

European Patent Office
Registry of the Enlarged Board of Appeal
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Case: G2/21

Referring decision: T 0116/18 dated 11 October 2021 re EP 2 484 209

Medicines for Europe

AMICUS BRIEF FOR G2/21

In its Communication concerning case G2/21 (OJ 2021, A102), the Enlarged Board of Appeal has kindly given third parties the opportunity to file written statements in accordance with Article 10 of the Rules of Procedure of the Enlarged Board of Appeal. Accordingly, Medicines for Europe hereby respectfully submits its written statement in the above captioned case.

In decision T 0116/18, the referring Board is asking the Enlarged Board of Appeal about the applicable standard of plausibility in the context of inventive step, in particular in applying the problem solution approach when formulating the objective technical problem. The referring Board indicates that the main request would not be allowable if post-published data cannot be taken into account. The referring Board has referred three questions to the EBA to ensure a uniform application of the law and because points of law of fundamental importance have arisen.

Before addressing the questions referred in detail, we would like to submit the following observations in relation to certain fundamental principles of patent law that are relevant in answering the referring Board's questions and which do not seem to be in dispute between the parties to the appeal proceedings from which the referral has arisen and in relation to which there is no divergence in the case law of the Boards of Appeal (nor national courts of the EPC member states).

Preliminary observations on fundamentals of patent law

- The patent system is based on the *quid pro quo* principle according to which the patentee is awarded an exclusive right – limited in time – in return for disclosing the invention to the public. This widely accepted principle is sometimes referred to as the “*patent bargain*”. See e.g. Lord Mansfield in 1778:

“The condition of giving encouragement is this: that you must specify upon record your invention in such a way as shall teach an artist, when your term is out, to make it - and to make it as well by your directions: for then at the end of the term, the public shall have benefit of it. The inventor has the benefit during the term, and the public have the benefit after ...”¹

- The EPO Boards of Appeal have consistently taken the “patent bargain” as a starting point for their decisions, see e.g. T0409/91 (“Fuel Oils”), in the context of art. 84/83 EPC, which has been cited by more than 100 Board decisions, 3.3 of the Reasons:

*“In the Board's judgment, this requirement reflects **the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified (see T 133/85, OJ EPO 1988, 441). This means that the definitions in the claims should essentially correspond to the scope of the invention as disclosed in the description.** In other words, as was stated in Decision T 26/81 (OJ EPO 1982, 211, point 4 of the reasons), the claims should not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art. Consequently, a technical feature which is described and highlighted in the description as being an essential feature of the invention, must also be a part of the independent claim or claims defining this invention (see also Decision T 133/85, point 2 of the reasons).”* (emphasis added)

- The EPO Boards of Appeal have equally consistently applied this “general legal principle” in the context of inventive step, and in the context of the problem solution approach in particular. See e.g. T0939/92 (“Triazoles”), which also has been cited over 100 times in later Board of Appeal decisions, 2.4.2 of the Reasons:

*“...it has for long been a **generally accepted legal principle that the extent of the patent monopoly should correspond to and be justified by the technical contribution to the art** (see T 409/91, OJ EPO , No. 3.3. and 3.4 of the reasons, and T 435/91, OJ EPO 1995, 188, reasons No. 2.2.1 and 2.2.2). Now, whereas in both the above decisions this general legal principle was applied in relation to the extent of the patent protection that was justified by reference to the requirements of Articles 83 and 84 EPC, **the same legal***

¹ Lord Mansfield in *Liardet v Johnson* (1778), quoted in Hulme, “On the History of Patent Law”, (1902) 18 LQR 280, 285, source UK Supreme Court 14 November 2018, *Warner-Lambert v. Generics (pregabalin)*, [2018]UKSC 56, par. 17.

principle also governs the decision that is required to be made under Article 56 EPC, for everything falling within a valid claim has to be inventive. If this is not the case, the claim must be amended so as to exclude obvious subject-matter in order to justify the monopoly.” (emphasis added)

