedy in the event of a late-onset pathology. As for adopting the date of deterioration of the condition, that would have required the victim to be able to pinpoint the date of emergence of the symptoms of the deterioration of her state of health, even though those symptoms were progressive by nature, and would have forced her to exercise a fresh judicial remedy each time her state of health deteriorated, which would have imposed an excessively formalistic approach on her and led to potential financial difficulties and legal uncertainty.

47. The Government further submitted that the principle of legal certainty had been complied with, because in deciding not to implement the limitation period set forth in Directive 85/374 cited above, and fixing the starting point for the limitation period on the date of stabilisation, the Court of Cassation had applied established case-law to the effect that during the intermediate period between the end of the time-limit for transposition of a directive and the entry into force of the transposition legislation the national court had to apply ordinary-law rules, since an interpretation consistent with the Directive would have led to an interpretation conflicting with national law (Cass. 1ère, 26 September 2012, no. 11-18.117).

48. Moreover, the Government considered that the applicant company had not been prevented from defending itself: it had had the opportunity before the domestic courts to challenge the two expert reports which had established the facts on which those courts had relied in finding a causal link between the injection and the onset of the disease, as well as the defectiveness of the product; it had also been able to request a further expert assessment. They added that there had been no infringement of the principle of equality of arms between the parties, because, on 3 September 2012, the Toulouse *tribunal de grande instance* had ordered a detailed preliminary expert assessment in order to evaluate the deterioration in the claimant's condition.

49. In the Government's view, the establishment of the starting point for the limitation period on the date of stabilisation had struck a fair balance between the applicant company's right to equality of arms certainty of the law and the victim's right of access to a tribunal.

2. The Court's assessment

50. The Court reiterates that the legal time-limits for statutory limitation, (*prescription*), which constitutes one of the legitimate restrictions on the right to a tribunal, serves several important purposes, namely to ensure legal certainty and finality, protect potential defendants from stale claims which might be difficult to counter and prevent any injustice which might arise if courts were required to decide upon events which took place in the distant past on the basis of evidence which might have become unreliable and incomplete because of the passage of time (see, for example, *Stubbings and Others v. the United Kingdom*, 22 October 1996, §§ 51-52, *Repots of Judgments and Decisions* 1996-IV; *Stagno v. Belgium*, no. 1062/07, § 26, 7 July 2009; and *Howald Moor and Others v. Switzerland*, nos. 52067/10 and 41072/11, §§ 71-72, 11 March 2014).

51. Relying on that finding, in the case of *Oleksandr Volkov v. Ukraine* (no. 21722/11, §§ 138-140, ECHR 2013) the Court examined the situation of a judge who had been dismissed for "breach of oath" and who had complained of the absence of limitation periods under domestic law in that type of proceedings. It observed that the applicant had been placed in a difficult position, having had to mount his defence with respect to events some of which had occurred in the distant past. Emphasising that such an open-ended approach to disciplinary cases involving the judiciary posed a serious threat to the principle of legal certainty, it found a violation of Article 6 § 1 on account of a breach of the principle of legal certainty caused by the lack of a limitation period.

52. Furthermore, the Court has on several occasions emphasised that the principle of legal certainty, which, in particular, guaranteed a certain stability in legal situations and contributed to public confidence in the courts, constituted one of the fundamental aspects of the rule of law (see, for example, *Lupeni Greek Catholic Parish and Others v. Romania* [GC], no. 76943/11, § 116, 29 November 2016).

53. That being so, the Court has also held that in cases concerning compensation for victims of bodily harm, the persons concerned should be entitled to take legal action where they were actually capable of evaluating the injury sustained, and that making them subject to a limitation which had expired before the date on which the injury had been assessed might have infringed their right to a tribunal. This was the conclusion reached by the Court in the case of *Eşim v. Turkey* (no. 59601/09, §§ 25-26, 17 September 2013), in which the applicant had been injured by a bullet in 1990. Doctors had not discovered the bullet lodged in his head until 2007. The domestic courts had ruled that his action for damages had been time-barred because it had been lodged after the expiry of the legal five-year time-limit, which had begun to run on the date of commission of the prejudicial act. The Court held that it could not be considered reasonable to expect the applicant to have lodged his compensation claim within five years, since it was

undisputed that he had been unaware of the bullet in his head on the date of expiry of the limitation period.

