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Plausibility in G2/21: has the elephant left the room?

Thorsten Bausch, Adam Lacy (Hoffmann Eitle) · Wednesday, March 29th, 2023

The concept of plausibility has caused great controversy in European patent law in recent years. It was hoped that the decision of the Enlarged Board of Appeal (EBA) of the EPO in G 2/21 would bring clarity. Since the referral questions by Board 3.3.02 were very clear and seemed to present reasonable alternatives from which the Enlarged Board could have selected one, this hope appeared justified. However, following the Enlarged Board's answer in G 2/21, many questions remain.

Plausibility in IP – A Brief History in pictures

It goes without saying that the term plausibility appears nowhere in the EPC and is no requirement of patentability, in contrast to novelty, inventive step and industrial applicability. Nonetheless, plausibility entered the realms of IP Law around the year 2005, when Technical Board of Appeal 3.3.08 came up with the following famous catchword:

The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.



Fig. 1: Plausibility enters the realms of Intellectual Property Law

(all pictures taken from commons.wikimedia.org)

Since the Board in T 1329/04 explained in quite some detail and with a scientific foundation why it considered the invention covered by claim 1 as too broad and speculative, this result of this decision did not raise a lot of controversies as such. Nonetheless, it of course opened the door for examiners and opponents to argue that an invention may not *solely* rely on post-published evidence for the effects asserted to be associated with the claimed subject-matter, absent a plausible showing that the teaching of the invention indeed solves the problem it purports to solve.

However, it did not take very long until this catchword was applied to other and in fact much more narrowly defined inventions, and even to claims covering only a single substance. Perhaps the most famous (or infamous) of these cases is the Dasatinib decision T 488/16, where a patent directed to a single (blockbuster) substance, i.e. dasatinib, was found to lack an inventive step, most likely because this substance had been buried/hidden in a plethora of other substances with very little concrete data and many possible mechanisms of action, i.e. many targets which dasatinib might bind to. Under these circumstances, TBA 3.3.01 held that the applicant was not allowed to rely on post-published evidence, even though the effect that dasatinib had was, among others, generically disclosed in the application as filed. A statement that “compounds have been tested in these assays and have shown activity” was considered too meagre by the Board to allow such reliance on post-published evidence. The elephant was now firmly settled in the China shop.



Fig. 2: Plausibility in EPO Dasatinib Decision T 488/16

The EPO's Case Law on plausibility then spilled over to the United Kingdom and developed a life of its own. The most famous decision might be the UK Supreme Court's Ruling in Warner-Lambert Company LLC v Generics (UK) Ltd, which was reported on this blog [here](#). This decision saw “*their Lordships split in opinion*“, with the majority voting that “*the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true*“. Plausibility was held as being just an aspect of the underlying principle of sufficiency. A roaring success for the concept of plausibility, which was thereby elevated to an aspect of a ground for revocation by itself.



Fig. 3: Plausibility reaches the UK Supreme Court in Warner-Lambert Company LLC v Generics (UK) Ltd

While Warner Lambert was a decision made in the context of a second medical use claim, this Case Law was soon also applied to product claims in the UK. If and when the activity of substantially all of the claimed substances is not plausibly shown in the application or was at least clear to a skilled person from their common general knowledge, then such claims will be found to lack plausibility, which in the UK will then result in their revocation for lack of industrial applicability without further ado. This is what recently happened, *inter alia*, in Gilead vs. NuCana 2023 EWHC 611. Good bye, Markush formulae.



Fig. 4: Plausibility used by the UK Courts to take the juice off further patents

G 2/21

Against this backdrop, G2/21 was eagerly awaited to provide an answer to the fundamental question: when can post-published evidence be relied upon to support a technical effect for establishing inventive step? Plausibility was considered relevant to answering this question by the referring Technical Board of Appeal (TBA) 3.3.02, which identified a divergence in previous decisions in the use of this concept to determine whether post-published evidence can be relied upon. The specific questions were as follows:

If for acknowledgement of inventive step the patent proprietor relies on a technical

effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):

- 1) Should an exception to the principle of free evaluation of evidence (see e.g. G 3/97, Reasons 5, and G 1/12, Reasons 31) be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests exclusively on the post-published evidence?
- 2) If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (ab initio plausibility)?
- 3) If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (ab initio implausibility)?