- In accordance with Article 52 (1) EPC patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. Furthermore, article 52 (2) EPC stipulates that “discoveries” and “scientific theories” (sub a) and “presentations of information” (sub d) shall not be regarded as inventions.
- Within a first-to-file system, such as the EPC, there is an incentive to file patent applications early. There may also be a desire to withhold certain information from a patent application in order to prevent said information from being disclosed to the public including competitors. This needs to be adequately balanced with the interests of the public as the patent system is there to promote innovation by rewarding inventors/applicants for an actual contribution to the art in exchange for a disclosure of the invention. If there is no such balance, the “patent bargain” is not met and in the end this will stifle competition and scientific progress.
- It is a basic principle recognized in the EPC that an “*applicant should not be allowed to improve his position by adding subject-matter [i.e. presenting “new technical information”, cf. G2/10, AC] not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application (see G 1/93, OJ 1994, 541). The public may not be confronted with an extent of protection, which could not have been established by a skilled person having studied the whole content of the technical disclosure of the originally filed patent application (T 157/90, see also T 187/91).*”²
- All of the above provisions, case law and legal principles must ensure that patents are not granted based on speculation and/or “hidden” future inventions but are granted in return for a genuine technical contribution to the art which is disclosed to the public at the relevant date.

The questions referred in T0116/18

² Case Law of the Boards of Appeal, II.E.1.1, In the context of Article 123(2) EPC. The Enlarged Board has also stressed the importance of the uniform concept of disclosure in G2/10, 4.6 of the Reasons: “It is vital that a uniform concept of disclosure is applied in all these respects and that the rights of an applicant are uniformly determined in all these contexts as extending to but at the same time as being limited to the disclosure made at the relevant point in time.”

The referring Board has referred three questions to the EBA:

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)?

Framing of the questions: free evaluation of evidence

At the outset, we note that the questions are framed as an “*an exception to the principle of free evaluation of evidence*”. We submit that the (free) evaluation of evidence is not the relevant legal framework for answering the essential underlying question in the present case which is if and when a patentee may rely on post-published evidence of an advantageous effect (i.e. facts) in support of inventive step.

As held in decisions G3/97 and G1/12 the principle of free evaluation of evidence (“*freie Beweiswürdigung*”) pertains to the allowability and the relative weight of certain means of evidence as proof for a particular fact which is relied upon by a party.

In this case, the fact alleged/relied upon is that – after the date of filing – a particular technical effect allegedly occurs, such as in the current referral an experiment that has been carried out

after the priority date which shows a particular (in this case allegedly synergistic insecticidal) effect. Whether such an alleged fact can be established (proven) depends on the available evidence which must be evaluated freely indeed as per G3/97 and G1/12.

The relevant question that ought to have been asked by the referring Board is therefore under which circumstances, if at all, the (post-filing) fact of a particular technical effect occurring may be relied upon in support of inventive step (particularly in formulating the objective technical problem). This is in fact already properly noted in the referring decision itself, at point 13.3.2 of the Reasons:

*“13.3.2 The following discussion is directed at **the question of whether post-published evidence can be taken into account on substantive grounds, depending on the plausibility of the technical effect** based on the evidence submitted as proof.”*
(emphasis added)

We submit that in order for (evidence of) such a post-published effect to be potentially relevant in the assessment of inventive step (in particular in formulating the objective technical problem in accordance with the problem solution approach), that effect must have already been made plausible in the application as filed. Or, in the words of the Dutch Court of Appeal in a recent decision:

“According to the settled case-law of the Boards of Appeal of the European Patent Office and this Court, when formulating the objective technical problem, the technical effects of the invention claimed by the patentee can be taken into consideration only if, having regard to what was disclosed in the original patent application and common general knowledge, the average person skilled in the art would have found it plausible at the relevant date that those effects actually occur. This so-called plausibility requirement derives from the general principle underlying patent law that the patent protection obtained must be in accordance with, and justified by, the contribution to the state of the art actually made on the relevant date.”³

Question 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?

³ Court of Appeal the Hague 29 June 2021, ECLI:NL:GHDHA:2021:2055, par. 4.4, unofficial translation. NB the alleged effect of “*improved antimicrobial and selective*” was not part of the claims of the patent in suit. The Court of Appeal held that the application as filed did not disclose let alone make plausible to the skilled person any such effect and formulated the objective technical problems as “finding an alternative”.

As submitted above, from a dogmatic point of view this is not a matter of “an exception to the principle of free evaluation of evidence”. Nevertheless, we submit that post-published evidence must be disregarded if and when the proof of the effect (i.e. the effect which is to be taken into account for formulating the objective technical problem in accordance with the problem solution approach) rests exclusively on such post-published evidence. The question presupposes that there is no proof of the effect relied upon to establish inventive step except for said post-published evidence (“exclusively”).

