Haley ▪ Guiliano

11/18/2021 | Legal Updates

New referral to the Enlarged Board of Appeal G2/21: when can post-published data be used to support an inventive step?

A new referral made to the Enlarged Board of Appeal, G2/21, is expected to provide clarity and consistency on the issue of the use of post-published data in prosecution and oppositions. Post-published data (data generated after the filing date of the application, also referred to as post-filed data) are often used during examination of a patent application or during opposition of a patent before the EPO to support an inventive step of the claimed subject matter.

When filing a patent application, particularly if the subject matter is in the life sciences area, it can be tricky to decide at what point to file; data may take years to produce but filing too early can mean the application does not meet the requirements of Article 83 EPC (sufficiency of disclosure). Frequently, the same drug targets are explored by several companies at the same time, meaning there is also a level of competition and a race to be the first to file, such that applications light on data may be filed.

In the past, little clarity had existed on whether data generated after the filing date of an application could be used to support an inventive step of the claimed subject matter at the EPO. Many applications relied on a “laundry list” of uses in the application as filed, until the applicant had data to support one or more of these uses, which could then form the basis of an inventive step argument. However, in T1329/04, it was determined by the Technical Board of Appeal (TBA) that the inventive effect must be plausible from the application as filed. This means that there must be something, usually in the form of experimental data, in the application that indicates the invention does what is argued; *i.e.,* it wasn’t completely unknown at the filing date. Although the actual use may be listed in the application, such that there is basis that would satisfy Article 123(2) EPC (added matter), there may be nothing to make credible that the claimed product could actually perform that function.

Several more TBA decisions in the meanwhile have tried to clarify this further, including decisions that reinforced the fact that additional data must support what is already in the application as filed rather than be something not already contemplated; decisions that allowed additional data to be used to support a reformulated technical problem; and decisions that allowed the use of data for the rebuttal of implausibility (see below for exemplary cases).

In the present case, T116/18 (interlocutory decision found here), which is an appeal to the TBA following an opposition, the issue of post-filed data arose when the opponent alleged that some of the combinations of compounds of the claim were not plausibly synergistic based on the information in the application as filed; this synergy was arguably *only* supported by post-filed data. The TBA noted the divergence in previous case law and therefore viewed it necessary to refer questions on this topic to the Enlarged Board of Appeal (EBA) under G2/21. The TBA has put forward:

"If for acknowledgement of inventive step the patent proprietor relies on a technical effect and has submitted data or other evidence to proof such effect, such data or other evidence having been generated only after the priority or filing date of the patent (post-published data):

1. *Should an exception to the principle of free evaluation of evidence (see e.g. G 1/12 reasons 31) be accepted in that the post-published data must be disregarded on the ground that the proof of the effect rests* ***exclusively*** *on such post-published data?*
2. *If the answer is yes (post-published data must be disregarded if the proof of the effect rests exclusively on these data): can post-published data be taken into consideration if based on the information in the patent application the skilled person at the relevant date would have considered the effect plausible (ab initio plausibility)?*
3. *If the answer to the first question is yes (post-published data must be disregarded if the proof of the effect rests exclusively on these data): can post-published data be taken into consideration if based on the information in the patent application the skilled person at the relevant date would have seen no reason to consider the effect implausible (ab initio implausibility)?"*

The TBA has provided a thorough analysis on why the questions should be referred to the EBA and set out in some detail what it considers to be the three divergent strands of how plausibility is assessed at the EPO currently.

The first strand discussed (to which question 2 relates) is that of *ab initio* plausibility. This means the claimed invention must be shown to be plausible in the application as filed in order to be able to rely on further, post-published, data. In this section of the discussion, the TBA refers to 1329/04 where post-filed data could not be relied on for inventive step since it considered that nothing in the application as filed rendered the technical effect plausible.

The second strand is *ab initio* implausibility; post-filed data can be taken into account provided the technical effect is not implausible. Here, the TBA refers to T919/15 where it was stated that there was nothing in the common general knowledge to render the effect implausible so that post-published data could be considered. This strand is referred to by way of question 3.

The third strand, and the strand to which question 1 relates, is that of no plausibility; should post-filed data be able to be relied on regardless of what is or is not made plausible/implausible in the application as filed? This strand covers the situation in which a technical problem is reformulated in view of new prior art, such that there could never have been relevant data in the application.

In its summary of these strands and the need for a referral in order to establish a consistent approach to the use of post-filed data and the concept of plausibility, the TBA has described it as a scale with no plausibility at one end and *ab initio* plausibility at the other end. In other words, no plausibility could result in patent applications being filed on a speculative basis with any experimental data being present in the application as filed being essentially unnecessary, *i.e.,* potentially before an invention has been made. The other end of the scale may mean that patents are only granted with claims directed to subject matter that has been explicitly exemplified in the application as filed, and no broadening of the claims to cover other (plausible) embodiments would be allowed.

Our expectation is that the answer to the first question will be yes (inventive step should not solely rely on only post-published data; there ought to be something in the application as filed relating to the technical effect). The next two questions are to determine whether the application should contain evidence of plausibility, or merely that the technical effect should not be implausible.

We would also expect the EBA to not significantly lower the bar from where it usually sits (*i.e.,* there should be at least something in the application that makes the inventive effect credible). However, it remains a possibility that plausibility of claimed subject may be assessed under the current statute, *e.g.,* Article 83 EPC (sufficiency of disclosure). We would rather not see the bar raised such that only exemplified embodiments can be claimed; this would significantly affect applicants either in the protection they can obtain and/or mean they face a substantial

delay in being able to file an application while enough data are generated.

We would expect an answer to these questions in about 12 to 24 months, which may also mean that any prosecution or opposition that is currently pending where the applicant/proprietor is relying on the use of post-filed data to argue for an inventive step may be stayed pending the outcome of this referral. In the meanwhile, it is sensible to include as many data as possible in an application at the filing date, where this is possible.

We shall report on updates in due course, and in the meantime, please contact Alison Care with any queries - https://www.hglaw.com/our-team/alison-care/