European Federation of Pharmaceutical Industries and Associations

Enlarged Board of Appeals

European Patent Office

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Enlarged Board of Appeal referral G 2/21

Amicus brief by EFPIA

*The **European Federation of Pharmaceutical Industries and Associations** (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. A list of EFPIA member companies and organisations can be found here: https://efpia.eu/about-us/membership/*

It goes without saying that for EFPIA it is crucial that Europe has a balanced patent system to safeguard the very considerable investment that its members make in pharmaceutical research, both in terms of providing strong patent protection for innovations and effective mechanisms for challenging invalid patents. EFPIA recognises and welcomes the central role that the EPO plays in this system, and offers the following comments to explain the views of its members on this referral to the Enlarged Board.

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1 Summary

1.1 EFPIA considers that the answer to question 1 should be "no", such that there is no need to answer questions 2 and 3. A key reason for this is because an initial assessment of plausibility before a technical effect can be relied upon for inventive step seems inconsistent with the EPO's long-standing practice of reformulation of the technical problem. We believe that this view is consistent with the EPO's approach to inventive step before T 1329/04 was decided, and indeed the approach taken in the various later decisions that have not followed T 1329/04.

1.2 To the extent that there is a need to prevent what the referring decision calls "speculative patenting" or "armchair inventions", EFPIA considers that there are already adequate safeguards under the EPO's established approach to Article 56 EPC, particularly under T 939/92, and Articles 83, 123(2) and 57 EPC etc. There is no need to create a further hurdle under Article 56 EPC (or for that matter Article 52 EPC, as mentioned briefly in the referring decision).

1.3 Nevertheless, EFPIA agrees with the case law that applies a concept of plausibility to Article 83 EPC, although it disagrees with the referring board that this requirement is necessarily the same as any corresponding requirement under Article 56 EPC. The difference arises because the technical effect that must be made plausible in an Article 83 EPC context is a feature of the claim, e.g. the disease to be treated in a second medical use claim. EFPIA considers that the EPO should continue to apply its established case law in this context on a case-by-case basis, e.g. the approach developed in the T 609/02 line of case law.

1.4 Although EFPIA sees this difference between Articles 56 and 83 EPC, if the Enlarged Board takes the view that the same standard should apply to both articles, then EFPIA considers that it is important not to remove the safeguard against speculating patenting that is provided under Article 83 EPC from decisions like T 609/02. As explained below, this safeguard is particularly important because of the link between Article 83 EPC and the enablement of prior art for the purposes of Article 54 EPC. Accordingly, if the Enlarged Board takes the view that a common standard of plausibility should apply to both Article 56 and 83 EPC, then EFPIA believes that the common standard should be set at the level of what the referring board calls "ab initio implausibility".

1.5 As a final point, EFPIA has concerns about the wording of the questions that the Enlarged Board has been asked to consider, e.g. in terms of the relevant date for assessing plausibility, and the extent to which this assessment relies "exclusively" on post-published evidence. We trust that the Enlarged Board will clarify these points if they are addressed in its decision.

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2 "Plausibility" under Article 56 EPC

2.1 The referred questions are framed narrowly in terms of the evidence that can be relied upon under Article 56 EPC. However, the referring decision covers a broader range of issues under Articles 56 and 83 EPC, e.g. "plausibility" and "speculative patenting". Before discussing these issues below, two important points need to be borne in mind.

2.2 The first is that **there is no single concept of "plausibility" in the EPO's case law**, and EFPIA considers that it would be unhelpful to try to find one that applies to all of the different scenarios where such concepts may arise. For example, the two decisions that the referring board cites for first raising these concepts under Articles 56 and 83 EPC (T 1329/04 and T 609/02[1]) do not propose identical legal tests, or even particularly similar ones. T 1329/04 talks about whether "*there is enough evidence in the application to make at least plausible that a solution was found to the problem which was purportedly solved*" in the context of inventive step[2], while T 609/02 does not use the word plausible[3], and instead sets out a specific test for determining whether a second medical use is sufficiently disclosed ("*It is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se*"). These different considerations reflect the different legal purposes of the two articles, and **these different concepts raised in the case law should not be approximated into a single notion of "plausibility"**. This would be an over-simplification of what are complicated areas of patent law.