Accepting the establishment of inventive step solely on the basis of post-filed facts/effects goes against the widely held and accepted principle that patent protection must be commensurate with and justified by a technical contribution to the art which is actually made (and disclosed) on the relevant date. A technical contribution that is made and/or disclosed only after the relevant date should as a matter of principle not be rewarded with a patent at or as of the relevant date. See above under “Preliminary observations on fundamentals of patent law”.

It is noted that this is especially pertinent in a first-to-file system. This is explained by the Board in T1329/04 (“Factor-9/JOHN HOPKINS”), see 10-12 of the reasons:

*“10. [...] At oral proceedings, it was argued that speculations of this kind should be permitted because of the “first to file approach” of the European patent system which forced the applicant to cover any and all subject-matter connected with its invention. The board is unable to endorse this reasoning. **On the contrary, in a first-to-file system the (earlier) filing date of the application, not the date at which the invention was made determines to whom of several persons having made an invention independently of each other, the right to a European patent belongs (cf. Article 60(2) EPC). Hence, it is particularly important in such a system that the application allows to conclude that the invention had been made, i.e. that a problem had indeed been solved, not merely put forward at the filing date of the application.** Therefore, the issue here is rather how much weight can be given to speculations in the application in the framework of assessing inventive step, which assessment requires that facts be established before starting the relevant reasoning. In the board's judgment, enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regard a specific one.*

11. [...] there is not enough evidence in the application to make at least plausible that a solution was found to the problem which was purportedly solved.

*12. [...] This approach would be in contradiction with the principle that inventive step, as all other criteria for patentability, must be ascertained as from the effective date of the patent. **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. (emphasis added)

The Enlarged Board of Appeal has also recognized (albeit a *contrario*) in the context of the uniform concept of disclosure in case G2/10 that an advantageous effect relied upon must be deducible from the application as filed, see 4.5.5 of the Reasons, second para.:

“In respect of inventive step the questions as to whether the problem has been solved over the whole breadth of the claim or whether an advantageous effect obtained by the remaining claimed subject-matter can be deduced from the application as filed may in particular become relevant.” (emphasis added)

Furthermore, one example in the case law of a patent application in the pharmaceutical field that clearly provided no contribution to the art at the relevant date can be found in the dasatinib case (T0488/16, “Dasatinib/BRISTOL-MYERS SQUIB”) in which the Board held:

“4.5 On page 50, line 4 to page 53, line 18, the application refers to assays “which can be employed in ascertaining the degree of activity of a compound (“test compound”) as PTK inhibitor” (see page 49, lines 29 to 30). The assays are generically described and refer to the “protein kinase of interest” and the “test compound” or “compounds of interest” to be assayed. No further details are provided in this respect. Nor are any results, for example IC or Ki values, provided. Indeed, there is no evidence at all in the application as filed that shows that any of the compounds falling within the scope of formula I, let alone dasatinib, is active as an inhibitor for any of the specific protein tyrosine kinases, except a mere assertion on page 50, lines 1 to 2 with reads that “Compounds described in the following Examples have been tested in one or more of these assays and have shown activity.” No further information is provided. No individual values or range of values are given. No information as to whether the observed “activity” is suitable for the intended use, i. e. the treatment of a number of diseases and disorders, is provided. In the board’s judgement, a mere verbal statement that “compounds have been found active” in the absence of any verifiable technical evidence is not sufficient to render it credible that the technical problem the application purports to solve, namely providing PTK inhibitors to treat disorders or diseases associated therewith, is indeed solved, in particular in the present case, where the invention is directed to a very broadly defined class of

compounds encompassing millions of structurally rather different candidates with unknown properties, where even the examples show a broad structural variation and where it is inherently unlikely for any skilled person that all of the compounds of the invention or at least a substantial amount of them will exhibit the alleged PTK inhibitory activity.

In the present case, there is also no evidence on file showing that, at the date of filing, the skilled person was in the possession of common general knowledge which, even in the absence of data, made it plausible that the compounds of the invention, in particular dasatinib, could be expected to show PTK inhibitory activity. The appellant's argument that a number of structurally different compounds are known as PTK inhibitors and are in clinical trials or near clinical development (see document (34), point 3 on pages 559 to page 565) is not pertinent in this context, as no conclusion with regard to PTK inhibitory activity of dasatinib can be drawn from this knowledge in the absence of any correlation between structural features and function.” (emphasis added).

