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It's all very plausible: the free evaluation of evidence at the European Patent Office

G 2/21 *Plausibility*, ECLI:EP:BA:2023:G000221.20230323

Introduction

The Enlarged Board of Appeal of the European Patent Office ("EPO") in its decision G 2/21 *Plausibility*[1] explored the issue of plausibility but also set out the rules on the admissibility of evidence in proceedings before the Office. The basic facts of the case are quite simple. The patent in question included a claim for an insecticide which was a mixture of thiamethoxam and one (or more) compounds from a particular chemical family. Significantly, this combination had greater (synergistic) effect as an insecticide than would be expected from thiamethoxam or the compound acting alongside each other in combination. The evidence supporting this synergistic effect was not available to the public before the filing date but became available later, commonly called "post-published evidence". The questions referred from the Technical Board of Appeal[2] were considered in two parts by the Enlarged Board. The first dealt with the rules on post-published evidence and the second dealt with how this is material to any assessment of "plausibility" in relation to inventive step and sufficiency.

Post-published evidence

The Enlarged Board explained that the general rule before the EPO[3] was that there should be a "free evaluation of evidence",[4] which:

> *… can be defined in abstract and general terms as allowing and, by the same token, requiring a judicial body, like the boards of appeal, to decide according to its own discretion and its own conviction, by taking account of the entire content of the parties' submissions and, where appropriate, any evidence admissibly submitted or taken, without observing formal rules, whether a contested factual assertion is to be regarded as true or false.*[5]

This free evaluation means that there are "no firm rules according to which certain types of evidence are, or are not, convincing".[6] While this is a very broad statement, it should be fitted into the wider context of the rules of evidence at the EPO where there are different standards of proof depending on the type of evidence. So, for instance, oral disclosures and prior use have a higher standard of proof than proving a patent document.[7] Nevertheless, the Enlarged Board went on to say that this "free evaluation" means that judges need to assess comprehensively and dutifully all the evidence properly submitted, with the decisive factor being whether the judge is personally convinced of the matter.[8] Put another way, it is not permissible to disregard admissible and submitted evidence where it is relevant to the final decision before the tribunal,[9] as all such evidence must be considered by the decision maker.[10]

These broad statements of principle make the question regarding post-published evidence relatively straightforward. Post-published evidence should be considered unless it is not relevant or is not required for determining the matter in issue.[11] In short, post-published evidence should be treated in the same way as other evidence.[12] The rules as to whether post-published evidence should be admissible were a pre-cursor to what was thought to be the "main" question before the Enlarged Board, namely what are the requirements of "plausibility"?

Plausibility

Plausibility largely arises in the context of post-published evidence. The issue, whether in terms of sufficiency or inventive step, is whether the patent application has disclosed enough to show that a particular technical effect is likely to occur. While not confined to second medical use claims, it is often relevant in that context. The difficulty with such claims is that a patent is filed when it is predicted that a pharmaceutical agent will have a particular effect but in the absence of any clinical trials (often even, absence of proof-of-concept trials) it is not possible to demonstrate it *does* have that effect. Once the trials are completed the effect can be proved[13] but these trials invariably take place after the priority date. The question has been, therefore, if the effect cannot be proved until later what is required to be shown in the patent application as filed?

The referring Board of Appeal[14] identified three approaches by the Boards over the years. The first type,[15] ab inito plausibility, allows post published evidence to be taken into account only if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved.[16] The second type,[17] ab initio implausibility, means that post-published evidence must always be taken into account if the purported technical effect is not implausible.[18] The third type[19] is where the concept of plausibility is rejected all together.[20]

Plausibility and inventive step

Notwithstanding this neat classification of cases, the Enlarged Board took the view that "plausibility" was used as a "generic catchword" referring to the purported technical effect which goes to the problem the invention solved[21] whether in assessing inventive step or sufficiency.[22] It reminded itself that there is no general requirement for experimental proof to substantiate patentability[23] but evidence may be needed:

> *…when examining inventive step if the case in hand allows the substantiation of doubts about the suitability of the claimed invention to solve the technical problem addressed*[24]

The Enlarged Board then went on to suggest that the three classification of cases are all based on some common ground, namely that the question is what the skilled person, with the common general knowledge in mind, understands at the filing date of the application as the *technical teaching* of the claimed invention.[25] Accordingly, what is loosely described as "plausibility" is really about whether or not the technical effect relied upon by the patent applicant (or proprietor) was derivable by the skilled person from the technical teaching and whether it was embodied by the originally disclosed application documents.[26] Even where the technical effect is proved by post-published evidence, the technical teaching must still be that

in the application as filed because the demonstration that such an effect does indeed exist cannot change the nature of the claimed invention.[27]

Thus, if the post-published evidence demonstrates a technical effect which was not derivable from the application as filed then the evidence is inadmissible. This is because the evidence is not relevant to any fact in issue, rather than because it happened to be published after the priority date. The Enlarged Board also discussed plausibility in relation to sufficiency even though eventually this aspect was not part of any answers it gave to the referred questions.

