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OPINION OF ADVOCATE GENERAL
Bobek
delivered on 7 March 2017 (1)
Case C-621/15
W
X
Y
v
Sanofi Pasteur MSD SNC

Caisse primaire d'assurance maladie des Hauts-de-Seine
-
Caisse Carpimko
(Request for a preliminary ruling from the Cour de cassation (Court of Cassation, France))
(Liability for defective products — Pharmaceutical laboratories — Vaccination against hepatitis B — Victim of multiple sclerosis — Burden of proof — Proof of damage by fault of vaccination and causal link between fault and damage resting on the claimant — Method of proof — System of presumptions — Lack of scientific consensus — Causal link)

I – Introduction

1. In 1998 and 1999, M. W. was vaccinated against hepatitis B. Shortly thereafter, he developed symptoms of multiple sclerosis. His condition deteriorated over the following years. He died in 2011.

2. Members of M. W.'s family ('the Ws' or 'the Appellants') brought an action for damages against Sanofi Pasteur MSD SNC, the manufacturer of the vaccine and one of three defendants in this case ('Sanofi' or 'the first Respondent'). The Appellants claimed that the deceased's multiple sclerosis had been caused by the vaccine. Their claim was rejected, however, for failure to prove a causal link between a defect in the vaccine and the harm suffered by M. W. In order to establish that link, the Appellants had relied on a rule under French law, according to which a causal link may be presumed if a disease manifests itself shortly after administration of the allegedly defective drug and there are no personal or family antecedents related to the disease.

3. The Appellants eventually brought the case before the Cour de cassation (Court of Cassation, France), which now asks this Court about the interpretation of the EU Product Liability Directive ('the Directive'). (2) Specifically, the referring court enquires whether: (i) the presumptions described above are compatible with that directive; (ii) systematic application of those presumptions is compatible with the Directive; and (iii) whether, if such presumptions are incompatible with the Directive, scientific evidence of a causal link must be adduced by the claimant.

II – Legal framework

A – *EU law*

1. Directive 85/374

4. The Directive harmonises certain rules relating to product liability through, among others, the following provisions:

'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.

…
Article 7
The producer shall not be liable as a result of this Directive if he proves:
…
(e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; …'

B – *French law*

5. At the material time, Article 1386-1 (now Article 1245-8) of the French Civil Code provided that the producer is liable for damage caused by its defective products, whether or not it has a contractual link with the victim. Article 1386-9 provides that the claimant must prove the damage, defect and causal link between defect and damage.

6. Furthermore, case-law from the Cour de cassation (Court of Cassation) holds that in relation to extra-contractual liability of pharmaceutical laboratories resulting from vaccinations produced by them, proof of a causal relationship between the defect in the product and the damage suffered by the person injured can be derived from 'serious, specific and consistent presumptions'. (3)

7. The Cour de cassation's (Court of Cassation's) case-law holds that a judge may find that the short period between the injection of the hepatitis B vaccine and the appearance of the first symptoms of multiple sclerosis, in conjunction with the lack of any personal or family antecedents of that disease, constitute such serious, specific and consistent presumptions. That can be the case even if medical research does not, in general, confirm the existence of such a link. (4)

III – **Facts, procedure and questions referred**

8. Between December 1998 and July 1999, M. W. received three injections of a hepatitis B vaccine, produced by Sanofi. In August 1999, M. W. began to present various conditions. In November 2000, he was diagnosed with multiple sclerosis. M. W.'s condition progressively worsened. He suffered from a functional disability of 90% and required round-the-clock care by the time of his death on 30 October 2011.

9. In 2006 M. W. and his wife and two daughters brought an action for extra-contractual liability against Sanofi for harm caused to him by the vaccines. They argued that the short period between the injection of the vaccine and the appearance of the first symptoms of multiple sclerosis, in conjunction with the lack of any personal or family antecedents of that disease, gave rise to serious, specific and consistent presumptions of a defect in the vaccine, and a causal link between that defect and M. W.'s illness.

10. The action was upheld at first instance by the Tribunal de Grande Instance de Nanterre (Regional Court, Nanterre, France). However it was then overturned on appeal by the Cour d'appel de Versailles (Court of Appeal, Versailles, France). The latter held that the elements invoked by the Ws led to a presumption of a causal link but were insufficient to establish a defect in the vaccine. The Cour de cassation (Court of Cassation) quashed the Court d'appel de Versailles's (Court of Appeal, Versailles's) judgment, holding that the latter had not given a legal basis for its decision in relation to the absence of defect of the vaccines.

11. The case was sent before the Cour d'appel de Paris (Court of Appeal, Paris, France), which again overturned the first instance judgment of the Tribunal de Grande Instance de Nanterre (Regional Court, Nanterre). The Cour d'appel de Paris (Court of Appeal, Paris) held that the short period between the injection of the vaccine and the appearance of the first symptoms of multiple sclerosis, in conjunction with the lack of any personal or family antecedents of that disease, could not give rise to serious, specific and consistent presumptions of a causal link between the vaccine and M. W.'s illness.

12. In that regard, the Cour d'appel de Paris (Court of Appeal, Paris) noted that there was no scientific consensus to support a causal relationship between the vaccination against hepatitis B and multiple sclerosis. National and international health authorities rejected the association between a likelihood of being affected by central or peripheral demyelinating disease (characteristic of multiple sclerosis) and the vaccination against hepatitis B. The Cour d'appel de Paris (Court of Appeal, Paris) also noted that the cause of multiple sclerosis was unknown. Finally, it referred to epidemiological studies showing that 92% to 95% of persons with multiple sclerosis had no antecedent in their family.

13. The judgment of the Cour d'appel de Paris (Court of Appeal, Paris) was again brought before the Cour de cassation (Court of Cassation), which decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'Question 1:

Must Article 4 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products be interpreted as precluding, in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method of proof by which the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease, notwithstanding the finding that medical research does not establish a relationship between the vaccine and the occurrence of the disease?