We fully agree with the reasoning and the decision reached by the Board of Appeal in T0488/16 that in this case it is clear that post-published evidence could not be relied upon to support an effect of dasatinib as the effect was not made plausible in the application as filed. Absent such disclosure all that the applicant ‘contributed’ to the art was the provision of a chemical compound which was capable of being synthesized which does not require inventive ingenuity (5.7 of the Reasons).

Finally, we note that this approach is also in line with the way that patent applications are to be drafted in accordance with the EPC, in particular with the requirement to provide a detailed description of the invention including any advantageous effects (notably Rule 42 (Rule 27 EPC 1973)). This was recognized by the Enlarged Board in G2/03, 2.3.3 of the Reasons:

*“For any further state of the art of which they are not aware, they draft fall-back positions for preferred (and more preferred) embodiments. In this way the invention as set out in the specification may appear like the skins of an onion and it becomes clear where the core of the invention is. The function and interaction of the technical features also may be elucidated by comparison with the state of the art. If applicants were allowed to wait for the state of the art to emerge from search and examination and to draw any necessary consequences therefrom during examination, they could tailor the patent around the state of the art revealed in proceedings before the EPO. **The need for a detailed description of the invention from the outset as a precautionary measure would become less important and the relevance of the novelty requirement for estab-***

lishing a certain difference between the known and the patentable would be weakened. The latter argument would be even more important if an advantageous effect obtained by a new chemical substance were not considered as a part of the invention but might be shown after the filing date at any stage of the proceedings (BGH GRUR 1972, 541 - "Imidazoline"; Schulte, 6th ed. 2001, § 1 PatG, note 282 referring to the German practice and note 283 referring to the different EPO practice requiring that the technical problem can be deduced from the application as filed (T 13/84, OJ EPO 1986, 253, Reasons, point 11)). In this case the applicant would be allowed to claim a broad class of compounds with yet unknown properties, disclaim those which turn out to be known and test the rest for advantageous properties in order to base its arguments on inventive step on them."

In conclusion, in view of all the foregoing, we submit Question 1 must be answered in the affirmative: a European patent may not be granted or upheld solely based on post-published evidence in support of the allegation that a particular technical effect has been achieved, i.e. an "advantageous property has been identified", or a particular problem has been solved vis-à-vis the prior art.

Questions 2 and 3 are both dependent on the answer to question 1 ("If the answer is yes..."). These questions will be dealt with together in the below.

Question 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)?

Question 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)?

Question 2 and 3 are related. In separating these questions the referring Board draws a distinction between two hypothetical categories of plausibility and implausibility (each with its own label) which does not do justice to the fundamental principles that underly the requirement that the application as filed must disclose the contribution to the art made by the invention.

As illustrated by reference to case law above, the plausibility requirement must be met on the relevant date and – as this requirement follows from and is part of the applicant/patentee's side of the “patent bargain” – it is for the applicant to positively ensure that the disclosure of its invention is adequate.

In the language used and the two categories defined by the referring Board, this position comes closest to “*ab initio plausibility*”. Whether an alleged effect was indeed disclosed adequately in the application as filed such that later on this effect may be confirmed by post-published data cannot be assessed in the abstract and depends on all circumstances of the case, including the common general knowledge of the skilled person at the relevant date. The burden of proof lies on the party relying on the fact in question, i.e. the patentee who alleges that a particular effect is adequately disclosed in support of an alleged inventive step bears the burden of proof to demonstrate this.

In any event, the burden cannot be put on the public to provide reasons why the alleged effect would have to be considered *implausible* at the relevant date. This would not only create legal uncertainty (the patentee could come up with all sorts of alleged effects that would then have to be made implausible by a third party) but would, importantly, be incompatible with the “patent bargain” which requires the patentee to have made and to disclose its contribution to the art at the relevant date.

Based on the above, we submit that question 2 should be answered in the affirmative provided that – under the circumstances of the particular case – the alleged effect is indeed made sufficiently plausible as to ensure that “*it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve*” (T1329/04, cited above).

We submit that Question 3 has to be answered in the negative.