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Plausibility at the EPO – good news for innovators?

In a welcome decision for patentees, an EPO pharmaceutical Board of Appeal establishes plausibility on the basis of the prior art, confirming that plausibility and obviousness are different tests

In recent decision T184/16 (Board 3.3.02 – Müller, Bertrand, Bühler), further guidance is provided on how the EPO's doctrine of "plausibility" should be applied for new chemical entity and second medical use patents. Against the backdrop of some recent stricter decisions from the Boards, this development provides welcome relief for applicants and patentees in the pharmaceutical sector.

The patent at issue claimed a genus of small molecules that were said to have inhibitory activity against sodium-dependent glucose transporter (SGLT) and therefore be useful in the treatment of diabetes-related conditions. The Board held that the compounds and their medical uses were inventive and sufficiently disclosed. In its reasoning, the Board confirmed that the plausibility requirement was met despite the patent containing no biological data supporting the SGLT inhibitory activity of the compounds or their medical uses.

Detailed summary

The patent in issue (EP 1 651 658) had been upheld in amended form after first instance proceedings before the Opposition Division. The opponent appealed, arguing that the medical use claims were insufficient and that the compound per se claims lacked inventive step.

Both of these arguments focussed on the absence of biological data in the patent, the opponent arguing that it was not plausible that the claimed compounds displayed the SGLT inhibitory effect or the consequent treatment effect for the claimed medical uses.

In its analysis the Board pointed out that, when considering plausibility, the disclosure of the application as filed must be considered together with the common general knowledge and the relevant prior art. The reference to common general knowledge and prior art is particularly interesting here as it seems to confirm that plausibility can be established based on a specific piece of prior art, rather than only on common general knowledge as a whole. The Board then walked through and endorsed some of the more pro-patentee case law on plausibility (e.g. T108/09, T1760/11, T919/15) before finding that:

"The board has no indication, nor has the appellant argued that there exists any, that there is prima facie any serious doubt that the claimed therapeutic effect can be obtained. Furthermore, there is no a priori reason or any indication in the common general knowledge that the claimed therapeutic effect cannot be obtained." (Reasons 2.6, emphasis added)

The Board also considered a prior art PCT application cited in the background section of the patent, which disclosed SGLT inhibitor compounds having the *"same core structure"* as those claimed in the patent. Unlike the patent, the cited PCT application did contain evidence that those similar compounds were SGLT inhibitors. In view of this prior art, and following a review of the case law, the Board held it to be plausible that the claimed compounds were SGLT inhibitors, despite the absence of biological data in the patent itself. Thus, in accordance with established EPO case law, the patentee was allowed to rely on its own post-published data to show that the claimed compounds were indeed SGLT inhibitors, and ultimately the claims were held to be enabled and inventive on the basis of this post-published evidence.

The Board's inventive step analysis is likely to provide comfort for patentees. In particular, the Board held that the claimed compounds were non-obvious in view of the compounds described in the prior art PCT application, in spite of the apparent reliance on those compounds having the *"same core structure"* to support the plausibility of the claimed compounds. In coming to this decision, the Board stated explicitly that the criteria for plausibility and obviousness were not the same:

"It is to be noted that this [the acknowledgement of plausibility] *is not in contradiction of the finding that the claimed subject-matter is non-obvious in view of the prior art. The criteria for plausibility and obviousness are different. On the one hand, as set out above, for plausibility of a claimed effect to be acknowledged, it is enough if there are no prima facie serious doubts that the effect can be obtained and conversely no a priori reason and indication in the common general knowledge that the effect cannot be obtained. On the other hand, obviousness is decided in the framework of the problem-solution approach, where generally an important consideration is whether the claimed solution is suggested and thus made obvious by the prior art."* (Reasons 11)

In a further positive aspect, based on the post-published data provided, the patentee was permitted to rely on the technical effect of providing improved SGLT inhibitors in its problem-solution analysis, even though it had relied on the less ambitious effect of mere SGLT inhibition per se in its plausibility arguments. Although the Board did not provide any commentary on the patentee's approach on this specific issue, it is encouraging to see that plausibility was acknowledged for the existence of a technical effect mentioned in general terms in the application as filed, without any requirement for the patentee to establish plausibility up to a higher threshold, e.g. for an *improved* effect as compared to the closest prior art. This suggests that the EPO should be primarily interested in plausibility of the "subjective" technical effect as stated in the application as filed, rather than the "objective" technical effect as formulated compared to the closest prior art. In this regard, the Board's approach here is consistent with comments from other Boards of Appeal on this point (e.g. see T1397/08 and T2371/13 from Board 3.3.10).

Commentary

This decision draws together a number of threads of patentee-friendly EPO case law on plausibility and is therefore likely to be of great interest to innovators in the pharmaceutical sector. In particular, the Board's endorsement of earlier decisions which set a low bar for plausibility will come as a relief to the owners of pharmaceutical patents of a certain vintage which contain little or no biological data.

In addition, the Board's explicit acknowledgement that the criteria for plausibility and obviousness are different provides welcome clarification. According to this decision, patentees can in principle argue that a particular effect is plausible because of similarities between a prior art reference and the claimed subject matter, whilst concurrently avoid a finding of obviousness over that same prior art.

This is particularly helpful for patentees facing so-called "squeeze" arguments in opposition proceedings, whereby an opponent argues that the claimed subject-matter must be either obvious or implausible based on a similar piece of prior art. This decision acknowledges the hypothetical possibility of escaping such a plausibility/obviousness squeeze, although it should be noted that in this particular case the squeeze was not argued by the opponent and so the decision stops short of providing practical guidance as to how this tightrope might be navigated for other patentees when faced with similar facts.

One final thing this decision emphasises is the importance of drafting and, for European purposes, the value of including relevant prior art in the background section. Whilst best practice continues to be to include as much supporting technical information as possible when drafting pharmaceutical patent applications, ideally in the form of biological data, in this case the reference to the prior art PCT application seems to have been enough to get the patentee home on plausibility before the Board despite the absence of data.

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