54. The Court reached a similar conclusion in the case of *Howald Moor and Others* (cited above, §§ 71-79), which concerned persons who had been exposed to asbestos and whose action for damages had been dismissed as being time-barred. The ten-year limitation period had begun running on the date of the exposure to asbestos, even though the applicants could not have known that they were ill at that time, given the latency period for diseases linked to exposure to the substance in question. The Court pointed out that even though it was convinced of the legitimacy of the aims pursued by the limitation (*prescription*) rules applied, in particular certainty of the law, it was unsure of the proportionality of their application in the instant case, given that the systematic application of those rules to victims of diseases which could only be diagnosed many years after the pathogenic events was liable to deprive those concerned of the ability to have their claims examined by the courts. Furthermore, where it had been scientifically proved that a person could not possibly have known know that he or she was suffering from a specific disease, that fact should be taken into account in calculating the limitation period. In the light of the exceptional circumstances of the instant case, the Court held that the application of limitation periods had restricted access to a tribunal to such an extent that the very substance of the applicants' right had been infringed.

55. It is true that in both those cases the victims had not known about their illnesses until the time-limits on actions for damages had expired. in the present case, the action for damages had not been statute-barred at the time of diagnosis of X's multiple sclerosis. Nonetheless, as previously pointed out (see paragraph 53 above), broadly speaking, the right to a tribunal is in issue where an action for damages lodged by a person whose physical integrity has been infringed becomes statute-barred before the person has actually been in a position to assess his or her injury. That is the situation in which X finds herself: in view of the evolutive nature of her illness and in the absence of stabilisation of the latter, she cannot fully evaluate her injury, and therefore is unable to sue the company having manufactured the vaccine on a date prior to such stabilisation, in order to obtain full compensation.

56. Thus the present case concerns a situation where one party's right under the Convention comes up against another party's Convention right: on the one hand, the applicant company's right to legal certainty, and on the other, X's right to a tribunal.

57. In such cases, the balancing of individual interests, which may well be contradictory, is a difficult matter and Contracting States must have a broad margin of appreciation in this respect (see, for example, *mutatis mutandis*, *MGN Limited v. the United Kingdom*, no. 39401/04, § 142, 18 January 2011, and *Ashby Donald and Others v. France*, no. 36769/08, § 40,

10 January 2013). Moreover, as regards, in particulier, the requisite balancing exercise, in the context of the statute-barring of actions for damages, between the victim's right of access to the courts and the defendant's right to legal certainty, the Court has pointed out that in applying the relevant procedural rules, domestic courts should avoid both excessive formalism that would impair the fairness of the proceedings and excessive flexibility such as would render nugatory the procedural requirements laid down in statutes (see *Eşim*, cited above, § 21).

58. Having regard to that margin of appreciation, therefore, it is not for the Court to interfere with the State's policy choices aimed at striking the said balance.

59. The Court notes that French law provides for statute-barring civil actions concerning non-contractual liability. At the material time the limitation period was ten years, and the Court of Cassation had specified that where the action concerned compensation for bodily injury, that period began running on the date of stabilisation of the victim's condition (see paragraphs 24-25 above). As pointed out by the Government, in fixing the starting point of the limitation period on the date of stabilisation, the relevant legislation aimed to enable the victim to obtain full compensation for his or her physical injury, the full extent of which could not be known until it had stabilised. This choice within the French legal system therefore lent greater weight to the right of victims of bodily injuries to a tribunal than to the right to legal certainty of those responsible for those injuries. The Court cannot criticise that choice as such. Where relevant, it reiterates in that connection the importance which the Convention attaches to the protection of physical integrity, which falls within the ambit of Articles 3 and 8 of the Convention. It further observes that this arrangement as implemented in the French legal system enables regard to be had to the fact that the needs of persons suffering from an evolutive disease such as multiple sclerosis, for instance in terms of assistance, are liable to increase as their illness progresses.

