



Vaccines and liability for defective products

Judgement of the European Court of Justice of 21 June, Case C-621/15, Sanofi Pasteur MSD

Background

The judgment of the European Court that we are discussing in this Capsulas is one example of the complexity of constructing European Community law. Given that accepting that a supranational organization approves and enforces common rules on some matters is very complicated, it is common that European Community law does not succeed in regulating with full details all those matters which it wishes to address. Therefore there are always gaps that will need to be governed by national rules.

This case refers to product liability of manufacturers in the event that their products have a defect and they cause a damage to the consumer. The European directive which aims to eliminate the discrepancies between national laws in this area establishes that manufacturers are responsible for damages caused by defects of their products; and that the injured person that claims a compensation has to prove the damage and the defect as well as the causal relationship between the defect and the damage. However, the directive does not specify if in order to prove the existence of the defect and the relation of causality, the injured person must provide specific and concrete evidence or if, on the contrary, the judges may consider that these circumstances have been proven on the basis of a set of evidence, the seriousness, specificity and consistency of which allows them to consider, with a sufficient high degree of probability, that such a conclusion corresponds to the reality of the situation. As you see, the matter is highly complex.

Evidence based on presumptions

The Court, in these circumstances, has decided that European law does not preclude a national court to consider, when medical research does not establish nor reject a relationship between the vaccine and the occurrence of a disease, that some facts alleged by the injured person constitute serious specific and consistent evidence enabling the court to conclude that there is a defect in the vaccine and that there is a causal link between that defect and the decease.

On the other hand, the court also rules that judges should ensure that when applying this evidence regime, they do not reverse the burden of the proof. The directive, the court says, precludes rules based on presumptions according to which where medical research neither establishes nor rules out existence of a link between the vaccine and the disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established if certain predetermined factual evidence is presented.

In Spain, accepting presumptions to prove the causal link between a defect and a damage has been exceptional, and this ruling by the court should not entail substantial changes in the rigorousness that must be applied in connection with evidence in these cases.