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Institute of Professional Representatives before the European Patent Office
Institut des mandataires agréés près l'Office européen des brevets

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Ausschuss für Europäische Patentpraxis
European Patent Practice Committee
Commission pour la Pratique du Brevet Européen

22nd April, 2022

The Enlarged Board of Appeal
Richard-Reitzner-Allee 8,
85540 Haar
Germany

Attention: Mr. Nicolas Michaleczek

via email: EBAamicuscuriae@epo.org

Dear Sirs,

Re: Enlarged Board of Appeal Case: G 2/21
Referring Appeal No. T 0116/18-3.3.02
EP-B 2 484 209
EP Application No. 12 002 626.5
Sumitomo Chemical Company Limited
Opponent: SYNGENTA LIMITED

INTRODUCTION

The present amicus curiae brief is filed on behalf of the Institute of Professional Representatives before the European Patent Office ("**epi**"). **epi** represents all 13,000 professional representatives from all the EPC member states. They represent a wide variety of users of the EPO, from individual inventors to multinational corporations.

epi presents this amicus curiae brief for the assistance of the Enlarged Board and would be pleased to provide any further explanation as would assist the Enlarged Board in considering the referred questions.

THE REFERENCE

Technical Board of Appeal 3.3.02 has referred three questions to the Enlarged Board of Appeal on the topic of "plausibility". The referred questions are set out below.

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)?

THE REFERRED QUESTIONS SHOULD BE REFORMULATED

epi considers that the questions formulated by the referring Board need to be reformulated, for the reasons set out below. In particular, **epi** considers that the first question does not clearly address the points the referring Board makes in the referring decision (see below) and this then leads to difficulty in addressing the second and third questions. **epi** sets out its suggestion for questions which could usefully be considered by the Enlarged Board.

Question 1 in the referring decision refers to the free evaluation of evidence. **epi** submits that this is **not** relevant to the points raised by the referring Board. **epi** is of the view that, at all instances of the EPO, free evaluation of evidence should be the rule and there should be no exception.

In fact, if there were any exception to this rule, it may deprive the instances of the EPO of an opportunity to deal expeditiously with a case. For instance, in a case where an applicant or proprietor has filed post-published evidence in an attempt to support a technical effect, it may be the case that, on a free evaluation of the post-published evidence, it is decided that it does not support the technical effect. In such a case, an instance at the EPO could rapidly move through the problem-and-solution approach by adopting a less ambitious problem. If that instance of the EPO were deprived of the opportunity to evaluate the post-published evidence freely, that instance would be unable readily to say that there was no technical effect, which would perhaps mean that the instance would have to assess plausibility before deciding that the evidence did not support the technical effect.

For instance, in the present case, if the Board had evaluated D21 and decided that it did not show a synergistic effect, the Board could readily have dealt with the remainder of the problem-and-solution approach. Thus, **epi** submits that, at every instance of the EPO, it should be allowable to evaluate any evidence presented to that instance to determine whether it is persuasive.

It is therefore considered that the questions should not be premised on present Question 1. Rather, to provide clear guidance to the users of the European patent system, the questions should start from the premise that post-published evidence must be evaluated to decide whether the technical effect actually occurs and should then ask whether the acceptance of this proof in the examination of the relevant grounds of patentability should be contingent on any “plausibility” considerations.

It is also considered that the second and third questions only follow on logically from the first question if each of them begins “Nevertheless, if …”. Without such wording, it is not possible to give a sensible answer to these questions.

epi suggests that the questions should be along the lines of:

1. Where post-published evidence filed in connection with a patent application or a patent granted on that application is found to provide proof of a technical effect, and the proof of the technical effect relies **exclusively** on the post-published evidence, **must** the evidence be taken into account in the examination of inventive step?

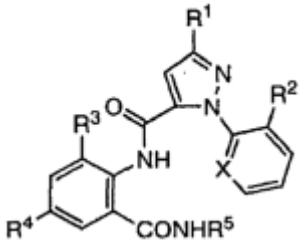
2. If the answer to Question 1 is "no", **must** the evidence be taken into account if, based on the information in the patent application or the common general knowledge, the skilled person at the filing date of the patent application would not have considered the effect implausible (*ab initio* implausibility)?