Question 2:

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

Question 3:

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

14. Written observations have been submitted by the Appellants and the first Respondent, as well as the Czech, German, and French Governments and the European Commission. The interested parties participating in the written stage, with the exception of the German Government, also presented oral argument at the hearing on 23 November 2016.

IV – **Assessment**

A – *Introduction*

15. Article 4 of the Directive provides that in product liability cases the injured person bears the burden of proving the damage, the defect and the causal relationship between defect and damage. This case is about what requirements and conditions EU law imposes on the way in which that burden can be discharged.

16. I note at the outset that the standard of proof and what evidence is sufficient to meet that standard are not harmonised by the Directive. In principle, those are therefore questions for national law to resolve, subject in particular to the conditions of equivalence and effectiveness. It is not this Court's role to deduce detailed rules of proof and evidence from those general principles, or indeed from a directive that sets down only basic rules for establishing liability, in relation to potentially millions of different products.

17. However, EU law does impose some limits in respect of proof and evidence, which I will develop further below, with a view to assisting the national court in their resolution of the case.

18. Before looking at the referring court's questions in more detail (D), I will begin with some general observations on the requirements of the Directive on proof and evidence (B) and a note on terminology (C).

B – *Requirements of the Directive as regards proof and evidence*

19. The Directive imposes on the injured party the burden of proving defect, damage and the causal link between those two. (5) The procedural consequence of this rule is clear: if the injured party fails to discharge that burden, its claim must be dismissed. (6)

20. However, as already stated by this Court, the Directive does not seek exhaustively to harmonise the sphere of liability for defective products beyond the matters regulated by it. (7) In particular, the Directive does not harmonise rules of proof and evidence to determine how the injured party can discharge its burden of proof. (8) With regard to the present case, the Directive does not provide a specific list of evidence an injured party must present to the national court. Nor does the Directive specify the admissibility of, or weight to be given to, evidence presented, or conclusions that can or must be drawn from it. (9)

21. It is therefore for the national legal order of each Member State, in accordance with the principle of procedural autonomy, to establish detailed rules of proof and evidence for practical implementation of the Directive. (10)

22. Moreover, given the very different nature of the products covered by the Directive, the type of damage they could cause and the way that damage might be caused, it is to be expected that those detailed rules may not be identical in all cases. Thus, in my opinion, within the confines of Article 4 of the Directive, Member States ought to be entitled to reasonably differentiate and adapt applicable evidentiary rules depending on the type(s) of products in question.

23. It has, furthermore, been acknowledged by this Court that, when laying down rules of proof and evidence, Member States may seek to redress imbalances between the consumer and the producer, which might for example result from asymmetry of information. (11) That possibility also reflects the broader EU law requirements of access to justice as well as consumer protection. (12) In connection with the previous point, it is clear that such an information asymmetry might be particularly acute in areas such as the liability of pharmaceutical companies.

24. However, in laying down rules of proof and evidence applying to cases falling within the scope of the Directive, the procedural autonomy of Member States is not unlimited. The combined effect of national rules of proof and evidence must respect the principles of equivalence and effectiveness. (13) Put differently, the national transposition of the provisions of the Directive in general and its Article 4 specifically must remain within the bounds of those provisions, while ensuring their effective implementation into the national legal system.

25. In particular, national rules of proof and evidence that unduly hamper the national court's ability to assess relevant evidence, (14) or that are not sufficiently rigorous so that they in practice result in a reversal of the burden of proof, would not be consistent with the principle of effectiveness. (15)

26. Whether the national rules of proof and evidence applied in the implementation of the Directive respect that principle is the main substantive question at the heart of this case.

27. Before making any general observations on the foregoing, I will first make some preliminary remarks on terminology and especially the concept of 'presumption'.

C – *Presumption*

28. The precise meaning of the term 'présomption' (in the original French), which is central to this case, gave rise to considerable debate at the oral hearing. It became apparent that at first glance identically sounding (or at least translated) notions are understood, and in fact operate, rather differently in the various national legal systems. As is often the case in a multilingual and multicultural EU legal system, a notion that apparently has the same name can have different meanings. (16)

29. Thus, under French law, I understand that 'présomption' can be defined as a method of legal reasoning whereby one fact that is not proven is inferred from another fact that has been proven. A presumption is said to be 'factual' when the judge is free to adopt such reasoning by induction in a specific case. A presumption is called 'legal',

that is, generally applicable, when the legislature infers one fact that is not proven from another fact that has been proven. A legal presumption is 'simple' when it can be rebutted by proof of the contrary. When it cannot be rebutted, it is said to be 'irrebuttable' or 'absolute'. (17)

30. A somewhat different, albeit similar approach exists under German law. (18) In contrast, the following passage on use of that notion in English law points to clear limits of a transliteration of the French term 'présomption' into the English 'presumption': 'In certain situations the court may draw inferences from the facts proved by a party. … these are no more than commonly recurring examples of circumstantial evidence. It is therefore a misconception to treat them as presumptions in the strict sense since at no time do they transfer the burden of proof to the person against whom the evidence is tendered … they are often, wrongly it is submitted referred to as "presumptions"'. (19)

31. The referring court uses the term 'présomption' in its request for a reference. That term has been translated in that way into the other language versions of the questions referred and published in the Official Journal, with the parties and interveners presenting their submissions to the Court using that term. Therefore, in order not to cause further terminological confusion at this stage, I will stick to that term. However, for the sake of clarity, I set out below how I use that concept. That corresponds to my understanding of the operation of that notion under French law, as helpfully outlined by the parties at the oral hearing.

32. Thus, in this Opinion, I will use the term 'presumption' to refer to a situation where a fact or set of facts (A) is established, and from it is inferred the likelihood of occurrence of another fact or set of facts (B). In terms of its practical operation, 'presumption' is used here to refer essentially to a form of *circumstantial evidence* or *indirect proof*.