Plausibility for sufficiency

The issue of plausibility of the technical effect in relation to the sufficiency of disclosure was explained in the following terms by the Enlarged Board:

> *… a technical effect, which in the case of for example a second medical use claim is usually a therapeutic effect, is a feature of the claim, so that the issue of whether it has been shown that this effect is achieved is a question of sufficiency of disclosure under Article 83 EPC …* [28]

This means, according to existing Boards of Appeal decisions, that where a claim is for a second medical use of a known therapeutic agent, it is necessary for the disclosure in the application to show that the known agent's use is "credible" for the new medical use.[29] Thus, the Enlarged Board concluded that the Boards of Appeal had accepted post-published evidence on a much narrower basis for sufficiency than they had for inventive step.[30] It stated the approach of the Boards of Appeal to be as follows:

> *In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence.*[31]

This is a summary of the decisions of the Boards of Appeal, rather than the Enlarged Board's own conclusions. It is also a little confusing. However, what the Enlarged Board appears to be saying is that for an application to be sufficient it either needs:

> (a) experimental proof in the application itself that there is a therapeutic effect; or
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> (b) in the absence of experimental proof being available at that time, that the proposed therapeutic effect is a "credible" one.

If it is "credible" from the documents as filed then post-published evidence can be admitted to support this effect. But if it is not "credible" it cannot be remedied by post-published evidence proving it actually does have the claimed effect. This appears to be comparable to the approach to plausibility before the English courts with its "reasonable prediction" principle.[32]

Concluding thoughts

The Enlarged Board has confirmed the wide and full application of the "free evaluation of evidence" at the EPO and that it applies without temporal limitation. Its discussion of

plausibility is much less developed, however. The Enlarged Board has identified the kernel of what plausibility is about – the technical effect behind the claimed invention – but as it itself admitted, much of the guidance it gave was very abstract.[33] Even though it may be general in nature, the Enlarged Board did still provide guidance in relation to inventive step but in relation to sufficiency it simply summarised the case law. It is a shame the Enlarged Board did not express its own view more clearly. At best it left us able to make a reasonable predication as to the correct approach.

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[1] ECLI:EP:BA:2023:G000221.20230323.
[2] T 116/18 *Syngenta Limited* [2022] OJ EPO A76.
[3] This applies to administrative divisions (G 2/22 *Plausibility*, [r 33]) and to the Boards of Appeal, [r 55].
[4] The Enlarged Board highlighted that this principle should be applied by all administrative and judicial departments of the EPO: G 2/21 *Plausibility*, [r 34]. It also suggested that it applied in all Contracting States: G 2/21 *Plausibility*, [r 47]–[r 54] (including England and Wales where such a term is not used and there are clear rules of admissibility).
[5] G 2/21 *Plausibility*, [r 30].
[6] G 2/21 *Plausibility*, [r 34]; also see T 482/89 *Appealable decision/DISCOVISION* [1992] OJ EPO 646, [r 2.1]. Accordingly, the examples of evidence in European Patent Convention, art 117 are exemplary: T 543/95 *Dampferzeuger für Gargeräte mit Entkalkungseinrichtung/LECHMETALL LANDSBERG GMBH EDELSTAHLERZEUGNISSE* (unpublished), 10 November 1997, [r 2] and T 142/97 *Apparatus for separating disc-shaped objects/STÖCKLI* [2000] OJ EPO 358,[r 2.2].
[7] See *Johnson, Roughton and Cook, The Law of Patents* (5th Ed, Butterworths 2022), [2.38]–[2.48].
[8] G 2/21 *Plausibility*, [r 31].
[9] G 2/21 *Plausibility*, [r 32] and [r 90]; also see T 1363/14 *Befestigungs- und Einstellvorrichtung für ein Schienenfahrzeug/ ALSTOM TRANSPORT TECHNOLOGIES* (unpublished), 30 May 2016, [r 2.2.4]; T 2238/15 *Planenaufbau eines Nutzfahrzeugs/SCHMITZ CARGOBULL AG* (unpublished), 11 April 2018, [r 2.2.6].
[10] G 2/21 *Plausibility*, [r 42].
[11] G 2/21 *Plausibility*, [r 43].
[12] G 2/21 *Plausibility*, [r 56] and [r 91].
[13] And if it cannot be proved the patent might is probably not worth defending.
[14] T 116/18 *Syngenta Limited* [2022] OJ EPO A76.
[15] T 116/18 *Syngenta Limited* [2022] OJ EPO A76, [r 13.4]–[r 13.4.4].
[16] G 2/21 *Plausibility*, [VI(6)].
[17] T 116/18 *Syngenta Limited* [2022] OJ EPO A76, [r 13.5]–[r 13.5.5].
[18] G 2/21 *Plausibility*, [VI(7)].
[19] T 116/18 *Syngenta Limited* [2022] OJ EPO A76, [r 13.5]–[r 13.5.5].
[20] G 2/21 *Plausibility*, [VI(8)].
[21] G 2/21 *Plausibility*, [r 58].
[22] G 2/21 *Plausibility*, [r 92].
[23] G 2/21 *Plausibility*, [r 60] citing T 578/06 *Pancreatic cells/IPSEN* (unpublished), 29 June 2011.
[24] T 578/06 *Pancreatic cells/IPSEN* (unpublished), 29 June 2011, [r 15]; cited G 2/21 *Plausibility*, [r 60].
[25] G 2/21 *Plausibility*, [r 71], [r 93] and [r 94].
[26] G 2/21 *Plausibility*, [r 72].
[27] G 2/21 *Plausibility*, [r 93].
[28] G 2/21 *Plausibility*, [r 74].
[29] G 2/21 *Plausibility*, [r 74].
[30] G 2/21 *Plausibility*, [r 77].
[31] G 2/21 *Plausibility*, [r 77].
[32] *Fibro-Gen Inc v Akebia Therapeautics* [2021] EWCA Civ 1279, [52] (appeal to the United Kingdom Supreme Court pending). It may of course be that "credible" is a higher or lower degree of certainty than "reasonable prediction" or "plausible" in the sense under the *Patents Act* 1977 (UK). But the basic approach is the same.
[33] G 2/21 *Plausibility*, [r 95].