60. Furthermore, while the Court understands why the applicant company might consider that the fact of taking the date of stabilisation as the starting point for the limitation period had had the consequence of exempting the civil action for damages from limitation on account of the evolutive nature of the disease, it cannot fully agree with that point of view. Indeed, it observes that the legislation provided for a limitation period and established the starting point for that period, which, however, was postponed because no stabilisation had been noted. Moreover, as submitted by the Government, in the absence of stabilisation, the limitation period began running at the latest on the date of the death of the victim of the bodily harm, whereby any action lodged by the heir then became statute-barred ten years after such death. Therefore, the action could not be said to have been exempted from statutory limitation.

61. Accordingly, there was no violation of Article 6 § 1 of the Convention on account of the procedure for fixing the starting point of the limitation period for the action for damages lodged against the applicant company.

II. ALLEGED VIOLATION OF ARTICLE 6 § 1 OF THE CONVENTION ON ACCOUNT OF THE FAILURE TO GIVE REASONS FOR THE DECISION REJECTING THE REQUEST FOR A PRELIMINARY RULING BY THE CJEU

62. Relying on Article 6 § 1, cited above, the applicant company complained that the Court of Cassation had rejected its request for a preliminary ruling by the CJEU without giving reasons.

A. Admissibility

63. Noting that that complaint is not manifestly ill-founded within the meaning of Article 35 § 3 (a) of the Convention and that it is not inadmissible on any other grounds, the Court declares it admissible.

B. Merits

1. The parties' submissions

(a) The applicant company

64. The applicant company argued that the Court of Cassation's refusal to refer to the CJEU the preliminary questions relating to Directive 85/374 which it had submitted had not been reasoned in the light of the *Cilfit* criteria. The company observed that in the absence of any reasoning it could not be known whether those questions had been deemed irrelevant, if they had concerned a clear provision or one that had already been interpreted by the CJEU, or if they had quite simply been ignored. It stated that on the date of its decision in the present case, the Court of Cassation had referred to the CJEU a set of similar preliminary questions relating to the said Directive, in a case comparable to the present one, involving a person who attributed her multiple sclerosis to an injection of the same hepatitis B vaccine (Civ. 1ère, 12 November 2015, no. 17-18.118).

65. The applicant company rejected the Government's argument that it was not for the domestic courts to interpret national law in the light of the aforementioned Directive 85/374 where the vaccine had already been put into circulation before the deadline for transposition of that Directive. It observed in that connection that the Toulouse Court of Appeal had not considered the dispute in the light of the Directive because the marketing of the vaccine in question had been authorised before that deadline. However, it submitted that consideration should have been given, not to the date on

which it was launched on to the market, but to the date on which it had actually been put into circulation. Since the vaccine was a product which expired within a few months, the applicability of the Directive should be assessed as of the date on which the manufacturer discontinued its production. In the instant case, having regard to the expiry dates, the vaccine must have been put into circulation during the eighteen months preceding the first injection, on 19 February 1992, that is to say after the 30 July 1988 deadline for the transposition of the instrument. The applicant company deduced that the domestic court should have interpreted domestic law in the light of the Directive and its purpose. In any event, even supposing that the vaccine had been put into circulation before that date, almost four years before the vaccination, the domestic court should have interpreted domestic law in conformity with the Directive, even before the expiry of the deadline for transposing it.

(b) The Government

66. The Government pointed out that the question whether a court had failed in its obligation to give reasons should be assessed in context. They stressed that where, in the framework of proceedings before a domestic court which were not subject to appeal, a party requested the referral to the CJEU of a request for a preliminary ruling, the *Cilfit* principles only applied when an EU law issue had been raised. That had not been the situation in the present case, since the three preliminary questions submitted to the Court of Cassation by the applicant company had concerned the interpretation of Directive 85/374, and the vaccine used in the instant case had been put into circulation prior to 30 July 1988, the deadline for the transposition of the Directive. Indeed, it followed from the CJEU's case-law that in such cases the domestic court did not have to interpret domestic law in the light of the Directive in question; it was simply required to refrain from interpreting domestic law in a manner liable to seriously jeopardise the achievement of the aim of the Directive when it came into force.