33. 'Presumptions' in the sense of circumstantial evidence as described above are a rather common phenomenon. They tend to reflect past experience of how events are normally likely to unfold, transformed into rules of thumb in order to ease and speed up the judicial process. In a way, they can be seen simply as a label to describe part of the process of convincing a judge which litigant should carry the day. The claimant presents the judge with some evidence of facts, from which the judge infers certain conclusions about the likelihood of other, related facts. At this stage, the claimant's case looks stronger. The defendant counters with further, solid evidence, tipping the scales back in their favour. (20) In response the claimant must come up with something more compelling or risk losing the case. (21)

34. For the purposes of my later analysis and again drawing inspiration from French law, I make a distinction here between 'legal' and 'factual' presumptions. I will use the term 'legal presumption' to refer to a presumption that a judge is *legally obliged to follow*. In other words, to use the example above, the judge *must* infer fact B from fact A, and in that sense his free assessment of evidence is to some extent inhibited. By contrast, I use 'factual presumption' here to refer to a situation where the *possibility* exists, in our example, for the judge to infer B from A, but only as part of her free assessment of evidence.

35. A second distinction important to this analysis is between rebuttable and irrebuttable presumptions. Going back to the example above, I consider a presumption to be *irrebuttable* if it is not possible for the other party to refute it, irrespective of what evidence that other party presents to the court. By contrast, a presumption is rebuttable if that other party can present further evidence that leads the judge to conclude in the overall assessment that the presumption cannot be sustained.

36. With these terminological clarifications in mind, I now turn to the national court's specific questions.

D – *National court's questions*

37. Does Article 4 of the Directive preclude a method whereby certain facts can give rise to a factual presumption that a vaccine is defective and caused a disease, even if medical research does not establish, on the general level, a causal relationship between the vaccine and the disease? Does the answer to that question change if the presumption is legal as opposed to factual? Must the causal link between vaccine and disease be established using scientific evidence? Those are in substance the national court's three questions.

38. To use the terminology developed above (under C), I understand the first question to be referring to a 'rebuttable factual presumption'. Thus, the judge examining the case has no obligation to apply the presumption and, even if she chooses to do so, it merely forms part of her global assessment of the facts. The defendant is therefore free to present further evidence to rebut the presumption. Such evidence can be in the form of elements directly contradicting the factual basis of the presumption, or any other elements that convince the judge that the case should be rejected. (22)

39. In my view, the Directive does not in principle preclude such factual presumptions. Nor does it require that specific weight be given to medical research or scientific research more generally.

40. As explained above in point 20, Article 4 of the Directive regulates burden of proof but not rules of evidence or method or standard of proof. In particular, it generally does not dictate the weight to be given to specific pieces of evidence or regulate use of presumptions.

41. I consider it helpful here to separate three aspects of the first question for the purposes of analysis, namely: (1) the role of medical research; (2) the use of presumptions; and (3) proof of causation versus proof of defect.

1. Medical research

42. The Directive requires the establishment of a causal relationship between defect and damage. However, it does not require that the causal relationship be established by any kind of specific evidence, medical or otherwise. Nor does the Directive dictate that absence of medical research establishing a causal relationship is conclusive proof of absence of defect or causal relationship. That is unsurprising given the very general nature of the Directive which applies to product liability in a vast number of sectors, (23) in relation to many of which medical research will simply be irrelevant.

43. Still, some general comments can be made about requirements for claimants to present evidence specifically in the form of medical research, and the role of such evidence. Under (a) below, I will consider whether medical research can be required as *a condition for a claim to succeed*. Under (b) I will consider whether medical research can be required in order for a *factual presumption to be triggered*.

a) Medical research as a condition for a claim to succeed

44. A requirement that, for the purposes of satisfying Article 4 of the Directive, a causal relationship be established specifically on the basis of medical research would, in my view, be incompatible with that provision and the principle of effectiveness for the following reasons.

45. First, such a specific evidential requirement could make it practically impossible to establish liability in cases where medical research is lacking *irrespective of the nature or quality of other evidence.* In such cases, the Directive would be denied effect and the national court's freedom to assess evidence unduly inhibited.

46. Second, judicial assessment of causation *in a specific situation* must be distinguished from scientific assessment of (potential) causation *as a general matter*. The latter may be relevant to the former and vice versa, but the two should not be confused. (24) Article 4 of the Directive imposes on the claimant the burden of proving that the substance administered to them caused the harm they suffered in its *individual* case. It does not require them to show that *general* medical research has established the potential harmfulness of the substance more generally. As a result, systematically imposing such an additional requirement would go far beyond Article 4 of the Directive. (25)

47. Third, providing that a producer should not be held liable in the absence of medical research establishing a causal link would also constitute a violation of Article 4 of the Directive by effectively extending the list of exceptions to liability listed in Article 7 of the Directive. Article 7(e) explicitly and specifically envisages that liability may be excluded where it is demonstrated that, at the time the product was placed on the market, it was not possible scientifically to establish the existence of a defect. (26) Had the legislature wished to insert further examples of situations where (absence of) medical research *must* exclude liability, it would have done so.

48. For those reasons, I consider that making the absence of general medical research systematic and conclusive grounds for rejecting the claimant's arguments would be problematic under the Directive and the principle of effectiveness.

49. That obviously does not mean that medical research is irrelevant in contexts like the present one. Quite on the contrary. As noted above, even if medical research establishes that a product presents a potential concern as a *general* matter, that is not the same as establishing that it caused harm in an *individual* case.

50. However, from an evidential point of view, it would be wrong to ignore that research. Thus, systematically dismissing evidence in the form of medical research as irrelevant would be just as problematic, in the light of the Directive and the principle of effectiveness, as systematically dismissing other types of evidence where medical research is lacking. Evidence submitted in the form of medical research must be given due consideration.

