

The board in T.814/12 held that it is established case law of the boards of appeal for a medical use claim to fulfil the requirements of Art. 83 EPC, unless this is already known to the skilled person at the priority date, that the patent has to disclose the suitability of the product to be manufactured for the claimed therapeutic application. A claimed therapeutic application may be proven by any kind of evidence as long as it reflects the therapeutic effect on which the therapeutic application relies (T.814/12, referring to T.609/02 in particular). In T.814/12 the board considered that by analogy the same requirements of Art. 83 EPC applied for diagnostic use claims.

In T.895/13 of 21 May 2015 the board stated that, pursuant to decision T.609/02, attaining the claimed therapeutic effect was a functional technical feature of a claim drawn up in the Swiss-type form. In its view, the same principle applied to purpose-related product claims drawn up in accordance with Art. 54(5) EPC. Accordingly, the therapeutic effect provided by the claimed subject-matter was to be examined in the context of the assessment of sufficiency of disclosure (Art. 83 EPC) (see G.1/03, point 2.5.2 of the Reasons) and not, as in the decision under appeal, in the context of the assessment of inventive step.

7.2.2 Evidence of therapeutic effect

The question is whether or not the skilled person, having regard to the disclosure of the patent and the common general knowledge at the relevant date of the application, would have considered that the compounds referred to in the claim are suitable to achieve the therapeutical effect (see T.609/02, point 9 of the Reasons). Or, in other words, whether it was plausible (or, in yet other words, whether it was credible) that the therapeutic effect could be achieved by the claimed composition (as recapitulated in T.966/18).

Either the application must provide suitable evidence for the claimed therapeutic effect or it must be derivable from the prior art or common general knowledge. The disclosure of experimental results in the application is not always required to establish sufficiency, in particular if the application discloses a **plausible** technical concept and there are no substantiated doubts that the claimed concept can be put into practice (T.950/13 citing T.578/06).

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a) Plausibility of therapeutic effect

If a therapeutic application is to be accepted as sufficiently disclosed, the application or the patent, respectively, and/or the common general knowledge has to provide some information rendering it technically **plausible** for the skilled person that the claimed compounds can be applied for the claimed therapeutic use (T.1599/06 citing T.609/02).

The requirement of sufficiency of disclosure is considered to be fulfilled with respect to a claim to a second medical use if the disclosure in the patent or the common general knowledge enables the skilled person to obtain the compound to be applied and to apply