



The importance of procedural aspects in damage claims regarding clinical trials

Judgment of the Court of Appeals of Madrid of 22 December 2021

Claims for damages are often brought against companies that are not the ones that allegedly caused the damages; but rather against companies of the same group which are closer to the plaintiff's territory. On many occasions, claims are filed against Spanish subsidiaries, even if they have not participated in the events leading to the claim. As discussed in previous CAPSULAS (October 2020 and March 2022), the Spanish Supreme Court recently issued various rulings against this practice. In this the judgment, the Court of Appeals of Madrid applies the doctrine of the Supreme Court to a claim regarding clinical trial related damages.

Against which company should damages claims be brought?

Damage claims should be brought against the sponsor of the clinical trial or the entity acting as its legal representative. In the case under analysis, the Court of Appeals dismisses the claim on the grounds that such claim was filed against the Spanish subsidiary of the sponsor rather than against the sponsor or its legal representative. Although the Spanish subsidiary belonged to the same group of the sponsor, it was not its legal representative (such representative was another company of the group domiciled at the Netherlands). On the other hand, the Spanish subsidiary had not connection with the clinical trial.

Furthermore, the Court states that the veil piercing doctrine cannot be applied since both the Spanish subsidiary and the sponsor were independent entities with distinct activities, and no fraudulent intent to evade liability appeared to exist.

Expert evidence

Despite considering that the Spanish subsidiary could not be sued, the Court analyses the merits of the case. The Court concludes that there is no causal link between the alleged damaged and the tested drug. This conclusion is reached on the basis of an expert report provided by the defendant and a report issued by a court-appointed expert.

Rules governing clinical trials state that damages caused to individuals participating in a clinical trial are presumed to derive from such clinical trial if they occur during the clinical trial or throughout the year following the same. This presumption, however, may be displaced by fact-based evidence showing that the damages did not result from the clinical trial itself but rather from other causes such as the evolution of the patient's illness. The Court emphasises that expert reports are a key piece of evidence to displace this type of presumptions.