3. If the answer to Question 2 is "no", **must** the evidence be taken into account if, based on the information in the patent application or the common general knowledge, the skilled person at the filing date of the patent application would have considered the effect plausible (*ab initio* plausibility)?

THE UNDERLYING CASE

The specific case concerns EP 2 484 209 B1 which was opposed. The decision of the Opposition Division was appealed. This appeal gave rise to the reference.

The claim in suit, so far as it is relevant for this brief, reads as follows:

> "An insecticide composition which comprises thiamethoxam and one or not less than two kinds of compounds being selected from a compound represented by the formula [Ia]:
>
> 
>
>
> [Ia]
>
> wherein R^1 is a halogen atom or a C_{1-6} haloalkyl group, R^2 is a halogen atom, R^3 and R^5 each are a C_{1-6} alkyl group, R^4 is a hydrogen or halogen atom, and X is N, or a salt thereof."

The patent acknowledges that both thiamethoxam and the compounds according to Formula Ia are known insecticides. The patent states that the inventors have found that mixtures of thiamethoxam and compounds according to Formula Ia can produce an insecticidal activity which is greater than that which would have been expected based on their respective individual activities. Thus, the patent asserts that there is a synergistic effect.

During the appeal proceedings, various documents were filed and there were arguments as to whether any of these documents should be admitted. Those arguments are not relevant to the referred Questions. The referring Board also dealt with objections of lack of sufficiency and lack of novelty. Those are also not relevant to the referred questions. In the referring decision, the Board did not decide on objections of lack of inventive step and was of the view that it could only do so after the referred Questions have been answered by the Enlarged Board.

According to the referring decision, when considering the question of inventive step, it was common ground between the parties that D4 is the closest prior art. The claim differs from D4 in that

thiamethoxam has been selected from a broader teaching in D4 and the compounds according to Formula Ia have been selected from a different broader teaching in D4.

The next step in the problem-and-solution approach was to ascertain whether this difference leads to a technical effect. The Proprietor asserted that D21 (post-published evidence) showed there is synergy between thiamethoxam and the compounds of Formula Ia. The Opponent asserted that D21 did not provide valid proof of a synergistic effect. The Board sided with the Proprietor, acknowledging that D21 did provide the requisite proof.

The referring Board had studied the case law and had come to the conclusion that there were three possible ways of determining whether such post-published evidence could be taken into account. The referring Board referred to these as "*Ab initio* plausibility", "*Ab initio* implausibility" and "No plausibility". The lines of case law referred to in connection with these ways are discussed below.

***Ab initio* plausibility**

The referring Board acknowledged that, according to T1329/04, T609/02, T 488/16, T 415/11, T1791/11 and T 895/13 and T433/05, it is a precondition for taking into account post-published evidence that the application as filed together with the common general knowledge at the filing date made it plausible that the effect was obtained.

***Ab initio* implausibility**

The referring Board also acknowledged that, according to T 919/15, T578/06, T536/07, T 1437/07, T266/10, T863/12, T 184/16 and T 2015/20, post-published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent application.

No plausibility

The referring Board also acknowledged that, according to T 31/18 and T 2371/13, post-published evidence can be relied on whether or not the technical effect relied on is made plausible or is not implausible on the basis of the application as filed and the common general knowledge.

The referring Board felt that it was necessary for the Enlarged Board to decide which of these lines of case law should be followed and therefore submitted to the Enlarged Board the three Questions set out above.

Further considerations

The referring Board also put in some details about other considerations which could have an effect on the answers the Enlarged Board gives to the questions. The referring Board refers to:

> "speculative patenting" or "armchair inventions";
>
> the problems which can arise where the citation of a new piece of art can lead to a requirement for reformulating the objective technical problem, referring to 1397/08, T 184/82 and T 1422/12; and
>
> the tension between plausibility and free evaluation of evidence, referring to G3/97 and G 1/12 as well as articles by R Jacob and A Slade.

IS THE REFERENCE ADMISSIBLE?

Article 112 (1) EPC provides that:

> "In order to ensure uniform application of the law, or if a point of law of fundamental importance arises: (a) the Board of Appeal shall … refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes …".

