

Post-filing data in the most recent case-law of the EPO

Can clinical trial results and other data confirming a specific technical effect of an invention be submitted after the patent application has been filed? In March 2023, the Enlarged Board of Appeal of the European Patent Office (EPO) issued a groundbreaking decision in case [G 2/21](#), setting a standard for assessing the admissibility of post-filing data.

In this edition of the Legal Report, we present the key theses presented in decision G 2/21 and then undertake an assessment of how it has influenced the EPO's further case-law over the past months.

Before the decision of the Enlarged Board of Appeal in case G 2/21

The case in which the EPO issued its groundbreaking decision concerned a dispute between Sumitomo Chemical and Syngenta. The former is the holder of European patent EP 2 484 209, which protects specific combinations of insecticides that produce a synergistic effect. The latter filed an opposition to the patent, alleging a lack of the inventive step.

The relevant opposition division dismissed Syngenta's opposition in 2017. Following its appeal, the case was referred to the Technical Board of Appeal in 2020, which in turn referred a question to the Enlarged Board of Appeal of whether data submitted after the filing date can be considered admissible in the examination ([T 116/18](#)).

In its decision to refer the question, the Technical Board of Appeal noted the discrepancies in the previous case-law with respect to the issue of post-filing data. Controversies surrounded the notion of **plausibility – i.e., the likelihood that the invention will produce the intended effect**. While not constituting a formal basis for refusing to grant a patent or for invalidating a patent already granted, plausibility was often cited in the EPO case-law in the context of the admissibility of taking into account data submitted after the filing date. We have already addressed the problem of plausibility here: [Clinical trials and the novelty of the invention](#) (our blog post from 2023).

The Technical Board of Appeal identified three strands of decisions in the EPO case-law differing in their approach to the concept of plausibility. First, there are decisions recognizing the admissibility of post-filing data provided that the technical effect combined with the technical features distinguishing the invention has been made plausible by the original application (so-called *ab initio* plausibility). Second, an alternative would be to take into account later data if there are no reasons to claim that the technical effect combined with the technical features distinguishing the invention has NOT been made plausible by the original application (so-called *ab initio* implausibility). Finally, there were certain decisions that completely rejected the concept of plausibility - according to that approach, any data confirming the technical effect of the invention may be admitted, regardless of the time from which they originate. In view of the noted divergent views, the need to unify the EPO's position became apparent.

Case G 2/21: the standard set by the Enlarged Board of Appeal

In response to the questions submitted to it, the Enlarged Board of Appeal proposed a new standard that completely rejects the notion of plausibility — which it characterized as an extralegal term devoid of specific meaning.

The main theses of the decision are as follows.

1. 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.
2. 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 should therefore be emphasised that **the Enlarged Board of Appeal opted for the broad understanding of the principle of free evaluation of evidence as precluding the rejection of certain materials solely on the grounds they were submitted after the filing date.** However, this does not mean that complete freedom is introduced in the matter of the admissibility of post-filing data. **It is made dependent on the fulfillment of a test comprising two criteria:**

- 1) A given technical effect is encompassed by the technical teaching;
- 2) A given technical effect is embodied by the same originally disclosed invention.

How to understand the concept of technical teaching? It is worth referring in that respect to the EPO publication: *Case Law of the Boards of Appeal – Case Law of the Boards of Appeal of the European Patent Office*. This document indicates that what is essential for the existence of a potentially patentable invention is the technical nature of the subject matter of patent claims. In this context specifically, mentioning a decision in case T 154/04, it defines technical teaching as “an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means”. The relationship between the two criteria is far from obvious (see more: [here](#)). As we will see below, looking at the subsequent practice of the EPO Boards of Appeal, it is the first element of the test (i.e., whether the technical effect is covered by the encompassed by the technical teaching) that is in principle decisive.

The test formulated in this way is not entirely unambiguous in itself and requires an individual assessment of each case. The decision undoubtedly opens up room for interpretation, and the Enlarged Board of Appeal has made it clear that it is aware of this level of abstraction.