Due to the structure of the questions, the EBA could have answered question 1) in the negative and got away without discussing the tricky plausibility questions 2) and 3). And it seems that they indeed pondered this possibility. Fortunately, though, the EBA did not just keep the principle of free evaluation of evidence free from any exceptions. They even went to some length to deliver a wide-ranging decision which makes several points about:

- a) free evaluation of evidence,
- b) the burden of proof for technical effects,
- c) the concept of plausibility,
- d) post-published evidence in the context of inventive step, and
- e) post-published evidence in the context of sufficiency.

Unfortunately, though, it is actually quite difficult to understand how to apply these general observations to the key issues in the referral. The EBA's opinion is also relatively light on reasoning which will make it difficult to apply the conclusions to new scenarios. In the following, we comment on what we consider to be the key findings of the EBA on a) – e).

a) Free evaluation of evidence

The EBA reviewed EPO and national law and concluded at reasons 55 and 56 that:

...the principle of free evaluation of evidence qualifies as a universally applicable principle in assessing any means of evidence by a board of appeal. Hence, evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had

not been public before the filing date of the patent in suit and was filed after that date.

So at least the answer to question 1) is clear: the EPO's door is open to post-published data, at least in certain circumstances. Guidance on when post-published data can be accepted is provided in d) and e) below.

b) Burden of proof for technical effects

The issue of who bears the burden of proof for technical effects achieved by the invention is hotly contested by Patentees and Opponents before the EPO. The EBA cut through this Gordian knot by summarizing established case law in a way that opponents will find useful at reason 26:

According to the established case law of the boards of appeal (see Case Law of the Boards of Appeal of the EPO (CLB), 10th edition, I.D.4.2, and the decisions therein) it rests with the patent applicant or proprietor to properly demonstrate that the purported advantages of the claimed invention have successfully been achieved.

Reason 58 makes a similar point: a patent applicant or proprietor must demonstrate [plausibility] in order to validly rely on an asserted but contested technical effect. This doesn't sit easily with, e.g. T 1797/09 discussed at III.G.5.1.1 of the CLB frequently cited by patentees. Unfortunately, the EBA doesn't provide much detail or reasoning on this point.

c) The concept of plausibility

Reason 58 makes clear that plausibility is not a requirement for patentability itself or an exception to free evaluation of evidence, but is at best a factor in deciding whether an effect can be relied upon:

The Enlarged Board considers the conceptional notion inherent in the term "plausibility", which is often used as a generic catchword, as not being a distinct condition of patentability and patent validity, but a criterion for the reliance on a purported technical effect. In this sense, it is not a specific exception to the principle of free evaluation of evidence but rather an assertion of fact and something that a patent applicant or proprietor must demonstrate in order to validly rely on an asserted but contested technical effect.

This is a significant divergence from e.g. the approach adopted in the UK, where plausibility has evolved into a separate non-statutory patentability test (see above). It also seems to undermine the critical role ascribed to plausibility by the referring TBA, who framed their questions 2) and 3) using the term "plausibility" after a detailed review of the diverging use of this concept in earlier decisions. In contrast, the EBA did not use it in their Order and referred to it somewhat dismissively as a "generic catchword". At this point in the decision, one might start to wonder whether the elephant of plausibility is being slowly led from the room – but as we will see, the EBA do not manage to remove it entirely.

d) Post-published evidence in the context of inventive step

The EBA then turned to the question of when post-published evidence can support an effect for inventive step, while studiously avoiding the term “plausibility”.

After a lengthy review of EPO case law which the referring TBA found divergent because different standards were applied to plausibility (i.e. in order of increasing strictness for patentee: no plausibility < ab initio implausibility < ab initio plausibility), the EBA at reason 71 identified common ground in all these cases:

...the core issue rests with the question of what the skilled person, with the common general knowledge in mind, understands at the filing date from the application as originally filed as the technical teaching of the claimed invention.

Following this analysis, at point 2 of the Order, they provide the following guidance:

A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

It is not entirely clear how to apply this test on inventive step – even the Board accepts at reason 95 that the criteria are “*abstract*” and that a decision must be made “based on the pertinent circumstances of each case”. (Who would have thought that?) On a literal understanding, the “derivable” test seems to be reminiscent of the low bar for accepting post-published evidence for effects without evidence/explicit disclosure in the application using the lax “no plausibility” standards. One might therefore assume that a different conclusion would be reached using the new test than in earlier TBA decisions applying the strict “ab initio plausibility” standard. On the contrary: the EBA indicates at reason 72 that applying their test leads to the same conclusions in all the decisions identified as divergent by the referring TBA!