It is also well accepted that a question can be referred if the case under consideration by the referring Board can only be decided once that question has been answered.

A decision on the referred questions is not decisive to the outcome of the case

epi considers that a decision on the referred Questions is **not** decisive for the outcome of the case.

The referring Board states:

> "For a referral to be admissible, it is generally considered necessary that the decision on the referral questions be decisive for the outcome of the referral case" (reasons 11.2); and
>
> "The outcome of the referral is decisive for the case at issue since whether post-published evidence D21 can be taken into account depends on this outcome, and since, furthermore, as has been set out above, if taken into account, D21 is relevant to a final decision on inventive step" (reasons 14).

However, the Board's analysis only establishes that a decision on inventive step will be decisive for the outcome of the case and that D21 is relevant to the decision on inventive step: if D21 is taken into account, inventive step can be acknowledged; if D21 is not taken into account, inventive step can be denied.

The Board does not explain why the decision whether or not to take D21 into account depends on the answers to the referred Questions. To do this, the Board would have needed to evaluate whether D21 would have been taken into account when applying one of the approaches to plausibility identified by the Board ("no plausibility", "*ab initio* plausibility" or "*ab initio* implausibility") but not the others. Evidently, if D21 is to be taken into account under each one of the three plausibility approaches, or if D21 is to be excluded from consideration under each one of the three approaches, then the question of which approach to apply has no relevance.

It is **epi**'s view that D21 needs to be taken into account under all three approaches. In particular, when applying the most restrictive one, *ab initio* plausibility, the application as filed demonstrates, in Test Examples 2 and 5, that the combination of thiamethoxam with compound I-1 or with compound I-4 acts synergistically against respectively *Spodoptera litura* and *Plutella xylostella* (reasons 12.4.1). These two insect species are listed in paragraph [0058] of the patent alongside *Chilo suppressalis*, which has been tested in D21, and all three species are said to belong to the same order *Lepidoptera*. Moreover, Tables 3 and 4 of the patent demonstrate, respectively, that Compound I-6 (also covered by claim 1) or Compound I-1, in combination with clothianidin, act synergistically against *Chilo suppressalis*. Paragraph [0003] of the application as published identifies clothianidin as belonging to the same neonicotinoid compound class as the claimed thiamethoxam.

Consequently, from the information included in the application as filed and the skilled person's common general knowledge, it would have been plausible that the combination of thiamethoxam and a compound of Formula Ia would also act synergistically against *Chilo suppressalis*, given that it does so against two other species from the same order *Lepidoptera*, and given that two compounds covered by Formula Ia act synergistically against *Chilo suppressalis* when combined with another neonicotinoid, clothianidin.

D21 thus needs to be taken into account under the *ab initio* plausibility approach. The other two approaches are more relaxed and so D21 would also need to be taken into account when they are applied. Hence, whichever way the referral goes, i.e. whichever plausibility approach is held to be the correct one, D21 must be taken into account and inventive step must be acknowledged. This, in effect, means that the decision on the referral Questions has no impact on, and thus cannot be decisive for, the outcome of the referred case.

THERE IS NO DIVERGENCE IN THE CASE LAW

The decisions referred to by the Board where the '*ab initio* plausibility' criterion had been applied concerned the situation where the technical problem solved by the invention had not been reformulated. The patent applications asserted that a certain effect had been achieved and the question was whether this had been made 'plausible' by the application as filed in view of the common general knowledge. The decisions relate to classic examples of (very) broad claims supported only by vague, if not speculative, descriptions.

On the contrary, the decisions referred to by the Board where the '*ab initio* plausibility' criterion had not been applied concerned the situation where the technical problem required reformulation in an objective manner in view of a new document as the closest prior art and therefore a new distinguishing feature.

It is submitted that the second line of decisions does not contradict the first line of decisions. It is settled case law of the Boards of Appeal that the definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting one forward, requires that it was at least made plausible by the disclosure in the application as filed that its teaching indeed solved the problem it purported to solve; see e.g. T 1329/04. The situation where the application as filed "purports to solve" a certain technical problem is obviously the one where the definition of the technical problem has not been changed. In such cases, the onus is understandably on the applicant in the first place to show that the problem is indeed solved, in particular when a very broad claim (sometimes covering thousands of compounds) is supported by almost nothing in the description.

