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

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Claim for damages against Sanofi Pasteur after multiple sclerosis appeared following vaccination against hepatitis B

In today's **Chamber** judgment[1] in the case of Sanofi Pasteur v. France (application no. 25137/16) the European Court of Human Rights held, unanimously, that there had been:

no violation of Article 6 § 1 (right to a fair hearing) of the European Convention on Human Rights on account of the method for calculating the starting point for the limitation period in respect of the compensation proceedings brought against the applicant company, and

a violation of Article 6 § 1 of the Convention, on account of the failure to provide reasons for the decision to refuse the applicant company's request that questions be referred to the Court of Justice of the European Union for a preliminary ruling.

The case concerned the liability of the Sanofi Pasteur company to an individual, a trainee nurse who was vaccinated against hepatitis B and subsequently contracted various illnesses, and the court order against the applicant company to pay damages.

With regard to the question of the limitation period for the compensation proceedings, the Court noted that the positive law at the relevant time provided for a ten-year period and, with regard to physical injury, set the starting point at the date of stabilisation: the limitation period was thus pushed back until such time as the victim's condition had stabilised. The Court held that it could not call into question the French system's choice to attach greater weight to the right of persons who had suffered physical injury to have access to a court than to the right to legal certainty of the persons responsible for those injuries.

With regard to the refusal of the request to submit preliminary questions to the Court of Justice of the European Union (CJEU), the Court found that the Court of Cassation had not given proper reasons for its decision.

Principal facts

The applicant is the Sanofi Pasteur limited company, a legal entity established under French law and based in Lyon.

In her capacity as a trainee nurse, X, who was born in 1972, had to be vaccinated against hepatitis B. In 1993 she was diagnosed with multiple sclerosis; in 1999 with Crohn's disease; and in 2004, with polymyositis.
In 2002 X filed an action for damages against the State with the administrative court, which action was allowed. The State was ordered to pay her EUR 656,803.83 in compensation for the bodily harm which she had sustained, and to pay her an annual pension of EUR 10,950.

In 2005 X brought civil proceedings against Sanofi Pasteur, seeking compensation on account of the worsening of the bodily harm for which she had been awarded damages. The action was declared

1. Under Articles 43 and 44 of the Convention, this Chamber judgment is not final. During the three-month period following its delivery, any party may request that the case be referred to the Grand Chamber of the Court. If such a request is made, a panel of five judges considers whether the case deserves further examination. In that event, the Grand Chamber will hear the case and deliver a final judgment. If the referral request is refused, the Chamber judgment will become final on that day.
Once a judgment becomes final, it is transmitted to the Committee of Ministers of the Council of Europe for supervision of its execution. Further information about the execution process can be found here: www.coe.int/t/dghl/monitoring/execution.

admissible by the Toulouse Regional Court and then the Toulouse Court of Appeal, starting the 10-year limitation period for actions on the date the condition had stabilised. Sanofi Pasteur was found liable for the harm sustained by X. Noting that the administrative court had ordered the State to pay compensation for the bodily harm, the civil court commissioned an expert assessment aimed, in particular, at ascertaining whether the victim's current condition pointed to a worsening of the harm already compensated.

The applicant company appealed on points of law. It complained that the Court of Appeal had started the limitation period on the date the condition had stabilised, whereas X's pathology could not in fact stabilise, which meant that her action was not subject to statutory limitation. The applicant company, in the alternative, invited the Court of Cassation to transmit requests for a preliminary ruling to the Court of Justice of the European Union. The first two questions proposed concerned Article 4 of Directive 85/374, which lays down that the victim must prove the damage, the defect and the causal relationship between defect and damage.

The first civil division of the Court of Cassation dismissed the appeals on points of law.

On 17 November 2015, in the light of the expert assessment, the Toulouse Regional Court ordered the applicant company to pay X the following amounts: EUR 8,050 in respect of the permanent functional deficiency, EUR 1,500 in respect of the suffering endured and the disfigurement, an annual pension of EUR 5,475 for the assistance of a third person, and EUR 2,000 in respect of procedural costs.

Complaints, procedure and composition of the Court

Relying, in particular, on Article 6 § 1 (right to a fair trial), the applicant company alleged that the fact of starting the limitation period for X's action on the date her condition had stabilised meant that her action was not subject to statutory limitation, given that the pathology underlying her condition could not stabilise. The applicant company also complained about the fact that the Court of Cassation had dismissed its request for preliminary rulings from the CJEU, without providing reasons. Finally, relying on Article 6 § 1 and Article 1 of Protocol No. 1, the applicant company complained that the finding against it had been based on the dual presumption of a causal link between the vaccination and X's illnesses and of the defectiveness of the vaccine.