2.3 The second point that EFPIA would like to emphasise is that T 1329/04 and T 609/02 attracted a lot of attention when they were issued in the mid-2000s for representing possible changes to the EPO's approach to Articles 56 and 83 EPC respectively, if they were followed in subsequent cases. Focusing for now on T 1329/04 and Article 56 EPC, EFPIA shares the referring board's concern in reason 13.7.1 that **requiring plausibility of a proposed technical effect based on information in the application as filed and the common general knowledge (only) seems incompatible with the decades of case law that has allowed reformulation of the technical problem**. The referring board refers to decisions T 31/18 and T 2371/13 for highlighting this incompatibility[4], which arises because a newly invoked technical effect to support a reformulated technical problem is unlikely to be supported by data in the application as filed (the relevant comparative tests would not have been carried out before the filing date). But reformulation has been a feature of EPO practice since its earliest days[5], and **EFPIA strongly believes that it would be**

[1] See reasons 13.4.1 and 13.4.2 of the referring decision.
[2] Reason 11.
[3] This word is only found in a summary of the appellant's position, see reason 10.
[4] See reasons 13.6.1-13.6.2.
[5] The board refers to T184/82 from 1984, for example.

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wrong to limit the ability of applicants to propose new technical effects to support their inventions, e.g. in response to new prior art. The 40+ years of case law that has developed this concept of reformulation and set out its limits already strikes the right balance. It should not be disturbed.

2.4 On the other hand, the policy rationale behind T 1329/04's expectation that an application makes its claimed solution "plausible" is understood. In the referring board's words, it is "*to prevent purely speculative claiming and thus to safeguard a balance between the actual technical contribution and the patent monopoly defined by the claims*"[6]. EFPIA agrees with this aim, but believes that existing safeguards are adequate, without needing to introduce a further requirement for "plausibility" into Article 56 EPC. In particular, the older line of case law based on T 939/92 already goes a long way towards achieving this aim, and EFPIA considers that **this T 939/92 case law sets out the correct approach for assessing whether a technical effect can be relied upon to support an inventive step**. Indeed, many of these decisions based on T 939/92 are expressed in terms of "plausibility", "credibility" and similar terms, although the Enlarged Board will appreciate that they are referring to a different concept from the "plausibility" in T 1329/04[7].

2.5 EFPIA's position is therefore that the EPO should continue to apply the long-established requirement from the T 939/92 line of case law for any technical effect that is relied upon to support an inventive step. This requirement is expressed in section I.D.4.3 of the *Case Law of the Boards of Appeal* in terms of "*When defining the objective technical problem an effect cannot be retained if it is not **credible** that the promised result is attainable throughout the entire range covered by a claim (T 741/91; T 626/90; T 939/92, OJ 1996,309; T 583/93, OJ 1996, 496).*"

2.6 The same requirement that **the proposed technical effect must be credibly achieved across the entire scope of the claims** should be applied to <u>all</u> such technical effects, whether they are proposed in the application as filed, or proposed for the first time during examination or opposition proceedings (e.g. as part of a reformulation of the technical problem in light of new prior art, as discussed above).

[6] Reason 13.4.1.

[7] The concept in T 939/92 is the plausibility of there being a technical effect <u>across the scope of the claims</u>, whereas the concept in T 1329/04 is usually the plausibility of there being <u>any</u> technical effect for even a <u>single</u> embodiment within the scope of the claims.

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What evidence can be used to prove a technical effect?

2.7 T 939/92 requires the EPO to assess whether, on the balance of probabilities, the proposed technical effect is achieved across the scope of the claims. In order to meet this standard, the applicant is able to refer to any type of evidence that supports the proposed technical effect, whether that evidence is in the application as filed or is provided to the EPO after the application has been filed, and whether that evidence was generated before or after the filing date. Similarly, the EPO or third parties challenging the existence of the technical effect should be able to refer to any type of evidence, of any date[8]. In the words of the referring decision, this means that "post-published evidence" can be used without restriction, and thus **EFPIA considers that the first question should be answered "no"**.