On the contrary, when the objective technical problem requires reformulation (but still within the scope of the original invention), for example in view of a document of which the applicant was unaware being cited as the closest prior art in the problem-and-solution approach, it is considered that an applicant should not be barred from presenting post-published evidence in support of his argument that the reformulated problem is actually solved[1]. Doing otherwise would mean that an applicant would have to anticipate any potentially differentiating features over a myriad of unknown prior art documents in order to provide at least some indications of plausibility in the application as filed, which is obviously impossible. It is submitted that the second line of case law is a very sensible approach to how to deal with post-published evidence in support of a technical effect in the situation where the proprietor is confronted with a reformulated objective technical problem. It should be more liberal than in situations where the applicant could and should have made the technical effect plausible at the filing date.

It is also submitted that there should be no distinction between types of invention. Depending on the technical field 'armchair inventions' are perfectly fine as long as the absence of specific examples

[1] In this respect, it is noted that an opponent or a third party can file documents allegedly showing that the technical effect is not achieved or cannot be achieved across the scope of the claim or that the effect has already been achieved, and it would seem to be unfair that an applicant or patent proprietor cannot respond to such filings by providing evidence of their own.

does not make the invention impossible to reproduce, even without any further explanation of how and why the invention works. As long as the invention does work and the skilled person is sufficiently enabled to work the invention based on the information in the application as filed, there is no reason to demand more from an applicant. However, claims covering a huge number of compounds that allegedly all solve the technical problem are suspicious right from the outset, at least when related to a biological effect. In such cases, it is appropriate to demand more from an applicant in order properly to support the assumption that the claimed effect really occurs over the entire scope.

epi therefore fails to see diverging case law of the Boards of Appeal in this respect. The Boards apply the case law consistently and on the basis of their technical evaluation of the facts of the case in question.

epi therefore considers that the referral is inadmissible.

PLAUSIBILITY IS NOT A VALID REQUIREMENT

Were the Enlarged Board to disagree with the above views, **epi** requests that the following comments are considered.

The basis for all the Questions is the tendency for some Boards to adopt a "plausibility" requirement when determining whether a claim involves an inventive step[2]. However, as noted in the referring decision, some Boards have said that there is no need for any sort of "plausibility" requirement. **epi** is of the view that there should be no "plausibility" requirement, for the following reasons.

There should be no "plausibility" requirement

The *quid pro quo* principle underpinning the patent system is that an exclusive right limited in time is granted in exchange for the disclosure of the invention. On publication of an application, the public receives the knowledge of the invention from the application as filed and is informed, either explicitly or implicitly, of any technical effect the invention may display vis-à-vis the closest prior art. The public may be supplied with proof of this effect, for instance in the application as filed or in the public file for the application or the granted patent if evidence is filed after the filing of the application. Assuming that the application meets all the relevant requirements of the EPC (Articles 52, 54, 56, 57, 83, 84 and 123 EPC), and the invention is not excluded from patentability (Article 53 EPC), it is granted as a patent. Importantly, the claimed subject matter must have been disclosed in the application as filed, otherwise Article 123(2) EPC would prevent the applicant from claiming it.

The evaluation of inventive step (Article 56 EPC) before the EPO assumes that a technical feature distinguishing the invention from the closest prior art is associated with a technical effect and requires that such a technical effect is not only alleged but also demonstrated. In the vast majority of cases, this does not lead to any particular complications. For example, the technical effect may be apparent from the nature of the technical feature or the application as filed may contain data demonstrating the technical effect vs. the closest prior art.

The question arises of how to approach inventions where the application as filed does not contain proof of the technical effect. A radical approach could be to deny any reliance on the existence of

[2] It is noted that if something is implausible, that shows that it is inventive. The more plausible something is, the less likely it is to be inventive. It therefore seems odd to talk about requiring plausibility to show inventive step. It would seem that plausibility should relate only to sufficiency of description.

the technical effect, leading to the formulation of a less ambitious objective technical problem and a higher likelihood of the invention being found obvious.

