

EIP

Does an ongoing phase 3 clinical trial and its published protocol suggest that the tested drug will be successful?

Summary

A recent EPO Boards of Appeal decision, T 0136/24, has examined the issue of “reasonable expectation of success” when the prior art discloses a protocol to an ongoing phase 3 clinical trial. How much weight should be given to such protocols when the outcome of the trial had yet to be published?

The facts

The patent of interest claimed a new anti-cancer drug, cabazitaxel, for use in treating a specific type of prostate cancer in patients who had previously undergone alternative therapy. The Opponents argued that the authorisation of a phase 3 trial necessarily implied that cabazitaxel had demonstrated success in previous clinical trials and preclinical models. Additionally, the Opponents alleged that as the trial was nearing completion at the patent’s priority date, this indicated that the trial had not been terminated prematurely due to poor results. Thus, the Opponents sought to put the burden of proof on the patentee, arguing that the use of cabazitaxel in this patient group should be deemed inventive only if there was any information plausibly contradicting a baseline expectation of success.

The Board's decision

The Board rejected these arguments, stating that the specific context must be considered. Here, only a single patient with the appropriate type of prostate cancer was included in the relevant phase 1 trial. Cabazitaxel for use in prostate cancer then proceeded immediately to phase 3 trials and therefore no phase 2 trial results were available. Finally, the mere fact that a clinical trial was nearing completion was deemed to reveal nothing without published details of interim reviews.

Take-home message

An ongoing phase 3 clinical trial and its published protocol should not necessarily result in a reasonable expectation that the tested drug will be successful. Instead, one must consider the specific circumstances, such as what prior trials had actually tested and demonstrated, and how much was known about the drug's clinical efficacy and safety profile in the relevant therapeutic indication.