The further fate of the patent held by Sumitomo Chemical

In case T-116/18, in connection with which the decision G 2/21 was issued, the dismissal of Syngenta's opposition was finally confirmed. The standard formulated by the Enlarged Board of Appeal was applied in practice for the first time, which allowed Sumitomo Chemical to effectively defend its patent EP 2 484 209. The Board of Appeal found that the inventive step as a condition of patentability may be based on a technical effect that has not been expressly indicated in the application or is not supported by the materials submitted therein. **The inventive step can therefore be established even solely on the basis of post-filing data.**

In interpreting the test proposed in G 2/21, the Board of Appeal found that the two criteria (the technical effect is encompassed by the technical teaching and embodied by the same originally disclosed invention technical instruction and embodiment of the technical effect in the claimed invention) referred in essence to one and the same feature. It underscored that the main objective of decision G 2/21 was to prevent applications for inventions that were speculative in nature.

Since then, the Boards of Appeal have issued a number of other decisions in which they have referred to the test formulated by the Enlarged Board of Appeal in G 2/21.

Decisions allowing post-filing data

There are quite a few decisions that have established the admissibility of post-filing data. Below we provide some examples:

Case T 885/21: the patent claims concerned the first medical use of an antibody-cytotoxin conjugate. The description focused on the features distinguishing the use from the prior art: advantageous homogeneity and improved stability. Materials submitted after the filing date constituted evidence confirming these very features. In the opinion of the Board of Appeal, the criteria of case G 2/21 were clearly met.

Case T 1329/21: the subject matter of the application was a cosmetic formula containing, among other things, cellulose particles of a specific size, and the description emphasised in particular increased absorbency and better spreadability. The Appeal Board had no doubt that the data submitted after the date of application in the form of a table relating to parameters such as oiliness and absorbency fell within the scope of the technical teaching. The results of the later experiment were therefore admitted.

Case T 728/21: the post-filing data in this case concerned the solubility of a tablet composition, the medical use of which in treating cystic fibrosis in certain patients was the subject of a patent application. The decision noted that the original application referred to the solubility of the tablets as an aspect of the claimed invention and described the composition of the tablets as an embodiment of that invention. The issue of dissolution was thus not, so to say, a rabbit pulled out of a hat, and the criteria in decision G 2/21 were fulfilled.

Case T 1989/19: the subject matter of the patent was crystalline thiotopium bromide, defined, among other things, on the basis of particle size and water content. It was the water content that was indicated as a property distinguishing the compound from the prior art. The patent holder, in order to confirm the inventive step, submitted data showing that this feature allows for obtaining a technical effect in the form of increased stability of the compound during storage. The opposing party claimed that such a technical effect had not been indicated in the application. The Board of Appeal found that the test from G 2/21 does not require, however, that a specific technical effect of the invention be indicated directly in the original application. In order for the test to be fulfilled, it is sufficient that there are no reasonable doubts that the reported invention will produce a specific technical effect in the light of the application filed and common general knowledge (see more: [here](#)).

Other decisions in which the Board of Appeals supported the admissibility of post-filing data include those issued in cases [T 2716/19](#), [T 2735/19](#), and [T 1445/21](#).

It is worth mentioning that in the EPO's case law there have also been decisions allowing post-filing data to be taken into account only partially. An example could be case [T 2046/21](#), where the patent application concerned a preservative-free mixture of bimatoprost and timolol for use in reducing intraocular pressure in a patient. The applicant submitted the results of the studies after the filing date and they were admitted to the extent to which they confirmed the technical effect indicated in the original application. However, the data that were supposed to refer to other effects, e.g., reducing intraocular pressure in a specific subgroup of patients, were not taken into account by the Board of Appeal.

Decisions not allowing post-filing data

It should be noted, however, that in individual cases, post-filing data have not been admitted. Based on these decisions, we are able to identify certain limitations on the possibility of relying on materials not disclosed at the time of filing for the purposes of demonstrating the inventive step. Below we cite examples of those cases.