51. By way of conclusion on this point, the above observations reflect what I consider can be seen as a general, default rule that flows from the principle of effectiveness, namely the free assessment of evidence by national judges in the application of EU law. (27) As discussed further below, that does not in itself prevent national law from attributing particular weight to specific pieces of evidence or attaching presumptions to them. However, it does imply that, in implementing Article 4 of the Directive, national rules of evidence would create a serious risk of conflict with the principle of effectiveness where they either (i) explicitly prohibit judges from taking potentially relevant evidence into account (28) or (ii) identify specific pieces of evidence as systematically constituting conclusive and irrebuttable evidence of a given fact. (29)

b) Medical research as a condition for triggering a presumption

52. In its first question, the referring court does not state explicitly that, absent any medical research, the claim would automatically fail. Rather, the question seems to imply that, if there is no medical research, the claim could still succeed but factual presumptions could not be used to that end. (30)

53. As with other detailed rules of proof and evidence, the Directive does not regulate the choice of whether or not to have recourse to factual presumptions and under what conditions. It is therefore generally a question for national law, subject to the principles of equivalence and effectiveness. *A fortiori* the refusal to trigger such a presumption where a specific evidential element is missing, such as medical research, is also a question for national law.

54. EU law is generally more concerned with unjustified *application* of presumptions that might result in a reversal of the burden of proof or otherwise compromise the principle of effectiveness, in particular because such application is based on irrelevant or insufficient evidence. (31) However, what is being discussed here is specifically a *refusal to apply* presumptions existing under national law where certain conditions are not met (absence of medical research).

55. Can such conditions conflict with the principle of effectiveness? At least in theory, yes. The Court has held, for example, in the field of competition law, that given the difficulties of proving collusion with direct evidence, it must be possible to do so with indirect evidence (that is, using 'factual presumptions', as defined above (32)). It is for the referring court to determine whether, in the circumstances of the present case, the exclusion of presumptions would make it impossible or excessively difficult for claimants to prove causation or defect, due to the absence of direct evidence, and thus potentially conflict with the principle of effectiveness.

56. I will not second guess that evaluation by the referring court. That being said, going beyond the precise wording of the question, my understanding of the case more broadly is not so much that there is a proposal to exclude *any* use of presumptions in the absence of medical research. Instead, what the referring court is trying to establish is whether the exclusion of a particular factual presumption (33) is warranted. In that sense, the practical issue the referring court wants to get to the bottom of is the sufficiency of the evidence underlying a specific presumption regularly used in this type of case.

57. I turn to that question now.

2. Presumptions

58. In accordance with the general approach to rules of proof and evidence set out above at (B), it is for the national court applying Article 4 of the Directive to conclude on the compatibility with the principles of equivalence and effectiveness of specific presumptions under national law.

59. However, on the assumption that the rule at issue is a 'rebuttable factual presumption', (34) I set out below some general guidance that may perhaps assist the national court in making its assessment.

60. As the Court has previously held, national rules of evidence may lack sufficient rigour, with the result that they would in practice reverse the burden of proof, and conflict with the principle of effectiveness. (35) Such a reversal of the burden of proof would in this case also result in a violation of Article 4 of the Directive. I understand that is indeed the main contention of the first Respondent in this case.

61. Under what circumstances might a presumption 'lack sufficient rigour'?

62. I see three scenarios where that might be the case: (a) no evidence is required and there is simply a presumption that the claimant has established its case; (b) the evidence on which the presumptions are based is irrelevant; or (c) the evidence is relevant but simply 'weak'.

a) Absence of any evidential basis for the presumption

63. As regards (a), the absence of the need for the claimant to present *any* evidence before its claim is considered as established would amount to a reversal of the burden of proof, in conflict with Article 4 of the Directive and the principle of effectiveness. (36) I understand that in the main case, the claimant is required to present certain evidence before the presumption is triggered and this scenario is therefore not discussed further here.

b) Presumption based on irrelevant evidence

64. As regards (b), by irrelevant I mean that there is no rational or logical link between the evidence presented and the inference drawn. For example, in the present case, it would, in my view, be problematic to take the first Respondent's turnover or number of employees as evidence that the products at issue are defective. Those two facts are simply, certainly at the first sight, unrelated.

65. Accepting inferences to be drawn from, and presumptions based on, irrelevant evidence alone would be tantamount to absolving the claimant from the need to present any evidence at all. As already set out above, that would result in a reversal of the burden of proof.

66. In its written pleadings, the first Respondent argues that there is no logical link between the evidence presented and the inferences being drawn. In that regard, it contends in particular that, given the uncertainty surrounding the cause of multiple sclerosis, the temporal proximity of vaccination and the onset of the disease is inconclusive. Indeed, such a temporal link might even *exclude* causation, if it were established that the disease had a long enough incubation period.

67. Whatever one's views on *post hoc ergo propter hoc* reasoning, the absolute irrelevance of the temporal link as argued by the first Respondent is not, in my opinion, of such blinding obviousness as the examples of turnover and number of employees proposed above.

68. However, I do not consider that it is this Court's role either to rule on whether the temporal link — or other evidential elements of the presumption under discussion — are pertinent or not, or engage in detailed discussion on the topic. There are at least two very compelling reasons why that is the case.

