



Where there is a lack of scientific consensus, the proof of the defect of the vaccine and of a causal link between the defect and the damage suffered may be made out by serious, specific and consistent evidence

The temporal proximity between the administering of a vaccine and the occurrence of a disease, the lack of personal and familial history of the person vaccinated and the existence of a significant number of reported cases of the disease occurring following such vaccines being administered may, where applicable, constitute sufficient evidence to make out such proof

Between the end of 1998 and the middle of 1999 Mr J. W was vaccinated against hepatitis B using a vaccine produced by Sanofi Pasteur. In August 1999, Mr W began to present with various troubles, which led to a diagnosis of multiple sclerosis in November 2000. Mr W died in 2011. Earlier, in 2006, he and his family had brought legal proceedings against Sanofi Pasteur to obtain compensation for the damage they claim Mr W suffered due to the vaccine.

The case was sent before the cour d'appel de Paris (Court of Appeal, Paris, France), which observed, inter alia, that there was no scientific consensus supporting a causal relationship between the vaccination against hepatitis B and the occurrence of multiple sclerosis. It held that no such causal link had been demonstrated and dismissed the action.

The French Cour de cassation (Court of Cassation), before which an appeal against the judgment of the Cour d'appel de Paris was brought, asks the Court of Justice whether, despite there being no scientific consensus and given that, under the EU directive on liability for defective products,¹ the injured person is required to prove the damage, the defect and the causal relationship, the court may base itself on serious, specific and consistent evidence enabling it to conclude that there is a causal link between the defect in a vaccine and that there is a causal link between the vaccine and the disease. Reference has been made in particular to Mr W's previous excellent state of health, the lack of family antecedents and the close temporal connection between the vaccination and the appearance of the disease.

In today's judgment, the Court holds that evidentiary rules allowing the court, where there is not certain and irrefutable evidence, to conclude that there is a defect in a vaccine and a causal link between the defect and a disease on the basis of a set of evidence the seriousness, specificity and consistency of which allows it to consider, with a sufficiently high degree of probability, that such a conclusion corresponds to the reality of the situation, are compatible with the Directive. Such evidentiary rules do not bring about a reversal of the burden of proof which it is for the victim to discharge, since that system places the burden on the victim to prove the various elements of his case which, taken together, will provide the court hearing the case with a basis for its conclusion as to the existence of a defect in the vaccine and a causal link between that defect and the damage suffered.

Moreover, excluding any method of proof other than certain proof based on medical research, could make it excessively difficult in many situations or, where it is common ground that medical research neither confirms nor rules out the existence of a causal link, impossible to establish

¹ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1985, L 210, p. 29).

producer liability, thereby undermining the effectiveness of the Directive and its objectives, which are to protect consumer health and safety and ensure a fair apportionment between the injured person and the producer of the risks inherent in modern technological production.

The Court nevertheless adds that national courts must ensure that the evidence adduced is sufficiently serious, specific and consistent to warrant the conclusion that, having regard also to the evidence produced and the arguments put forward by the producer, a defect in the product appears to be the most plausible explanation for the occurrence of the damage. National courts must also safeguard their own freedom of assessment in determining whether such proof has been made out to the requisite legal standard, until such time as they consider themselves in a position to draw a definitive conclusion on the matter.

In the present case, the Court considers that the temporal proximity between the administering of a vaccine and the occurrence of a disease, the lack of personal and familial history of that disease, together with the existence of a significant number of reported cases of the disease occurring following such vaccines being administered, appears on the face of it to constitute evidence which, taken together, may lead a national court to consider that a victim has discharged his burden of proof. That could be the case *inter alia* where that evidence leads the court to consider, first, that the administering of the vaccine is the most plausible explanation for the occurrence of the disease and, second, that the vaccine therefore does not offer the safety that one is entitled to expect.

The Court adds that it is not possible for the national legislature or the national courts to introduce a method of proof under which the existence of a causal link between the defect attributed to a vaccine and the damage suffered by the victim will automatically be established when certain predetermined causation-related factual evidence is presented, as that would have the consequence of the burden of proof provided for in the Directive being undermined.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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