The application was lodged with the European Court of Human Rights on 28 April 2016.

Judgment was given by a Chamber of seven judges, composed as follows:

Síofra **O'Leary** (Ireland), *President*,
Gabriele **Kucsko-Stadlmayer** (Austria),
Ganna **Yudkivska** (Ukraine),
André **Potocki** (France),
Yonko **Grozev** (Bulgaria),
Lətif **Hüseynov** (Azerbaijan),
Anja **Seibert-Fohr** (Germany),

and also Claudia **Westerdiek**, *Section Registrar.*

Decision of the Court

Article 6 § 1

As regards the calculation of the starting point of the limitation period:

The Court noted that at the relevant time the limitation period for civil proceedings for non-contractual damage was ten years. The Court of Cassation had specified that, where the action was intended to obtain compensation for physical injury, this time period began to run from the date on which the illness had stabilised ("consolidation").

As the Government had pointed out, by fixing the starting point as the date on which the illness had stabilised, the law sought to enable a victim to secure full compensation for the damage, the extent of which could only be ascertained once his or her condition had stabilised. It followed that the choice made in the French legal system had been to attach greater weight to the right of persons who had suffered physical injury to have access to a court than to the right to legal certainty of the persons responsible for this injury.

In that connection, the Court reiterated the importance attached by the Convention to the protection of physical integrity and noted that this method of calculation made it possible to take account of the fact that the needs of individuals suffering from a progressive illness such as multiple sclerosis could increase as their condition developed, for example in terms of the assistance required.

Noting also that there had not been, strictly speaking, statutory limitation, the Court concluded that there had been no violation of Article 6 § 1 on account of the method of calculating the starting point of the limitation period for bringing the compensation proceedings against the applicant company.

As regards the failure to provide reasons for the decision to dismiss the request for questions to be referred to the CJEU for a preliminary ruling:

When a question concerning, in particular, the interpretation of the Treaty on the Functioning of the European Union or acts taken by the EU institutions was raised in a case pending before a national court or tribunal against whose decisions there was no judicial remedy under national law – such as the Court of Cassation –, that court or tribunal was required to bring the matter before the CJEU for a preliminary ruling.

However, this obligation was not absolute. The CJEU's *Cilfit* case-law showed that it was for these national courts to decide whether a decision on a question of EU law was necessary to enable them to give judgment; accordingly, they were not obliged to refer a question concerning the interpretation of EU law raised before them if they established that the question was irrelevant, that the EU provision in question had already been interpreted by the CJEU or that the correct application of EU law was so obvious as to leave no scope for any reasonable doubt.

The Court reiterated that the Convention did not guarantee, as such, any right to have a case referred by a domestic court to the CJEU for a preliminary ruling. However, Article 6 § 1 required the domestic courts to give reasons for any decision refusing to refer a question for a preliminary ruling, especially where the applicable law allowed for such a refusal only on an exceptional basis.

In Ullens de Schooten and Rezabek, the Court had stated that the national courts against whose decisions there was no judicial remedy under national law, and which refused to request a preliminary ruling from the CJEU on a question raised before them concerning the interpretation of European Union law, were required to give reasons for such a refusal in the light of the exceptions provided for by the case-law of the CJEU.

In the present case, the Court of Cassation had merely stated that it was dismissing the applicant company's request "and that there [was] no need to refer questions to the Court of Justice of the European Union for a preliminary ruling". The Court of Cassation had thus not expressly referred to one of the three *Cilfit* criteria. In addition, nothing indicated that it had found that the relevant provisions of EU law "had already been interpreted by the CJEU" or that "the correct application of EU law was so obvious as to leave no scope for any reasonable doubt". Furthermore, the Court was

unable to find in the grounds of the Court of Cassation's judgment any possible indication that, as the Government submitted, it had considered that the proposed questions were "irrelevant".

It was therefore not clear from the reasoning in the Court of Cassation's judgment whether those grounds had been examined under the *Cilfit* criteria and, accordingly, on the basis of which criteria the Court of Cassation had decided not to refer the questions to the CJEU.

Further emphasising that the circumstances of the case and what was at stake in the proceedings for the applicant company had required a particularly clear explanation for the decision not to refer that company's questions to the CJEU for a preliminary ruling, the Court held that there had been a violation of Article 6 § 1 of the Convention.

Article 6 § 1 and Article 1 of Protocol No. 1

The Court noted that the applicant company had not raised this complaint before the Court of Cassation and that it had thus failed to exhaust domestic remedies. This part of the application was therefore inadmissible.

Just satisfaction (Article 41)

The Court held that France was to pay the applicant company 5,000 euros (EUR) in respect of costs and expenses.

The judgment is available only in French.

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