69. First, as mentioned above, the national court has couched its question in general terms, without including the various conditions of application of the presumption. Indeed, although discussed to some extent in the observations of the parties, the precise content of those conditions remains unclear. (37)

70. Second, giving detailed comment here would come perilously close to attributing specific weight to individual pieces of evidence in particular types of product liability cases. Such pronouncements would, in my view, be incompatible with the nature of the preliminary reference procedure, the notion of national procedural autonomy and the freedom of assessment of evidence by national courts.

c) Relevant but 'weak' evidence

71. As regards (c), as it is not this Court's role to give detailed pronouncements on the pertinence of individual pieces of evidence, a fortiori it is not this Court's role to state whether, taken together, pieces of relevant evidence justify a particular presumption. Indeed, the question of whether or not a presumption is justified may be an even more subjective one than that of relevancy. Two examples drawn from the field of EU competition law help illustrate this point. (38)

72. First, in defending its decisions against actions for annulment, the European Commission can rely on a rebuttable (39) factual (40) presumption that a parent company has exercised control over its wholly owned subsidiary and — on that basis be held liable for — a breach of EU competition law by that subsidiary. (41) No evidence of actual participation is required. The 100% shareholding is enough. That presumption has been questioned on many occasions. One concern is that a 100% shareholding is simply an insufficient basis for the presumption. (42) In other words, the presumption could be said to lack evidential rigour. It would be wrong to pretend that those arguments as to lack of evidential rigour do not exist or are somehow far-fetched. (43) However, the Court has clearly and iteratively endorsed the presumption. (44)

73. Second, in cartel cases, the Commission must prove the existence of an agreement or concerted practice. Often this must be done using circumstantial evidence (namely presumptions within the meaning used here). The sufficiency of that evidence is generally assessed on a case-by-case basis. However, on many occasions, the Court has repeated that parallel conduct of undertakings *alone* is insufficient evidence to justify a presumption of collusion. In other words, the Court has introduced a legal rule making it clear that such evidence on its own is simply too weak. (45)

74. Granted, the above examples are drawn from a very different substantive legal field, but it is one where the case-law on evidential rigour and presumptions is particularly abundant. As such, I consider that they help illustrate, in the EU law context, the delicate and ultimately rather subjective and often very case-dependent nature of any definitive statement on the adequacy of specific pieces of evidence, or general rules as to the weight of such evidence and presumptions attaching to it.

75. In conclusion, before having recourse to a particular factual presumption, the national court must be convinced that it is based on relevant evidence and is sufficiently rigorous as to comply with the principle of effectiveness, and not to amount in practice to a reversal of the burden of proof contrary to Article 4 of the Directive.

3. Defect and causation

76. In its first question, the national court specifies that the presumption applies *both* to the causal link and the defect. To be clear, the reasoning set out above in relation to the general possibility for national law to provide for factual presumptions and the limits imposed by EU law on that faculty apply equally to presumptions relating to defect and causal link.

77. I would nonetheless add three further observations.

78. First, I understand that the elements of fact providing a basis for the presumption of defect and causation are the same. I consider that such an approach is not in itself contrary to Article 4 of the Directive or the principle of effectiveness. In accordance with the reasoning set out above, EU law does not prescribe specific evidential requirements in relation to defect and causal link or specify that the evidential basis for defect and causal link must be different.

79. Second, in its pleadings, the first Respondent states that the defect is inferred from the causal link.

80. That is not the way in which the referring court phrases its question. The first question rather implies that the same facts form the basis for both elements — causal link and defect. As set out above, whether those facts are relevant and form a sufficient basis for the conclusion that each of those elements is established is a question for the referring court.

81. What if the first Respondent were correct and technically what is happening under national law is that the defect is being inferred from the causal link?

82. I do not consider that approach by inference as problematic in itself. In practice, the evidence being used to establish causal link is serving indirectly to establish defect. That approach to evidence is analogous to a presumption as defined above. The inference of defect (which is difficult to prove directly due in this case to the 'destruction' of the product though use (46)) comes from more indirect evidence. (47) Similar to the case of presumptions, the issue of substance under EU law is again whether the inference is based on relevant and sufficient evidence.

83. Third, as in the case of presumptions of causal link, generally any detailed assessment of the relevancy and sufficiency of specific pieces of evidence as the basis for inferences of defect is a matter for the national court.

84. However, there is one aspect of proof of defect that must be considered here, because it relates to the very definition of 'defect'.

85. Under Article 6 of the Directive, a product is defective when it 'does not provide the safety which a person is entitled to expect, taking all circumstances into account'. The first Respondent argues in particular on that basis that the elements establishing causal link between product and damage in an individual case cannot alone suffice to establish defectiveness. A broader assessment of the cost/benefits of the product is required, going beyond the concrete case.

86. I disagree.

87. The Directive does not explicitly state that the notion of defect requires, beyond the *specific* case under examination, that the product is more *generally* harmful or potentially harmful, or engage in a broader analysis of costs and benefits of the product to society. It is true that the Article 6 definition of defect and the related recital are couched in non-specific terms (the safety that 'a person' or 'the public at large' is entitled to expect). However, in my view that language is at most ambiguous. My understanding is rather that it essentially refers to baseline expectations of the product under normal conditions of use. It does not mean that where the product is used normally and causes serious harm in an individual case, that a conclusion of defectiveness necessarily requires a balancing of the costs and benefits of the product.

88. In parallel to what was already stated above with regard to the relationship between general medical research and the individual case, (48) imposing such a requirement with regard to defect would in my opinion amount to creating (or at least boldly deducing) new conditions of liability.

89. Nor can the first Respondent rely on the judgment in *Boston Scientific*, which it cites to support its thesis. (49) In that case, specific medical devices in a production batch were found to be defective. The question in *Boston Scientific* was whether the defectiveness of other devices in the same batch could be inferred from that finding. That is very different from the proposition that a specific product can be considered defective only if the product is more generally found to be unsafe.

90. In the light of the above, and addressing the scenario raised in the referring court's first question, I consider that Article 4 of the Directive does not preclude factual presumptions of causal link and defect. However, any such presumption must respect the principles of equivalence and effectiveness and the minimal requirements of Article 4. The presumption must be sufficiently rigorous so as not to result in a reversal of the burden of proof. In particular, they must be based on relevant and sufficient evidence.

91. Does that answer change if the presumption of causation is a *legal* presumption (as opposed to a factual one)? That is in essence the referring court's second question.

92. I refer to the reasoning above according to which rules of proof and evidence including the use of and conditions underlying presumptions are a matter for national law, subject to the principles of equivalence and effectiveness. The final decision as to whether those principles are respected in the present case is one for the national court to determine.

