

EIP



G 2/21 applied by the referring EPO Technical Board; useful guidance on the test for reliance on post-published evidence in the post plausibility era

The referring Board to [G 2/21](#) has now published its full written decision in [T 0116/18](#), following the issuance of the minutes in September. The Decision attempts to clarify the requirements of [G 2/21](#), particularly in relation to the rather murky criteria set out by the Enlarged Board regarding the circumstances in which a technical effect proven by post-published evidence can be relied upon for inventive step. Whilst shedding light on [G 2/21](#), the Board in [T 0116/18](#) were not afraid to completely do away with 'plausibility' when considering inventive step, in turn recognising the divergence between EPO and UK jurisprudence.

G 2/21 recap

As covered in our [earlier article](#), the referred questions in [G 2/21](#) addressed two issues; (i) whether the principle of free evaluation of evidence requires a qualification in respect of certain evidence relied on for a technical effect in the assessment of inventive step, and (ii) the relevant criteria to be applied with regard to such an effect.

In answering the second of these questions, the Enlarged Board ordered (Headnote II):

"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"

p2

The question was answered at a high level of abstraction, leaving significant room for argument as to how explicit the teaching in the original application needs to be.

The new test

The Board in T 0116/18 noted that in formulating the order of G 2/21, there was no reference to 'plausibility' whatsoever. On the contrary, "it used new legal terminology that had not been applied so far in the context of inventive step." (r.11.3.2).

It is all well and good having a new test for determining whether post-published evidence can be relied upon, but... what is this new test? As mentioned earlier, G 2/21 offers no real guidance on how to assess whether the skilled person would derive a technical effect as being (i) encompassed by the technical teaching and (ii) embodied by the same originally disclosed invention. T 0116/18 now provides us with the most comprehensive analysis of requirements (i) and (ii) to date.

(i) encompassed by the technical teaching

The decision sets out that for requirement (i) to be met, "the purported technical effect together with the claimed subject-matter need only be conceptually comprised by the broadest technical teaching of the application as filed." (r.11.10). Therefore, it is not necessary to have literal basis in the application as filed for the effect, rather, it is enough that the skilled person "recognises that said effect is necessarily relevant to the claimed subject-matter". In other words, the technical effect must at least be linked to the broad disclosure of the invention in some way.

(ii) embodied by the same originally disclosed invention

For requirement (ii) to be satisfied, the Board concluded that the following is to be asked: "would the skilled person [...] have legitimate reason to doubt that the purported technical effect can be achieved with the claimed subject-matter?" (r.11.11). Again, the Board confirmed that it is not a precondition to have literal basis, even stating that it is "of little use to focus on selected wording of the application as filed" (r.11.13.1).

The Board goes on to note that the application as filed also does not need to have experimental proof that the technical effect is achieved. This is firstly because G 2/21 makes clear reference to the possibility of relying on an effect "even at a later stage" i.e. after the filing date. Secondly, the EPC does not require experimental proof for patentability and this must hold true for the present test.

Plausibility is dead, long live encompassed and embodied!

It is evident from both G 2/21 and T 0116/18 that the term 'plausibility' has fallen out of favour in the context of inventive step, or at the very least is no longer a generic catchword. Has the dial actually been shifted though?

Before G 2/21 (and as set out in the referring decision) there were three lines of so-called plausibility case law: the ab initio plausibility standard, the ab initio implausibility standard and the no plausibility standard; each standard being more lenient than the previous. That said, more recent EPO practice had seemingly developed into requiring evidence that an effect is at least plausible in the application as filed i.e. ab initio plausibility. This meant that "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 indeed solves the problem it purports to solve." (T 1329/04 ; Johns Hopkins).

G 2/21 has potentially relaxed the so-called plausibility standard somewhat, making life easier for applicants and proprietors looking to rely on post-published data. The Board made clear that their interpretation of G 2/21 is different from the "ab initio plausibility standard" (r. 12) and is instead its own test. The new test now asks, inter alia, whether a technical effect is "embodied" by the originally disclosed invention, rather than said effect being made "plausible".

Earlier decisions applying G 2/21

T 0116/18 is not the first decision to have applied G 2/21. In T 873/21, post-published evidence was taken into account in support of inventive step based on G 2/21, but in T 258/21, post-published evidence was not considered. Would either of these decisions have reached different conclusions in light of T 0116/18?

The claims T 873/21 was concerned with related to a combination of velagliflozin (A) and pergolide (B) for use in treating/preventing Equine Metabolic Syndrome (EMS), Equine Pituitary Pars Intermedia Dysfunction (PPID), and/or laminitis in an equine animal. The proprietor was allowed to reply on post-published data supporting a synergistic effect because said effect was "clearly the preferred combination". Moreover, the Board noted that the effect substantiated by the post-filed data was derivable from the original application, and that the post-published evidence "only provided a quantification of the obtained improvement" (in insulin sensitivity) described in the original application.

Applying the teachings of T 0116/18 to the facts of this case would likely have resulted in the same conclusion. The technical effect together with the claimed subject-matter was

conceptually comprised by the broadest technical teaching of the application as filed because it was preferred i.e. (i) encompassed. Further, the skilled person had no legitimate reason to doubt that the purported technical effect could be achieved with the claimed subject-matter based on what was already known in the art about compounds A and B i.e. (ii) it was embodied by the same originally disclosed invention.

T 258/21 concerned claims directed at the use of clevidipine for reducing ischemic stroke damage in a subject with an ischemic stroke. There was no experimental data in the application as filed. In short, the Board noted that the relevant technical effect was “neither contemplated nor even suggested” in the original application. Indeed, no technical effect directly linked to the distinguishing feature, namely the reduction of ischemic stroke damage had been demonstrated in the application. As such, post published data could not be relied upon.

Once again, applying the teachings of T 0116/18 to the facts would likely have resulted in the same conclusion. The technical effect together with the claimed subject-matter was not conceptually comprised by the broadest technical teaching of the application as filed because it was not neither contemplated nor even suggested i.e., was not encompassed. What’s more, the common general knowledge and prior art was silent on the behaviour of clevidipine in ischemic stroke patients and the application provided no data on this whatsoever; the skilled person had legitimate reason to doubt that the purported technical effect could even be achieved i.e., it was not embodied by the same originally disclosed invention.

Final comments

T 0116/18 provides us with some much-needed guidance the new test for determining whether post-published evidence can be relied upon for inventive step. Practitioners, examiners and even other Boards can now point to this case to support their arguments for why post-published evidence may or may not be used.

Whilst earlier decisions applying G 2/21 may not have resulted in a different outcome if they had T 0116/18 at hand, this new decision should hopefully aid in the uniform application of the test set out by the Enlarged Board in the coming years.