

Coronavirus and civil procedure – Particularities of drug liability trials (in Germany)

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Court business (worldwide) remains restricted as a result of ongoing protective measures. People are returning only slowly to their workplaces. In addition, everyone is currently obliged to wear face coverings in shops and on public transport. Courts are therefore looking for alternative ways of holding scheduled hearings in order to safeguard the right to due legal process. For example, they are more and more frequently allowing video hearings in civil proceedings, conducting digital hearings in international court proceedings or using written proceedings as a practical alternative? – (in German) to cope with the large number of future and summarily postponed oral hearings. See also our other articles on emergency judicial relief in times of COVID-19 in Germany, arbitration proceedings and oral hearings in times of COVID-19 (in German) and preservation of evidence in times of coronavirus.

Particularities of drug liability trials

The COVID-19 pandemic is also leading to difficulties in drug liability trials, especially because of the particularities of this type of proceedings. In drug liability trials, courts tend to rely on the expertise of external experts, such as physicians and pharmacists, more frequently than in other types of civil proceedings. Their specialist knowledge is often required in order to reconstruct medical histories and explain causal links, for example.

While in general civil proceedings the burden of statement and proof regarding all facts establishing the claim usually lies with the claimant, drug liability trials are, in some cases, subject to a statutory relaxation of the burden of proof in favour of the claimant ("**patient**"). One of the rules that govern such trials is the presumption that the drug in question has caused the asserted damage if it is capable of causing the damage in the specific case (sec. 84 para. 2 sentence 1 of the German Drug Act (Arzneimittelgesetz – "**AMG**"). This presumption does not apply if at least one other circumstance is also capable of causing the damage (sec. 84 para. 2 sentence 3 AMG). The pharmaceutical entrepreneur must therefore state and, if necessary, prove other circumstances capable of causing the damage in order to prevent the presumption of causation being applied and to reimpose the burden of proving the causation of the damage on

the patient. To this end, the pharmaceutical entrepreneur itself usually needs experts to help it assess the patient's specific individual case.

Experts also play a key role in general when it comes to clarifying a patient's medical history. In drug liability cases, this is often an extremely complex and lengthy task, which means that a thorough examination is essential for decision-making. Furthermore, the patient's (prior) medical history is significant as a means of determining the cause of the alleged complaints. In this respect, there is often a need for several experts from different specialist areas, who, if appropriate, will examine the patient, analyse the treatment records, prepare expert opinions and present their findings to the court and the parties at the oral hearing.

Court's perception and expert evidence as primary decision aids

Alongside other resources (including doctor's letters as certificates), the main decision-making tools used by the court in a drug liability trial – assuming that facts exist which have been presented in a substantiated manner – are its perception and hearing of the patient in person as well as the expert evidence. Clarifying the patient's medical history is essential for a drug liability trial.

Restrictions on the furnishing of evidence due to COVID-19

In times of the COVID-19 pandemic, the restrictions and statutory protective measures are having an impact on the furnishing of evidence in drug liability trials. As potential experts such as epidemiologists are currently heavily involved in dealing with the crisis, it can be more difficult and take longer than usual to engage an expert privately or to have an expert appointed by a court. Depending on a patient's age or state of health, it may also be unreasonable to expect them to visit an expert in person or to appear in person before a court or a judge applied to. However, the use of video hearings in drug liability trials does not appear to be an adequate way of resolving the issues of liability in this highly sensitive area. It remains to be seen to what extent the possibilities for furnishing evidence will continue to be limited or the situation will be improved by the easing of restrictions.

Conclusion

The means stipulated in the German Code of Civil Procedure (Zivilprozessordnung – ZPO) for continuing proceedings without appointments at the court or personal contact, such as video hearings, the taking of evidence before a judge applied to, or purely written proceedings, are not always expedient in drug liability trials, which are usually complex. Therefore, if a court requests the use of such alternative means, a strategic decision must be made on the basis of the individual case.

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