93. I would, however, add the following three observations.

94. First, I consider that as a general rule irrebuttable legal presumptions — meaning the obligation for a judge to infer certain facts, which cannot then be challenged *irrespective of what evidence is presented by the other party* — are more likely to raise concerns and may well conflict with the principle of effectiveness. I refer in this regard to point 51 above in relation to the judge's free assessment of evidence. However, my understanding from the oral hearing is that the presumptions invoked in this case are not irrebuttable and I will therefore not consider this aspect in further detail.

95. Second, although not strictly speaking 'irrebuttable', a legal presumption can sometimes only be reversed by adducing evidence that specifically *undermines the very basis of the presumption*. In such cases, again, significant limits are imposed on the judge's free assessment of evidence in a way that may well conflict with the principle of effectiveness.

96. Thus, where A serves as a basis for a rebuttable presumption of B, it can in theory be rebutted either by: (i) adducing proof that A has not in fact been established, or (ii) providing further evidence 'C' that, in the judge's global assessment of the facts, results in the presumption being overturned. The former scenario constitutes a greater limitation on the judge' free assessment of evidence.

97. Third, as explained above, in order for factual presumptions to respect the principle of effectiveness they must be based on relevant evidence that is sufficient to sustain the inferences drawn. That also applies in the case of legal presumptions.

98. The difference lies in the fact that, by definition, the national judge *must* apply legal presumptions where the required factual elements are proven by the claimant. As a result, there is clearly a greater possibility for the presumption to be applied in concrete cases where in reality it is not justified.

99. However, in my opinion such a possibility does not in and of itself conflict with the principle of effectiveness. Indeed, it is almost inevitable that legal presumptions, given their automatic nature will be 'wrong' in specific cases. Their purpose is not perfection of outcome but the efficient administration of justice. The key is that, if the legal presumption is wrongly triggered, there is the practical possibility for the defendant to rebut the presumption by presenting relevant evidence. That again underlines the importance of the *rebuttable* nature of any legal presumption.

100. Given the answers to the referring court's previous questions, there is no need to address the national court's third question, which relates to the value of scientific research. However, as part of the answer to the referring court's first question, I have set out a number of observations relating to the value attributed specifically to evidence in the form of medical research. To the extent it may assist the referring court, those observations are, in my view, equally valid as concerns the importance and limits of scientific evidence more generally.

V – **Conclusion**

101. In the light of the above, I propose that the Court respond to the questions posed by the Cour de cassation (Court of Cassation) as follows:

Article 4 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products does not in itself preclude, in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method by which the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease, notwithstanding the finding that general medical research does not establish a relationship between the vaccine and the occurrence of the disease, provided that such a method of proof does not effectively result in a reversal of the burden of proof of default, damage or causal link between those two.

In particular, such a method of proof may only involve presumptions that:

– rely on evidence which is both relevant and sufficiently rigorous to sustain the inferences drawn;

– are rebuttable;

– do not unduly curtail free assessment of evidence by the national court, in particular by preventing the national judge, without prejudice to general national rules on admissibility of evidence, from taking account of relevant evidence, or requiring that specific pieces of evidence are treated as conclusive proof that one or more of the conditions of Article 4 are fulfilled, irrespective of what other evidence is presented;

– do not prevent the national judges from giving due consideration to any relevant medical research presented to the national court, without prejudice to rules on admissibility of evidence, or impose as an absolute requirement that medical research be presented in order to demonstrate defect or causal link.

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1 – Original language: English.

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2 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).

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3 'Présomptions graves, précises et concordantes.' The precise meaning of the term 'presumptions', which would arguably translate more naturally into English as 'circumstantial evidence' is further discussed below in points 28 to 35.

4 As confirmed in the request for a preliminary ruling. No specific case-law is cited by the referring court. However, according to the written observations submitted to the Court these principles appear to be confirmed and developed over a number of cases including two judgments dated 22 May 2008 (Cass. Civ. 1ère, Bull. Civ. I, No 148 and No 149).

5 See Article 4 of the Directive and judgment of 20 November 2014, *Novo Nordisk Pharma* (C-310/13, EU:C:2014:2385, paragraph 26). This reflects the general procedural rule that a party alleging a fact normally bears the burden of proving that fact (see, as regards EU law, Opinion of Advocate General Trstenjak in *C.A.S.* v *Commission* (C-204/07 P, EU:C:2008:175, point 114). See in relation to product liability: Lovells, Product liability in the European Union — A report for the European Commission — 2003 (The Lovells Report), p. 19.

6 On the genesis and the background of Article 4 more generally, see Taschner, H.C., and Frietsch, E., *Produkthaftungsgesetz und EG-Produkthaftungsrichtlinie*, *Kommentar*, 2nd edition, Beck, Munich, 1990, pp. 219 to 222.

7 Judgment of 20 November 2014, *Novo Nordisk Pharma* (C-310/13, EU:C:2014:2385, paragraph 24 and the case-law cited).

8 Judgment of 20 November 2014, *Novo Nordisk Pharma* (C-310/13, EU:C:2014:2385, paragraph 29); Opinion of Advocate General Szpunar in *Novo Nordisk Pharma* (C-310/13, EU:C:2014:1825, points 21 to 24). See also the Fourth Report of 8 September 2011, which is on the implementation of the Directive, COM(2011) 547 final, p. 7.

9 Article 7 of the Directive does list some specific situations in which liability will be excluded on the basis of particular pieces of evidence. Those are not directly relevant to this case but are referred to further in point 47 below.

10 See, for example, particularly in relation to national procedural autonomy and rules of proof and evidence, judgments of 22 January 1975, *Unkel* (55/74, EU:C:1975:5, paragraph 12, subparagraph 3); of 10 April 2003, *Steffensen* (C-276/01, EU:C:2003:228, paragraph 60); of 28 June 2007, *Bonn Fleisch* (C-1/06, EU:C:2007:396, paragraph 51, subparagraph 2); and of 15 October 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690, paragraph 43).