67. The Government deduced that the domestic courts should only have applied the law as provided in Articles 1382 and 1147 of the Civil Code, such that the requests for a preliminary ruling submitted by the applicant company had been unlikely to have any impact on the settlement of the dispute. Therefore, it was allegedly on the basis of the ineffectiveness of the requests submitted for a preliminary ruling that the Court of Cassation had dismissed the appeal, "without any need to seek a preliminary ruling from the CJEU". The Government considered that the lack of reasoning for the refusal to refer the requests for a preliminary ruling on provisions which were by nature inapplicable to the case, that is to say the failure to reply to an ineffective plea base on the application of the European Directive, had not had the effect of violating the applicant company's right to a fair trial. They added that that refusal had not been arbitrary because the referral had

in any case been impossible, given that no EU legal rules had been applicable. Finally, the Government emphasised that while it was true that on the date on which it had delivered judgment in the instant case the Court of Cassation had referred to the CJEU similar requests for preliminary rulings concerning Directive 85/374 in a different case involving the applicant company and a person who had developed multiple sclerosis following his/her hepatitis B vaccination, that case had concerned vaccinations carried out in December 1998 and in 1999, that is, after the entry into force of the 19 May 1998 law transposing the Directive; the action had thus been based on the new Article 1386-1 of the Civil Code (see paragraph 26 above), which had resulted from that transposition, and EU law had therefore been applicable.

1. The Court's assessment

68. As the Court pointed out in the judgment in the case of *Ullens de Schooten and Rezabek v. Belgium* (nos. 3989/07 and 38353/07, § 56, 20 September 2011), under the third paragraph of Article 234 of the Treaty establishing the European Community (former Article 177 and, since 1 December 2009, Article 267 of the Treaty on the Functioning of the European Union), when a question concerning, in particular, the interpretation of the Treaty is raised in a case pending before a national court or tribunal against whose decisions there is no judicial remedy under national law – such as, in the present case, the Court of Cassation –, that court or tribunal is required to bring the matter before the Court of Justice for a preliminary ruling. However, this obligation is not absolute. It transpires from the *Cilfit* case-law of the Court of Justice that it is for the national courts against whose decisions there is no judicial remedy under national law, like other national courts, to decide "whether a decision on a question of Community law is necessary to enable them to give judgment". The *Cilfit* judgment states in this connection that, accordingly, they are not obliged to refer a question concerning the interpretation of Community law raised before them if they establish that the question "is irrelevant", that "the Community provision in question has already been interpreted by the Court [of Justice]" or that "the correct application of Community law is so obvious as to leave no scope for any reasonable doubt" (see paragraphs 35-38 above).

69. The Convention does not guarantee, as such, any right to have a case referred by a domestic court to the CJEU for a preliminary ruling (see *Baydar v. the Netherlands*, no. 55385/14, § 39, 24 April 2018; see also *Ullens de Schooten and Rezabek*, cited above, § 57). However, Article 6 § 1 requires the domestic courts to give reasons for any decision refusing to refer a request for a preliminary ruling, especially where the applicable law allows for such a refusal only on an exceptional basis. The Court has inferred from this that when it hears a complaint alleging a violation of

Article 6 § 1 on this basis, its task consists in ensuring that the impugned refusal has been duly accompanied by such reasoning. That being said, whilst this verification has to be made thoroughly, it is not for the Court to examine any errors that might have been committed by the domestic courts in interpreting or applying the relevant law (see *Ullens de Schooten and Rezabek*, cited above, §§ 60-61, and *Dhahbi v. Italy*, no. 17120/09, § 31, 8 April 2014). On that latter point, it has also pointed out that it is primarily for the national authorities, notably the courts, to interpret and apply domestic law, if necessary in conformity with Community law, the Court's role being confined to ascertaining whether the effects of such adjudication are compatible with the Convention (see *Ullens de Schooten and Rezabek*, cited above, § 54).