Such an extreme approach is not followed by the EPO for good reasons, a principal one being that the technical effect needs to be demonstrated vis-à-vis the closest prior art, which may not be known when the application is filed and which may change, even repeatedly, during prosecution of the application and opposition against the granted patent. It would be unfair on the applicant if evaluation of inventive step did not allow for the opportunity to demonstrate a technical effect of the invention vis-à-vis the closest prior art and to reformulate the objective technical problem after the effective date of a claim. This is commonly done by submitting post-published evidence proving the technical effect.

Moreover, the application as filed should disclose, at the filing date, the use to which the invention will be put, if this is not clear or implicit from the application, and should refer to the technical effect which the invention achieves vis-à-vis the closest prior art, thus showing that it solves an objective technical problem. In many cases, the application provides examples where the fact that the technical effect is achieved is demonstrated. It is only in cases where the evidence in the application is absent or inadequate that proof of the technical effect may need to be provided later.

It is often the case that, during prosecution of an application or an opposition, prior art is raised of which the applicant was unaware when drafting the application. This new prior art may be used to attack inventive step. In order to allow an applicant to deal with such new prior art and a new inventive step argument based on it, it is well-accepted practice that the applicant or proprietor is allowed to reformulate the objective technical problem. Generally, the reformulated problem must be based on, or at least closely related to, the disclosure in the application as filed. It is often said that the newly formulated objective technical problem must be within the spirit of the invention as originally disclosed (see reasons 13.7.2)[3].

The requirement for "plausibility" is not found in the EPC but has been introduced by a number of decisions of the Boards of Appeal. It could be argued that this goes beyond the safeguards referred to above, in that it additionally asks whether the skilled person would have considered the later-proven technical effect either plausible or at least not implausible based on the information contained in the application as filed and common general knowledge. The introduction of this requirement may stem from the conviction that the established safeguards are not sufficient and that an additional measure is necessary to ensure that the purpose of the EPC is properly respected in general or, perhaps, only with respect to claims which are seen as overly "speculative".

However, it must be kept in mind that Article 56 is not the only provision of the EPC which limits the protection which is validly granted. Several other EPC provisions ensure that the invention must be technical in nature and that its technical purpose is communicated to the public. Article 52 EPC excludes non-technical matters, including discoveries as such, from the realm of patentable inventions and also requires that the invention must be susceptible of industrial application. Article 83 EPC requires that there must be sufficient information in the patent application to enable the

[3] To take an entirely hypothetical example, if an application claims compound A, the description identifies the compound as suitable to treat cancer and the EPO identifies prior art disclosing a closely related compound A* for the treatment of cancer, post-published evidence demonstrating that compound A has improved uptake into cancer cells compared to compound A* may be accepted and may allow reformulation of the technical problem as how to modify compound A* to improve its uptake by cancer cells. In contrast, one should expect virtually no success presenting post-published evidence showing that compound A protects plants against drought and trying to reformulate the technical problem as how to modify compound A* to make it protect plants in drought conditions.

skilled person to put the invention into effect. This requires the application to provide technical teaching unless this is provided by the common general knowledge.

Rule 29(3) EPC adds the specific requirement that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. Rule 42(1)(a) and (c) EPC require that the description should specify the technical field to which the invention relates and renders the technical problem and its solution understandable.

The question therefore arises whether the "plausibility" requirement serves the objectives of the EPC better than the existing safeguards beyond Article 56 EPC. As with every system for granting patents in the modern industrial world, the EPC is rooted in the belief that time-limited exclusive rights granted for inventions can benefit the public if they are coupled with the obligation to disclose the invention, such that the public can improve on the invention and eventually commercially exploit the invention freely after the patent expires or lapses.

In other words, the pertinent inquiry is: does denying patents for inventions the inventive step of which relies on a later-proven technical effect, which is within the spirit of the invention as originally disclosed, but the existence of which would not have been deemed either plausible or at least not implausible by the skilled person based on the application as filed and common general knowledge, increase the benefits that the public reaps from the existence of the patent system?

