

# G2/21: POST-FILED DATA AND THE END OF 'PLAUSIBILITY'

The EPO's Enlarged Board of Appeal has released its long-awaited decision in [G2/21](#) "Plausibility", as announced in [a press release](#) yesterday. The decision deals with the issue when post-filing evidence is accepted by the EPO to support a technical effect upon which a patentee relies for inventive step. The Enlarged Board was asked to consider, among other questions, whether such a technical effect must have been considered plausible at the filing date. **Apart from discouraging use of the term 'plausibility' itself, the decision gives little reason to expect a significant change in approach to the acceptance of post-filing evidence.**

To describe this decision as 'hotly anticipated' might be an understatement. Indeed, in November 2021 the EPO took the step of actively delaying examination and opposition proceedings for cases where the decision depended entirely on the outcome of G2/21.

The question of the amount of experimental or theoretical evidence that is necessary to provide in a patent application is highly important to applicants and patent attorneys, especially in fields relating to medical and pharmaceutical research. Almost always, there is a balance to be struck between getting a patent application on file as early as possible, and the time needed to collect supporting data.

The EPO's approach to assessing non-obviousness also makes it difficult to determine what evidence might be useful while preparing a patent application. The distinguishing features of a claimed invention over the state of the art, and therefore the technical effect provided by these differences, depends on what is chosen as the closest prior art, which might not have been known at filing date. Applicants often find themselves in a situation where they have to rely on post-published evidence to support a technical effect. Over the years, a body of case law has developed that denies applicants the ability to rely on such evidence under certain circumstances.

## Post-filed data

According to the referring Technical Board of Appeal, the case law on the question of when post-filing evidence can be used to support a technical effect can be divided into separate strands. These have been characterised as setting different levels of 'plausibility' for an alleged technical effect in the original patent application. In the referring Board's view, the most stringent test, "*ab initio* plausibility", would mean that post-published evidence could 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 that the purported technical effect could be achieved. However, such a stringent approach could potentially be in conflict with the principle of free evaluation of evidence,

The Enlarged Board considered the general principle of free evaluation of evidence under the European Patent Convention (EPC) and many of its member states. It concluded that the principle requires a judicial body to be able to take account of the entire content of the parties' submissions and any admissibly submitted evidence, in order to decide according to its own discretion and conviction. The Enlarged Board also noted the lack of any strict requirement for experimental proof for an invention to be patentable under the EPC. Hence, it decided that **evidence submitted by an applicant or patentee to prove a technical effect may not be disregarded solely on the ground that such evidence had not been public before the patent's filing date.**

### Technical effects, and a farewell to plausibility

With this in mind, the Enlarged Board turned to the concept of ‘plausibility’. It considered this term to be a generic catchword that does not amount to a distinctive legal concept or specific requirement for patent eligibility or validity in the EPC. In this the Board appears to be in agreement with many commentators who have noted that “plausibility” is not a statutory patentability requirement in any EPC contracting state.

Instead, the Enlarged Board considers “plausibility” to be merely a criterion that can be used to determine whether a patentee can rely on an alleged technical effect. As such, it is an assertion of fact that the patentee must demonstrate in order to validly rely on an asserted but contested technical effect.

In analysing recent decisions of the Technical Boards of Appeal, the Enlarged Board, unlike the referring technical board, identified a common theme among them. It considered the core issue to rest with the question of what the skilled person, with the common general knowledge understands at the filing date from the application as originally filed as the technical teaching of the claimed invention. It concluded that the outcomes in the cases it reviewed would not have been different if this principle had been applied, despite these cases taking an apparently different approach to the concept of plausibility.

As a result, the Enlarged Board decided that a patentee may rely upon post-filed evidence in support of a technical effect **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.**

Given the heated debates around “plausibility” over the years, it is understandable that Board felt the urge to move away from this term. The elephant in the room is that the principles the Board derived from the previous decisions seem to lack as much clarity as the original catchphrase. Indeed, the Enlarged Board acknowledged that the guiding principles provided in its decision are abstract and will require a case-by-case assessment. In short, the referring Board and future Technical Boards of Appeal will have to grapple with how to apply these principles to the facts of cases before them. They can take comfort from the fact that following the old ways of considering ‘plausibility’ seems to lead to the same result.

### A note on sufficiency of disclosure

Although not central to the case at hand, the Enlarged Board also commented on the concept of ‘plausibility’ as it has been used in case law in relation to *sufficiency of disclosure* (or “enablement”).

It concluded that the scope for relying on post-filed evidence is much narrower under sufficiency of disclosure compared to the situation under inventive step, especially for claims to a medical use of a given composition, as in such cases the therapeutic effect of that use is a feature of the claim in itself.

Consistent with existing case law, the Enlarged Board held *obiter* that to meet the sufficiency requirement, 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, it would not be credible to the skilled person that the therapeutic effect is achieved. The Board emphasised that a lack of disclosure in this respect **cannot** be remedied by post-published evidence.

## Summary

The Enlarged Board's clarification that providing supporting data after the filing date of an application is possible should be good news for many users of the European patent system. It is difficult to say, however, whether the Enlarged Board's new guiding principles provide more certainty on when a technical effect can be taken into account, compared to the 'plausibility' tests used in various forms in previous decisions.

At this point, apart from the demise of the term 'plausibility' itself, there is little reason to expect a significant change in approach in the near future.

Perhaps more tangible are the Board's comments on sufficiency of disclosure. It seems that a more objective (and seemingly higher) bar is to be cleared when a therapeutic effect is claimed. As an aside, the Enlarged Board seemingly has no concern with employing the term 'credible' in this context, despite its use interchangeably with the term 'plausible' in many previous decisions of the Technical Boards of Appeal. As before, a patent application without at least some supporting data or detailed scientific rationale in the pharmaceutical, chemical or life science space may expect to struggle, in particular if challenged.

**For more detailed advice in relation to any of the issues discussed above, or for advice relating to other matters regarding European practice, please do not hesitate to get in contact with your E+F representative or email us at [elkfife@elkfife.com](mailto:elkfife@elkfife.com).**