2.8 The referring decision discusses possible forms of evidence to support a proposed technical effect in reason 13.4, namely experimental data and scientific explanation. For the avoidance of any doubt, EFPIA considers that there should be no restrictions in this regard either. Non-exhaustive examples of suitable evidence to support a proposed technical effect (whether provided in the application as filed or after the application has been filed) therefore include the results of physical experiments ("wet data"), the results of *in silico* experiments/modelling, and rational explanations based on established scientific principles and/or information in the prior art.

2.9 As discussed above, EFPIA considers that this approach from T 939/92 already provides significant protection against "speculative patenting" or "armchair inventions". In particular, it prevents patents for inventions that do not provide an inventive technical effect, while allowing patents for inventions that were shown or correctly predicted in the application as filed to provide an inventive technical effect. Further safeguards are provided by Articles 83 (see below), 123(2) (with its many restrictions on what can actually be claimed based on the text of an application as filed), and 57 (the need for an invention to be susceptible of industrial application) etc. Accordingly, **there is no need to create a further hurdle of "plausibility" under Article 56 EPC**. On this point, we agree with the concern raised in reason 13.7.4 of the referring decision that it is "*questionable whether Article 56 EPC is a proper legal basis for plausibility*". For the avoidance of any doubt, we also think that this is true of Article 52 EPC, which is mentioned later on in reason 13.7.4, and is similarly silent on a requirement for plausibility.

[8] This "equality of arms" is important. The referring board alludes to a need for equal treatment in reason 11.3 of its decision.

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The referred questions can be answered, but they are unclear in various ways

2.10 As noted above, in response to the specific questions raised by the referring board, EFPIA therefore considers that the answer to the first question in the context of Article 56 EPC should be "no", which means that there is no need to answer questions 2 and 3. However, the questions are unclear in various respects, and EFPIA therefore urges caution if the Enlarged Board chooses to answer them directly.

2.11 For example, the use of "exclusively" in the first question[9] is unclear: did the referring board intend to exclude from the Enlarged Board's analysis situations where there is at least "partial" proof of the technical effect in the application as filed? If so, then how does this concept of partial proof in the application as filed differ from/overlap with the concepts of ab initio plausibility and ab initio implausibility in the second and third questions? The references to "proof" in this context are also unclear: what standard of proof is being applied, and does the referring board have in mind all of the evidence that proves the alleged fact, or merely the evidence that tips the assessment over the relevant standard of proof?

2.12 The words "plausibility" and "implausibility" in the second[10] and third[11] questions are also open to interpretation. As noted above, a concept of "plausibility" *per se* is not found in any of the articles of the EPC, and the referring board's attempt to subdivide this concept into "ab initio plausibility" and "ab initio implausibility" is sometimes difficult to reconcile with the facts of the underlying case law. A good example of this difficulty can be seen from T 1329/04, which the referring board proposes as the leading case with an "ab initio plausibility" standard. As the referring board summarises, the application in T 1329/04 was refused because "*the board in question noted that GDF-9 did not have the structural features generally accepted for members of the TGF-β superfamily*". However, this fact that the claimed product lacked the common feature that would have established it as a member of a known group sounds much more like an example of ab initio implausibility than a failure to establish ab initio plausibility. Given the highly fact-specific nature of many of these discussions, the dividing line between "ab initio plausibility" and "ab initio implausibility" may not be so clear in practice, and there are probably elements of both standards in

[9] 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?

[10] 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)?

[11] 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)?

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most decisions. Indeed, the possible overlap between these standards might explain what the referring board discusses in reason 13.5.4: "*some of the decisions discussed above that apply the ab initio implausibility standard contain statements according to which they do not contradict T 1329/04, i.e. a decision considered by the current board to apply the ab initio plausibility standard*". In other words, the boards who are said by the referring board to have applied a different standard compared to T 1329/04 themselves felt that they were applying the same standard. Accordingly, if the Enlarged Board endorses any concepts of "plausibility" and/or "implausibility" in its decision, then it is requested to explain exactly how they should be assessed.