11 Judgment of 20 November 2014, *Novo Nordisk Pharma* (C-310/13, EU:C:2014:2385, in particular paragraphs 27 and 32).

12 In relation to consumer protection, see the transversally applicable Article 12 TFEU: 'Consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities'.

13 See, for example, judgment of 10 April 2003, *Steffensen* (C-276/01, EU:C:2003:228, paragraph 60).

14 Which may indeed amount to a breach of the principle of effective judicial control or the right to a fair trial. See, in this sense, judgments of 15 May 1986, *Johnston* (C-222/84, EU:C:1986:206, paragraph 20), and of 10 April 2003, *Steffensen* (C-276/01, EU:C:2003:228, paragraphs 69 to 79). In some cases, application of national procedural rules may result in relevant evidence being considered as inadmissible, and the national court prevented from taking it into account. For example, the evidence may have been obtained illegally or presented out of time. Such restrictions do not, in themselves, conflict with the principles of equivalence and effectiveness. I understand that there is no specific issue of admissibility of evidence in this case and will not discuss here the compatibility with those principles of limits placed on admissibility of evidence.

15 Judgment of 15 October 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690, paragraph 43). In the absence of detailed information on rules of proof and evidence applicable to similar cases under national law, I limit my observations here to the principle of effectiveness and do not discuss the principle of equivalence.

16 Therefore rendering the comparative examination of such notions of considerable importance; for the practical significance of such examination in the context of product liability cases, and the differences in approaches to implementation of the Directive across the Member States, see Brook, Burton, Forrester and Underhill, in Canivet, Guy, Andenas, Mads, and Fairgrieve, Duncan, *Comparative Law before theCourts*, BIICL, 2004, pp. 57 to 83.

17 This definition of presumption is taken from *Lexique des termes juridiques 2015-2016*, Guinchard, S., and Debard, T., (dir.), 23rd edition, Dalloz, 2015, Paris: 'Mode de raisonnement juridique en vertu duquel de l'établissement d'un fait on induit un autre fait qui n'est pas prouvé. La présomption est dite de l'homme (ou du juge) lorsque le magistrat tient lui-même et en toute liberté ce raisonnement par induction, pour un cas particulier; elle n'est admise que lorsque la preuve par témoins est autorisée. La présomption est légale, c'est-à-dire instaurée de manière générale, lorsque le législateur tire lui-même d'un fait établi un autre fait dont la preuve n'est pas apportée. La présomption légale est simple lorsqu'elle peut être combattue par la preuve du contraire. Lorsque la présomption ne peut être renversée, elle est dite irréfragable ou absolue. Les présomptions simples sont dites également *juris tantum*, les présomptions irréfragables sont désignées parfois par l'expression *latine juris et de jure*. On qualifie de présomption mixte la

présomption dont la preuve contraire est réglementée par le législateur, qui restreint les moyens de preuve ou l'objet de la preuve.'

18 German law distinguishes between presumptions which allow a (set of) fact(s) or legal consequence to be inferred from another (set of) fact(s). Pursuant to German law, there seems to be a rather clear-cut rule on the procedural role of presumptions (Vermutungen), as far as they are codified in a statute. In such a case, the procedural consequence is that the object of the presumption no longer requires proof. There is no room for appraisal by the judge. Proof of the contrary by the opposing party, however, remains possible, unless the presumption is defined, in the statute, to be non-rebuttable. Such (statutory) presumptions are, under rather unanimous German doctrine, construed as rules on the burden of proof (see, for example, Prütting, Dr H., *Münchener Kommentar zur Zivilprozessordnung*, 5th edition, Beck, Munich, 2016, § 292 No 26). It would appear that German doctrine would understand the term 'presumption' as construed in this Opinion rather as indirect or prima facie evidence, which, as such, does not alter the burden of proof (see: Prütting, Dr H., *Münchener Kommentar zur Zivilprozessordnung*, 5th edition, Beck, Munich, 2016, § 286 No 51).

19 Iller, M., *Civil Evidence: The Essential Guide*, Sweet & Maxwell, London, 2006, pp. 124 to 125. Further on presumptions and operation of burden of proof in English law in general, see, for example, Munday, R., *Evidence*, 8th ed., Oxford University Press, Oxford, 2015, pp. 63 to 105.

20 Assuming the presumption is rebuttable. I will discuss the specific case of irrebuttable presumptions further below.

21 In the context of competition law, where proof and evidence is much more closely regulated by EU law, Advocate General Szpunar described the process of convincing the authority and the interplay between presumption and burden of proof in the following terms: 'These presumptions do not shift the burden of proof onto the addressee of the competition authority's decision. They allow the authority to draw a certain conclusion on the basis of common experience. The resulting prima facie conclusion may be rebutted by contrary evidence, failing which that conclusion will be considered as adequate to discharge the burden of proof, which continues to lie with the administrative authority' in *Eturas and Others* (C-74/14, EU:C:2015:493, point 99).

22 See below, point 96.

23 The Court has confirmed already that the Directive applies to cases of harm allegedly caused by defective vaccines (see, for example, judgment of 2 December 2009, *Aventis Pasteur* (C-358/08, EU:C:2009:744)).

24 In the *Boston Scientific* case it was established that a batch of medical devices contained some devices shown to suffer from a particular defect. From that fact, it was inferred that other individual devices in the batch could be classified as defective (judgment of 5 March 2015, *Boston Scientific Medizintechnik* (C-503/13 and C-504/13, EU:C:2015:148, paragraph 43). The judgment helps illustrate the point that (i) proof of defectiveness generally and in relation to a specific case are distinct, and (ii) they are of potential relevance to each other evidentially. In relation to specific and general defectiveness of the product see below, in points 85 to 89.

25 As regards imposing the burden of proof on the claimant for additional elements, see by analogy the line of case-law on passing on, beginning with *San Giorgio* (judgments of 9 November 1983, *San Giorgio* (C-199/82, EU:C:1983:318); of 9 February 1999, *Dilexport* (C-343/96, EU:C:1999:59); and of 9 December 2003, *Commission* v *Italy* (C-129/00, EU:C:2003:656)).