70. The Court further specified in *Ullens de Schooten and Rezabek* (§ 62) that, in the specific context of the third paragraph of Article 267 of the TFEU, this means that national courts against whose decisions there is no remedy under national law, which refuse to refer to the Court of Justice a preliminary question on the interpretation of Community law that has been raised before them, are obliged to give reasons for their refusal in the light of the exceptions provided for in the case-law of the Court of Justice.

71. The Court has confirmed those principles in subsequent judgments and decisions, while pointing out that, where a superior domestic court has rejected a request with summary reasoning because it raised no fundamentally important legal issues or had no prospects of success, it can sometimes be acceptable under Article 6 of the Convention, for that court to refrain from dealing explicitly with the request for a referral submitted in that context (see, in particular, *Baydar*, cited above, §§ 42, 46 and 48). The same applies where the appeal on points of law was declared inadmissible for failing to comply with the conditions of admissibility (see *Astikos Kai Paratheristikos Oikodomikos Synetairismos Axiomatikon and Karagiorgos v. Greece* (dec.), nos. 29382/16 and 489/17, § 47, 9 May 2017). In such cases, the replies to the questions envisaged, whatever they might be, would have no impact on the outcome of the case (ibid.). The Court also accepts that, *in concreto*, the reasons for the rejection of the request for a preliminary ruling under the *Cilfit* criteria can be deduced from the reasoning of the remainder of the decision given by the court in question (see *Krikorian v. France* (dec.), no. 6459/07, §§ 97-99, 26 November 2013; *Harisch v. Germany*, no. 50053/16, §§ 37-42, 11 April 2019; and *Ogieriakhi v. Ireland* (dec.), no. 57551/17, § 62, 30 April 2019) or from reasons considered implicit in the decision rejecting the request (see *Repcevirág Szövetkezet v. Hungary*, no. 70750/14, §§ 57-58, 30 April 2019).

72. In the instant case, the requests for a preliminary ruling which the applicant company had hoped would be referred to the CJEU by the Court of Cassation, and which concerned the interpretation of Articles 4 and 6 of Directive 85/374, had been very precisely worded in accordance with the

requirements of domestic law (see paragraphs 17-18 above) (cf. *Somorjai v. Hungary*, no. 60934/13, §§ 59-60, 28 August 2018). Moreover, that fact was never in dispute between the parties.

73. Furthermore, the Court of Cassation did not declare the applicant company's appeal on points of law inadmissible or lacking arguable grounds of appeal, but rejected it. Thus the first hypothesis mentioned in paragraph 71 above is not relevant here.

74. Secondly, in reply to the applicant company's request for a preliminary ruling from the CJEU, the Court of Cassation merely stated that it had decided to reject the applicant company's appeal "without any need arising to request a preliminary ruling from the Court of Justice of the European Union" (see paragraph 21 above).

75. The Court of Cassation therefore did not explicitly refer to any of the three *Cilfit* criteria, and there is nothing to suggest that it considered that the relevant provisions of EU law had "already been interpreted" by the CJEU or that "the proper application of EU law was so obvious as to leave no scope for any reasonable doubt"; nor did the Government claim that that had been the case.

76. On the other hand, the Government would appear to consider that the phrase "without any need arising to request a preliminary ruling from the Court of Justice of the European Union" indicated that the Court of Cassation had concluded that the requests in question had been "irrelevant". They argued in that regard that no issue of interpretation of Directive 85/374 could arise because the impugned vaccine had been put into circulation before the deadline for transposition of the Directive.

77. The Court nevertheless cannot discern in the reasoning of the cassation judgment anything to suggest that that was the approach adopted by the Court of Cassation.