The answer is **no**. As explained above, the public does receive the knowledge of the invention in the application as filed and is also informed, by virtue of the post-published evidence, of any technical effect the invention may display vis-à-vis the closest prior art, at the latest before the patent issues or survives an opposition or other validity challenge. The public evidently benefits from the knowledge of the invention as described in the application as filed since, as of the publication date of the application, the public can further explore and build upon this information. The public equally benefits from the knowledge of the technical effect of the invention compared to the closest prior art, even if proven by post-published evidence at a later date, since this information helps the public to appreciate the benefits and value of the invention, which can then be freely exploited once the patent expires or lapses. All the effort and expense of supplying the public with this information lies with the applicant and the effort required to prove a technical effect of the invention relative to the closest prior art will be comparable before and after the filing date of the application.

The introduction of the "plausibility" requirement considerably **detracts** from these benefits, because applicants would necessarily adapt their behaviour to optimise their own position in the new circumstances.

For example, an applicant faced with a new document which is used as the closest prior art might still perform experiments to assess whether the invention displays some technical effect vis-à-vis this prior art. However, once such a technical effect is identified, the applicant would have to assess whether a persuasive argument could be made that the technical effect would have been plausible in view of the information contained in the application as filed. If not, the applicant may decide not to submit the post-published evidence, but rather abandon the application or patent. While this would eliminate a legal obstacle preventing the commercial exploitation of the invention by the public, it would also deprive the public of precisely the sort of valuable information that could motivate it to engage in said exploitation. A counterargument that the public could also further explore the invention to identify its potential benefits cannot stand, because the public lacks the applicant's incentive to do so, namely the prospect of obtaining an exclusive right allowing the

applicant to recover its investment. As a consequence, potentially valuable inventions would fall into disuse or the public would not benefit from the disclosure of valuable information.

Also, the applicant's inclinations as to when an application is ready to be filed would be affected. Because "plausibility" is an ambiguous and complex concept, applicants might decide to delay filing an application until actual proof of a technical effect is available for various aspects and embodiments of the invention. Although this would allow the public to consult this proof in the application as published, the downside would be that the later filing of the application would delay the public's knowledge of the invention and would also stretch the patentee's exclusivity farther into the future.

Furthermore, because the proof of a technical effect may be accrued at distinct time points for various aspects and embodiments of the invention, applicants could be motivated to pursue such related aspects and embodiments in separate applications, where previously they would have bundled them in a single application. Such fragmentation would undesirably confront the public with a multitude of patent applications and patents in situations where traditionally they would have needed to deal with only a single one.

For at least these reasons, the introduction of a "plausibility" requirement, a concept not found anywhere in the EPC and abstruse at best, would also be detrimental to the EPC's and the EPO's main beneficiary, the public of the EPC contracting states. **Therefore, the implementation of any "plausibility" requirement should be emphatically avoided.** Therefore both *ab initio* plausibility and *ab initio* implausibility should not be concepts used in determining inventive step.

The above observations as applied to T 1329/04

T 1329/04 is a seminal case and is discussed in reasons 13.4.1 of the referring decision. The invention concerned a new polypeptide, GDF-9, which the applicant stated was a new member of the transforming growth factor-β (TGF-β) superfamily. The Board in that case observed that GDF-9 did not have the structural features generally accepted for members of the TGF-β superfamily and that the application as filed did not contain any evidence as to whether the mode of action of GDF-9 permitted assignment to the TGF-β superfamily. The Board in that case refused to consider post-published evidence showing that GDF-9 in fact was a growth differentiation factor because the application as filed did not plausibly establish that GDF-9 was a new member of the TGF-β superfamily and eventually denied inventive step.

However, the application as filed did disclose the claimed invention – the GDF-9 protein – to the public. The application as filed further correctly identified GDF-9 as a member of the TGF-β superfamily. What was lacking in the application as filed was actual proof of the predicted activity of GDF-9 and hence proof that the postulated technical problem of providing a further member of the TGF-β superfamily had indeed been solved. This information was supplied by the applicant later on.

The applicant thus offered all components that would normally justify the grant of a patent – an invention which could be reproduced and which was eventually proven to solve the postulated technical problem, wherein the solution was not obvious. Yet, grant of a patent was denied. For reasons detailed in the previous section, this outcome was and remains highly undesirable.