2.13 Finally, EFPIA is not convinced that the referring board has fully addressed the appellant's concern discussed in reason 15 that "*the questions should define the effective date more clearly. For example, in case of a patent claiming priority, it should be indicated whether the relevant date was the priority or the filing date*". Questions 2 and 3 refer to an assessment of whether the skilled person at the filing date would have considered the effect plausible or implausible. But this formulation leaves open the question of whether the plausibility (or lack of implausibility) should be assessed as of the priority date if the applicant is relying on that earlier date for patentability. EFPIA considers that any such requirement for plausibility/lack of implausibility under Article 56 EPC as of the priority date would go beyond the requirements of Article 87 EPC already set out by the Enlarged Board in G 2/98, but this issue should be addressed if the Board proceeds to answer questions 2 and 3 in this referral.

3 "Plausibility" under Article 83 EPC

3.1 The questions that have been referred to the Enlarged Board are limited to inventive step under Article 56 EPC. Nevertheless, the referring board discusses various decisions under Article 83 EPC, where concepts of "plausibility" are also sometimes raised. The Enlarged Board may therefore feel the need to comment on Article 83 EPC as well. For the avoidance of any doubt, EFPIA considers that **the EPO's current case law under Article 83 EPC already strikes the right balance when it comes to concepts of "plausibility" in the context of sufficiency**, and provides an important safeguard against speculative patenting. However, the standards set by this case law do not fit neatly into the referring board's concepts of "ab initio plausibility" of "ab initio implausibility". This is illustrated by the comparison in paragraph 2.2 above of the inventive step test in T 1329/04 with the sufficiency test in T 609/02. T 609/02 is clearly discussing a concept related to "plausibility" in the sense of T 1329/04, but it is a narrower concept focused on the particular requirements of second medical use claims. This narrower focus in T 609/02 is a common feature of case law under Article 83 EPC, which tends to relate to specific issues arising from different types of claim or different types of invention. In contrast, decisions like T 1329/04 under Article 56 EPC deal with a concept that applies to all claims and inventions, namely the definition of the technical problem that is always required as part of the problem-solution approach.

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3.2 Looking at the referring board's reasons in more detail, it drew its parallel between Articles 83 and 56 in reason 13.3.1 on the basis of the statements in G 1/03 about technical effects that are either recited in the claim (in which case the achievement of the effect is a matter for Article 83 EPC) or not recited in the claim (in which case it is a matter for Article 56 EPC, as dealt with in our comments above). **For technical effects that are recited in the claims**, EFPIA again considers that these situations are already adequately dealt with by existing case law under Article 83 EPC, and so there is no need to set further requirements. It is better for the boards to continue to deal with these situations on an issue-by-issue basis (like in T 609/02), because sufficiency of disclosure is dependent on the precise nature of the claims and the technical facts involved. It is difficult and potentially unhelpful to try to identify criteria that apply in all situations.

3.3 Indeed, T 609/02 is a good example of this settled case law under Article 83 EPC, relating to a common type of claim that recites a technical effect (the disease to be treated in a second medical use claim). EFPIA considers that the EPO should continue to apply the long-established requirement from the T 609/02 line of cases for these technical effects[12]. This case law does impose a limitation on the free evaluation of evidence that can be relied upon to support the claimed technical effect. In the words of the *Case Law of the Boards of Appeal*, the technical effect must first be rendered "technically plausible" by the application as filed before post-published evidence may be taken into account to confirm that the technical effect can be achieved. However, it is again important to note that this requirement to be "technically plausible" does not necessarily fit neatly into the concepts of "ab initio plausibility" and "ab initio implausibility" set out in the referring decision. As we have already seen, the test as it was originally worded in T 609/02 is set out in a specific way, reflecting the particular type of claim and the technical facts involved.