78. Clearly the judgment of the Court of Cassation at least comprises a reference to the preliminary rulings requested by the applicant company (in the phrase "without any need arising to request a preliminary ruling from the Court of Justice of the European Union") (contrast *Dhahbi*, cited above). Yet that judgment does not state the reasons for considering that the issues raised were not worth referring to the CJEU (ibid., §§ 32-34; see also *Schipani and Others v. Italy*, no. 38369/09, §§ 70-71, 21 July 2015, and *Baltic Master LTD. v. Lithuania*, no. 55092/16, §§ 41-43, 16 April 2019). The reasoning of the Court of Cassation's judgment therefore does not demonstrate whether those issues were examined in the light of the *Cilfit* criteria, and if so, which of those criteria the Court of Cassation had used as the basis for deciding not to transmit them to the CJEU.

79. Lastly, the Court considers that the circumstances of the present case would have required, in particular, an explicit justification of the decision not to refer to the CJEU the requests for a preliminary ruling submitted by the applicant company.

80. It observes that it transpires from the casefile that in his opinion before the Court of Cassation the Advocate-General considered whether Directive 85/374 should be taken into account, whereas, in breach of the deadline laid down in Article 19 of the Directive (which deadline had expired on 30 July 1988), it had not yet been transposed into French law at the material time (it was transposed under Law no. 98-389 of 19 May 1998). He pointed out that in 2003, in a similar case, the Court of Cassation had ruled that the applicable domestic law should be interpreted in the light of that Directive, further noting that that had been the approach adopted by the trial court in the present case. The Court also notes that on the date of delivery of the judgment in the instant case, the Court of Cassation referred similar requests for a preliminary rule to the CJEU concerning the Directive, in a case which could in some respects be compared to the present one and to which the applicant company was a party (see paragraphs 64 and 67 above). In that connection, and in view of what was at stake in the proceedings for the applicant company, it was particularly important to obtain clarification of the reason for the rejection of its request for a referral to the CJEU for a preliminary ruling.

81. There has therefore been a violation of Article 6 § 1 of the Convention.

III. ALLEGED VIOLATION OF ARTICLE 6 § 1 OF THE CONVENTION AND ARTICLE 1 OF PROTOCOL NO. 1 ON ACCOUNT OF THE APPLICANT COMPANY'S ALLEGED CONVICTION ON THE BASIS OF A DOUBLE IRREBUTTABLE PRESUMPTION

82. Relying on Article 6 § 1 of the Convention and Article 1 of Protocol No. 1, the applicant company complained that it had been "convicted" on the basis of a double presumption of a causal link between the vaccination and the pathologies affecting X, on the one hand, and the defectiveness of the vaccine, on the other; given that the presumption was irrebuttable *de facto*, it not only violated its right to a fair trial but also disproportionately infringed the right to enjoyment of property.

83. The Government submitted that the applicant company had not exhausted the available domestic remedies within the meaning of Article 35 of the Convention. They primarily argued that he had failed to put forward the complaint in question before the Court of Cassation, noting in that connection that while that court had complained, in the fifth limb of its second ground of appeal, of a reversal of the burden of proof, it had, however, not found any violation of the rights to a fair trial and to respect for property. Subsequently, with specific regard to Article 1 of Protocol No. 1, the Government noted that the decision directly affecting the property of the applicant company was not the decision subsequently leading to the

cassation judgment of 12 November 2015, which merely noted the admissibility of the action for damages and the applicant company's liability, but the judgment given by the Toulouse *tribunal de grande instance* on 17 November 2015, ordering the company to pay specific amounts of money in compensation (see paragraph 22 above). The Government pointed out that the applicant company had failed to appeal against that judgment.

84. The applicant company replied that it had raised that complaint in substance before the Court of Cassation in the framework of the fifth limb of its second ground of appeal.