Applying this understanding to the aforementioned decisions, not in reviewing them but in an attempt to test the Enlarged Board’s understanding, the Enlarged Board is satisfied that the outcome in each particular case would not have been different from the actual finding of the respective board of appeal. Irrespective of the use of the terminological notion of plausibility, the cited decisions appear to show that the particular board of appeal focussed on the question whether or not the technical effect relied upon by the patent applicant or proprietor was derivable for the person skilled in the art from the technical teaching of the application documents.

Thus, according to the EBA applying this test should allow accepting post-published evidence for effects without evidence (or even explicit disclosure) in the application, in line with e.g. reason 2.5.2 of T 31/18. At the same time applying the test should also lead to the same conclusion as in T 488/16 reason 4.5, where post-published evidence was not accepted for effects explicitly asserted

but not evidenced in the application. While the EBA still saw common ground between these decisions, it will remain a bit of a mystery how their opposite outcomes can be reconciled, if at all possible. At least, it is rather unclear how exactly the EBA's new test is to be applied.

Although the EBA doesn't seem to give express guidance, one clue derivable from the decision is in the reasoning on sufficiency of disclosure discussed below.

e) Post-published evidence in the context of sufficiency of therapeutic effects

First and foremost, whether the inventive step or sufficiency is at issue depends on the claims: effects not specified in the claims are dealt with under inventive step while effects specified in the claims are dealt with under sufficiency. Concerning sufficiency, the EBA held at reason 74 that

...it is necessary that the patent at the date of its filing renders it credible that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application.

Note here that the "generic catchword" has snuck back into the EBA's reasoning albeit under the synonym for plausible, "credible". The elephant seems not to have gone after all. After reviewing several TBA decisions, the EBA states at reason 77 that:

...the scope of reliance on post published evidence is much narrower under sufficiency of disclosure compared to the situation under inventive step. 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.

Thus, a relatively strict standard is to be applied for supporting an effect using post-published data for sufficiency of disclosure. To use the referring TBA's terminology, at least ab initio plausibility seems to be required. Inventive step meanwhile seems to require a lower standard: while the test is not entirely clear, the effect must be "derivable as encompassed by the technical teaching and embodied by the original invention". Given that the EPA explicitly requires no proof of the effect in the context of inventive step, this may keep the door open for (credibly?) asserting a certain effect in the application as filed and providing the data later.

Conclusion

In summary, G 2/21 generally provides ammunition for opponents seeking to place the burden on patentee for demonstrating a technical effect. It also clearly places the burden on patentee for sufficiency of therapeutic effects, and makes it difficult to address this issue with post-published data. While it is not entirely clear how to apply the test for post-published data concerning inventive step, the bar seems to be lower than for sufficiency.

What does all of this mean in terms of the future of plausibility in EPO Case Law? Has the elephant finally left the room?



Fig. 5: Whether the elephant is really gone for good is in the eye of the beholder.

Even after a thorough reading of G 2/21, this is tough to answer. Clearly, the Enlarged Board does not like plausibility as a concept or criterion. But what, if anything, will replace it?

Perhaps it is time to update the African proverb “when elephants fight, it is the grass that suffers” to:

When the EBA fights the plausibility elephant, it is legal certainty that suffers.

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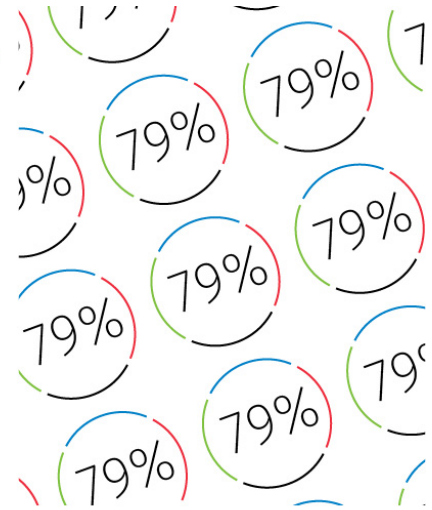
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