3.4 It follows from the above that EFPIA considers that **it is correct to treat Article 83 EPC and Article 56 EPC differently**, imposing a limitation on the evidence that can be used to support a technical effect under Article 83 EPC, but not under Article 56 EPC. This difference arises from the fact highlighted in G 1/03 that the technical effect is a limiting feature of the claim when the issue is dealt with under Article 83 EPC, whereas it is not a limiting feature under Article 56 EPC. This makes a significant difference to how the patentability of the claim is assessed overall. In particular, by virtue of being a limiting feature, a technical effect that is recited in a claim defines the scope of protection, excluding embodiments that do not possess the claimed technical effect. This means that the claim is no longer open to challenge under the T 939/92 line of case law discussed above: the technical effect is by definition achieved across the scope of the claim because it is a functional

[12] E.g. as expressed in section II.C.7.2 of the Case Law of the Boards of Appeal: "*If a therapeutic application is to be accepted as sufficiently disclosed, the application or the patent, respectively, and/or the common general knowledge has to provide some information rendering it* ***technically plausible*** *for the skilled person that the claimed compounds can be applied for the claimed therapeutic use (T 1599/06 citing T 609/02). Post-published evidence may be taken into account, but only to back-up the findings in the application in relation to the use of the compound(s) as a pharmaceutical (T 609/02, T 950/13).*"

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requirement of that claim[13]. Given this advantage under Article 56 EPC, and to ensure that the scope of protection is commensurate with the application's contribution to the art, it makes sense for Article 83 EPC to require the technical effect to have been established in the application as filed, or made "technically plausible" in the words of the *Case Law of the Boards of Appeal* passage discussed above.

3.5 There is another important reason why Articles 83 and 56 should be treated differently in this regard. This reason arises from the fact that sufficiency of disclosure under Article 83 EPC is directly linked to the concept of "enablement" under Article 54 EPC. This link is particularly relevant to the second medical use situation considered in the T 609/02 line of case law. If there was no requirement to make the claimed medical use "technically plausible" in the application as filed under Article 83 EPC, then logically there would be no requirement for it to be plausible in the prior art either, for that prior art to be novelty-destroying for the medical use. Clearly, this approach would represent a major change to the EPO's practice under Article 54 EPC, where an unsupported disclosure of a medical use in the prior art is not considered to be novelty-destroying[14].

A possible alternative approach

3.6 For these reasons, EFPIA considers that it is correct to treat Article 83 EPC and Article 56 EPC differently when it comes to these issues of "plausibility" of technical effects. Nevertheless, if the Enlarged Board does not agree and instead determines that the same standard must be applied to technical effects whether they are recited in the claim (Article 83 EPC) or not recited in the claim (Article 56 EPC), then EFPIA considers that the **same limitation** on the free evaluation of evidence should apply in both situations. In other words, the suitability of the invention to achieve the technical effect should be made plausible in the application as filed before post-published evidence may be taken into account. However, in order to ensure a degree of balance between: 1) the need of applicants to be able to reformulate the technical problem in light of cited prior art (Article 56 EPC); and 2) the need for patent applications or prior art documents to disclose the suitability of an invention to achieve a claimed technical effect (Articles 83 and 54 EPC), the EPO should assess this plausibility requirement by determining whether, on the balance of probabilities, the skilled person would not have considered that the effect could not be achieved based on the information in the application and their common general knowledge.

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[13] See, for example, T5/06 for this principle being applied to a second medical use claim: "*In [T 939/92] the claims under consideration related to a group of chemical compounds "per se", ie the effect is not expressed in a claim. To that extent, this decision did not apply to the present case, which relates to a use claim.*"

[14] E.g. as expressed in section I.C.4.11 of the Case Law of the Boards of Appeal: "*for the requirement of reproducibility to be considered as fulfilled in relation to a medical use it is necessary that the disclosure in the prior-art document is such as to make it **credible** that the therapeutic effect on which the disclosed treatment relies can be achieved (T 609/02).*"

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3.7 In other words, if the Enlarged Board does not agree with EFPIA's view that it is right to treat Article 83 EPC and Article 56 EPC differently, then the Board should endorse the "ab initio implausibility" approach outlined in the referring decision, which allows post-published evidence to be taken into consideration if, based on the information in the application as filed and the common general knowledge, the skilled person at the relevant date would have seen no reason to consider the effect implausible.

EFPIA, 29th April 2022

Yours faithfully,

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