85. The Court reiterated that the rule on prior exhaustion of domestic remedies laid down in Article 35 § 1 of the Convention did not require merely that applications should be made to the appropriate domestic courts and that use should be made of effective remedies designed to challenge decisions already given; it normally required also that the complaints intended to be brought subsequently before the Court should have been made to those same courts, at least in substance and in compliance with the formal requirements and time-limits laid down in domestic law (see, among many other authorities, *Gäfgen v. Germany* [GC], no. 22978/05, § 142, ECHR 2010). In the present case, the applicant company raised before the Court of Cassation the issue of the burden of proof in the framework of the fifth limb of its second ground of appeal (see paragraph 15 above). In that ground of appeal, however, the company mentioned neither Article 6 § 1 of the Convention nor Article 1 of Protocol No. 1, and it drew no conclusion as to any infringement of its right to a fair trial or its right to respect for its property. The Court deduces that it failed, even in substance, to submit any prior argument to the Court of Cassation regarding the present complaint, and that it has therefore not duly exhausted the available domestic remedies.

86. Accordingly, this part of the application is inadmissible pursuant to Article 35 §§ 1 and 4 of the Convention.

IV. APPLICATION OF ARTICLE 41 OF THE CONVENTION

87. Article 41 of the Convention provides:

> "If the Court finds that there has been a violation of the Convention or the Protocols thereto, and if the internal law of the High Contracting Party concerned allows only partial reparation to be made, the Court shall, if necessary, afford just satisfaction to the injured party."

A. Damage

88. As regards Article 41 of the Convention, the applicant company stated that a finding of a violation of the Convention would in itself

constitute suffisiante just satisfaction and that there would be no need to award it financial compensation in respect of the violations noted.

89. The Government did not comment on that point.

90. The Court took note of the statement by the applicant company. It noted that the finding of a violation of Article 6 § 1 contained in the present judgment constituted just satisfaction for any damage sustained by the applicant company.

B. Costs and expenses

91. The applicant company claimed 14,000 euros (EUR) for the costs and expenses incurred before the domestic courts and EUR 15,000 for those incurred before the Court. It provided invoices corresponding to those amounts.

92. The Government considered that the sum claimed by the applicant company was excessive and that a total of EUR 5,000 would seem reasonable.

93. According to the Court's case-law, an applicant is entitled to the reimbursement of costs and expenses only in so far as it has been shown that these were actually and necessarily incurred and are reasonable as to quantum. In the present case, regard being had to the documents in its possession and the above criteria, the Court considers it reasonable to award a sum of EUR 5,000, covering costs under all heads, and awards it to the applicant company.

C. Default interest

94. The Court considers it appropriate that the default interest rate should be based on the marginal lending rate of the European Central Bank, to which should be added three percentage points.

FOR THESE REASONS, THE COURT, UNANIMOUSLY,

1. *Declares* the application admissible as regards the complaint under Article 6 § 1 of the Convention concerning the procedure for establishing the starting point of the limitation period for lodging the action for damages against the applicant company;

2. *Declares* the application admissible as regards the complaint under Article 6 § 1 of the Convention concerning the lack of reasoning for the decision to dismiss the applicant company's request to seek a preliminary ruling from the CJEU;

3. *Declares* the remainder of the application inadmissible;

4. *Holds* that there has been no violation of Article 6 § 1 of the Convention on account of the procedure for establishing the starting point of the limitation period for lodging the action for damages against the applicant company;

5. *Holds* that there has been a violation of Article 6 § 1 of the Convention on account of the failure to provide reasons for the decision to dismiss the applicant company's request to seek a preliminary ruling from the CJEU;

6. *Holds* that the finding of a violation constitutes in itself sufficient just satisfaction for the non-pecuniary damage sustained by the applicant;

7. *Holds*
   (a) that the respondent State is to pay the applicant, within three months from the date on which the judgment becomes final in accordance with Article 44 § 2 of the Convention, EUR 5,000 (five thousand euros, plus any tax that may be chargeable to the applicant company, in respect of costs and expenses
   (b) that from the expiry of the above-mentioned three months until settlement simple interest shall be payable on the above amounts at a rate equal to the marginal lending rate of the European Central Bank during the default period plus three percentage points;

8. *Dismisses* the remainder of the claim for just satisfaction.

Done in French, and notified in writing on 13 February 2020, pursuant to Rule 77 §§ 2 and 3 of the Rules of Court.

{signature_p_2}

Claudia Westerdiek
Registrar

Síofra O'Leary
President