Case [T 852/20](#): it was concluded that the technical effect achieved by using a specific crystalline form of vemurafenib (different from the crystalline form forming part of the prior art) was not covered by the technical teaching, because the relevant part of the patent description referred only to the amorphous form of the compound. Thus, it was not possible to infer from the technical teaching contained in the application that one crystalline form of the compound was superior to the other. Consequently, the specific technical effect did not translate into the existence of the inventive step.

Case [T 258/21](#): the patent application concerned the use of clevidipine in the treatment of ischemic stroke. The original application did not contain any data that would refer to a therapeutic effect — no examples, no numbers. In filing an appeal, the applicant provided such material but the Board of Appeal found that the technical effect that the applicant sought to demonstrate was in no way apparent from the application (see: [here](#)).

Case [T 887/21](#): the patent application concerned a method for preventing secondary infections following viral infections such as influenza, which would not require the use of antibiotics and would be characterized by a convenient and safe method of administration. The Board of Appeal assessed that the technical effect, which was to be proven by the submitted post-filing data, was not related to the hypothesis concerning the possible effect formulated in the application. The results of the studies referred to later by the applicant concerned the use of a method different from that originally indicated and referred specifically to the case of combating *Salmonella typhimurium* bacteria (while infections of the digestive tract were mentioned only once in the application, in a very imprecise manner). They did not therefore constitute evidence confirming the theses contained in the application but entirely new information. The invention cannot, as the Board of Appeal found, be based only on knowledge that became available after the filing date.

Case [T 1994/22](#): the application concerned a polymorphic form of the vasodilator selexipag, which is used to treat long-term pulmonary hypertension. In the opposition proceedings, the patent holder submitted post-filing data relating to a feature of the claimed polymorph that was not mentioned at all in the original application — namely, test results showing the claimed polymorph's higher photostability than the alternatives. The application referred only in general terms

to the high quality and stability of the medicinal product. The Board of Appeal found that such an imprecise formulation would not encompass a specific technical effect related to photostability. This limitation can be described as a common sense one; as the Board of Appeal itself noted, if the vague and general reference to high quality were interpreted as sufficiently broad to encompass any technical effect, the first criterion in decision G 2/21 would be devoid of any meaning (see more: [here](#)).

It is also worth emphasizing that the issue addressed in decision G 2/21 refers only and exclusively to the possibility of providing additional evidence for the purposes of assessing the inventive step, i.e., evidence confirming the possibility of obtaining a technical effect indicated in the application and constituting the essence of the examined invention. This should not be confused with the admissibility of supplementing the description of the application after it has been filed in order to meet the requirements specified in Art. 83 EPC, according to which the invention itself should be disclosed in the application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In the event that patent claims describe an invention not disclosed in the original version of the application, such deficiency cannot be remedied later, at the stage of the proceedings.

This issue is addressed in para. 77 of decision G 2/21, where we read that the possibility of relying on post-filing data is much more limited in the context of the sufficient disclosure requirement (Art. 83 EPC). As indicated by the Board of Appeal, “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”. It is underscored that the submission of post-filing data cannot remedy such a deficiency.

Conclusion

Decision G 2/21 has undoubtedly become the main point of reference for the consideration of the post-filing data admissibility. The controversial concept of plausibility has been replaced by a test which, although formally two-part, boils down to answering the question of whether a specific technical effect is encompassed by technical teaching. This term, open to interpretation in itself, requires an individual assessment of each case. In the months that followed the decision of the Enlarged Board of Appeal, there has been a string of decisions of the Boards of Appeals clarifying to some extent a standard regarding how precise the specification of the technical effect in the original application should be. The prevailing liberal approach is beneficial for patent holders because it does not require them to present explicitly a given technical effect in the application — yet, it

remains imperative that the technical effect can still be derived from the originally filed application.