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Does a Clinical Trial render the Pharmaceutical Formulation used therein Public?

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The new and noteworthy decision T 670/20 by Technical Board of Appeal 3.3.07 provides more legal certainty for patentees of formulation patents.

The proprietors of pharmaceutical formulation and pharmaceutical use patents do often not have it easy, if and when – as is often the case – they have conducted clinical trials before the priority date of their patent. Let me leave 2nd medical use patents for another post and focus on pharmaceutical formulation patents for the moment. The owners of such patents are nowadays quite regularly confronted with the argument that their patents lacks novelty, because the patented formulation had already been used in clinical trials before the priority date and thereby become publicly available. Opponents usually refer to T 7/07 to support their case. In this decision it was held that the sponsor of the clinical trial concerning an anti-baby pill had lost control over the drugs after these had been handed out to the participants of the trial as members of the public who were not bound to secrecy.

Conversely, in T 670/20 the Board clarified that T 7/07 was limited to its particular circumstances and that clinical trials that were set up so that the patients had to return unused medication do generally not render the formulation public, even if the patients were allowed to take the medication home. The patients in case T 670/20 were under the obligation to take the tablets according to a prescribed scheme and to prepare respective documentation. The TBA held that under these circumstances the patients did not represent the public and the tablets were not prior art.

The Board summarized its findings in the following catchword:

> The clinical trials were carried out in accordance with the EMEA Guidelines for Good Clinical Practice. These guidelines explicitly require adherence to the prescribed protocol and assurance of drug accountability. This set-up of the trials implies that the patients who decided to participate in the trials agreed, following their informed consent, to use the provided medication according to instruction or to return the unused medication. Accordingly, the participating patients who were provided with the tablets under investigation entered into a special relationship with the investigators of the trials and were with regard to the provided tablets not members of the public that could freely dispose over these

> tablets. (see section 4.3)

The appellants further argued that the patients may have been requested to return unused tablets, but that in the absence of any legal sanction, no parallel to a confidentiality agreement could be assumed on such basis, especially as full compliance by all patients would not be likely. The Board did not accept this argument, though. An obligation is an obligation, irrespectively of any sanction on non-compliance. The Board further held that "the possibility of non-compliance to the instructed use an return of the tablets by the participating patients does not affect the essence of this agreement."

This new decision might provide some relief to patent proprietors in this field, at least to the extent that "standard" clinical trials are concerned. Nonetheless, it goes without saying that each case will be decided on its own merits. Thus, it is unlikely that this decision will settle this question once and for all times.

(Disclosure: Members of the author's law firm represented the patentee in this case)

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