26 See in this regard also, Taschner, H.C., and Frietsch, E., *Produkthaftungsgesetz und EG-Produkthaftungsrichtlinie, Kommentar*, 2nd edition, Beck, Munich, 1990, p. 186.

27 The requirement of free assessment of evidence has in practice been confirmed on several occasions by Court. See, for example judgments of 15 May 1986, *Johnston* (222/84, EU:C:1986:206, paragraphs 17 to 21), and of 10 April 2003, *Steffensen* (C-276/01, EU:C:2003:228, paragraph 80). The requirement of free assessment of evidence has also been stated more generally in the context of direct actions based on EU competition law (see, for example, judgment of 8 July 2004, *Dalmine* v *Commission* (T-50/00, EU:T:2004:220, paragraphs 72 and 73); and Opinion of Advocate General Vesterdorf, *Rhône Poulenc* v *Commission* (T-1/89, EU:T:1991:38, p. 954). Indeed, the assessment of evidence has been described by the Court as an 'essential aspect of the judicial function since, regardless of the interpretation adopted by the national court seised of a particular case, the application of those provisions to that case will often depend on the assessment which the court has made of the facts and the value and relevance of the evidence adduced for that purpose by the parties to the dispute', judgment of 13 June 2006, *Traghetti del Mediterraneo* (C-173/03, EU:C:2006:391, paragraph 38).

28 As mentioned above, this is without prejudice to rules on admissibility, for example due to late submission of evidence or the fact that it was obtained illegally (see above, at footnote 14).

29 Judgment of 15 May 1986, *Johnston* (222/84, EU:C:1986:206, paragraph 20).

30 The question literally refers to the exclusion of *any* presumptions. However, the context clearly implies that what is being specifically envisaged is exclusion of the presumption under examination in this case.

31 See below in points 62 to 75.

32 See, for example, judgment of 21 January 2016, *Eturas and Others* (C-74/14, EU:C:2016:42, paragraphs 35 to 37).

33 The one described above in point 1.

34 As defined above in points 32 to 35.

35 Judgment of 15 October 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690, paragraph 43).

36 See the line of case-law in *San Giorgio* referred to above in footnote 25.

37 My understanding is that the general conditions are: (i) absence of personal or family antecedents and (ii) temporal link between vaccination and onset of the disease. However, the exact meaning of those conditions is not clear from the file as to whether they have some degree of flexibility (for example, length of temporal link). The first Respondent also refers in its pleadings to a third condition, namely, absence of known predisposition of the victim to the disease.

38 For the avoidance of doubt, although for illustrative purposes some reference is made below to EU competition law — which, for the most part, might be considered to be 'criminal' in nature — the reasoning set out in this Opinion relates to presumptions used in the context of extra-contractual liability under the Directive. It is therefore clear that EU competition law requires a higher standard of proof (beyond reasonable doubt) than that normally applicable in civil cases (balance of probabilities). However, with that caveat, the examples are useful for the purposes of illustration.

39 The fact that the presumption is in theory rebuttable has been confirmed by the Court on many occasions (see, for example, judgment of 19 July 2012, *Alliance One International and Standard Commercial Tobacco* v *Commission and Commission* v *Alliance One International and Others* (C-628/10 P and C-14/11 P, not published, EU:C:2012:479, paragraph 48)). The presumption has, however, often been subject to the criticism that it is irrebuttable in practice. See, for example, Temple Lang, J., 'How Can the Problem of the Liability of a Parent Company for Price Fixing by a Wholly-owned Subsidiary Be Resolved?', *Fordham International Law Journal*, Volume 37, Issue 5 2014, footnote 14 and accompanying text.

40 Although very regularly invoked by the Commission, there is no obligation to do so (judgment of 24 September 2009, *Erste Group Bank and Others* v *Commission* (C-125/07 P, C-133/07 P, C-135/07 P and C-137/07 P, EU:C:2009:576, paragraphs 76 to 83)).

41 Judgment of 10 September 2009, *Akzo Nobel and Others* v *Commission* (C-97/08 P, EU:C:2009:536, paragraphs 60 and 61).

42 Although the criticisms tend to focus more on the rebuttable nature of the presumption (see footnote 39).

43 It was, for example, explicitly questioned by the General Court in *Bolloré*: 'although the evidence relating to the 100% shareholding in its subsidiary provides a strong indication that the parent is able to exercise a decisive influence over the subsidiary's conduct on the market, this is not in itself sufficient to attribute liability to the parent for the conduct of its subsidiary … Something more than the extent of the shareholding must be shown, but this may be in the form of indicia'. (judgment of 26 April 2007, *Bolloré and Others* v *Commission* (T-109/02, T-118/02, T-122/02, T-125/02, T-126/02, T-128/02, T-129/02, T-132/02 and T-136/02, EU:T:2007:115, paragraph 132)).

44 Judgment of 10 September 2009, *Akzo Nobel and Others* v *Commission* (C-97/08 P, EU:C:2009:536, paragraphs 60 and 61).

45 See, for example, judgment of 31 March 1993, *Ahlström Osakeyhtiö and Others* v *Commission* (C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85, EU:C:1993:120, paragraph 71).

46 Namely, by way of injection into the patient.

47 In a similar vein, one may imagine a scenario in which a number of people (but not necessarily all) will fall ill following a dinner in a given restaurant on a given day. When investigating the incident (and potentially also deciding on the liability of the restaurant) days or weeks later, the food those people consumed is likely to be no longer existent. Thus, no samples and no proof of actual defect of the food served can be provided. That does not preclude the conclusion, however, that *absent* any other reasonable explanation, the food they ate might be considered as defective by inference from the events that ensued.

48 Point 46.

49 Judgment of 5 March 2015, *Boston Scientific Medizintechnik* (C-503/13 and C-504/13, EU:C:2015:148).