The 'problem' of arbitrary speculation

The temptation to import some consideration of "plausibility" into the evaluation of inventive step or enablement can perhaps be ascribed to the fact that, in technical areas where technical effects are typically less predictable, such as chemistry and biotechnology, arbitrary speculation is

undemanding. This produces a concern (perhaps only imagined) that applicants, instead of labouring to uncover and demonstrate the technical effects so that proof can be included in the application as filed, may be tempted to assert the existence of various technical effects based solely on arbitrary speculation and leave the hard work for later. One can in all fairness wonder why the applicant should deserve a patent if all he has to offer is an arbitrary speculation as to the technical effect of something that would, in the absence of a technical effect, be considered obvious under the problem-and-solution approach?

At the outset, one must emphasise that the door to patentability should certainly **not** be shut for applications which rely on speculation, prediction or intuition to predict the technical effect the invention achieves. Evaluating whether a speculation or prediction is arbitrary or informed (for example, by consideration of some facts only available to the inventors or by consideration of facts available to everyone but approached from an entirely different angle by the inventors) is nearly impossible, since this would require an insight into the state of the inventor's knowledge and thinking process which inspired the invention. However, the applicant is under no obligation to divulge this information and, in fact, should be entitled to keep such valuable information secret, for example as a reservoir of future inventions.

A formalised practice denying the occurrence of a technical effect in all situations where the effect does not appear plausible to the skilled person at the filing date of the application (even if proven subsequently) would certainly be the end of arbitrary speculation. Unfortunately, it would also disproportionately imperil inventions for which the technical effect described in the application is the result of informed and valid prediction, the underlying rationale of which is kept secret. This would be undesirable because, as already explained, the proof that the technical effect occurs and that the corresponding objective technical problem has been solved will eventually need to be supplied and this proof is no less valuable to the public if supplied in post-published evidence than if supplied in the application as filed.

As noted above, a "plausibility" requirement is not needed because other requirements of the European patent system exist that can and should mitigate against this supposed problem of arbitrary speculation. These other requirements are adequate. Therefore, there is no need for a "plausibility" requirement.

We have discussed the impact of the familiar EPC provisions. However, perhaps the most pertinent feature of the EP system that curbs such speculation is the substantial cost of obtaining, validating and maintaining European patents. As already explained, the fact that the technical effect exists and that the corresponding objective technical problem has been solved must eventually be proved. Moreover, where the objective technical problem is reformulated in view of more relevant prior art, the new problem needs to be within the spirit of the originally-disclosed invention. If these facts are decisive for the assessment of inventive step, but remain unproven, the chances are high that the application will be refused or the patent revoked. Habitually pursuing European patents based on nothing more than arbitrary speculation as to the technical effect achieved by the claimed subject matter will quickly become a prohibitively costly endeavour. Speculating without restraint may be easy. Predicting correctly is not.

This can be compounded by the consideration of unity of invention under Article 82 and Rule 44 EPC, which can coerce the applicant to pursue each invention or group of inventions not linked to form a single general inventive concept in a separate and equally costly application.

Article 123(2) EPC can also play a role. For example, later data showing that a certain technical effect is associated with a particular combination of features may be of no benefit if that specific combination can only be constructed by making undisclosed selections from two or more lists of features or by introducing an intermediate generalisation, actions which are precluded by Article 123(2) EPC.

The safeguards discussed in the previous sections may also be deployed, such as:

> Article 52 EPC excluding non-technical matters, including discoveries as such, from the realm of inventions and prescribing that the invention must be susceptible of industrial application;
>
> Article 83 EPC requiring that the skilled person must be able to achieve the technical effect; and
>
> Rule 29(3) EPC requiring that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Finally, given that an applicant is also the most likely person to continue building upon, modifying and improving on its earlier inventions, an overly broad and speculative earlier disclosure may do more harm than good, since it may anticipate or render obvious the applicant's own future inventions. This detrimentally shortens useful patent term, which will be calculated from the filing date of the earlier application, rather than from the later filing date of potential follow-on applications.

The following examines the above considerations when applied to a **hypothetical situation**. Let us assume that an inventor discovers a novel fungus and isolates therefrom 50 novel, structurally-unrelated substances. An application is filed claiming *inter alia* the 50 substances and generically also any combination thereof.

In view of the lack of structural similarity between the substances, an *a priori* lack of unity objection under Article 82 EPC can be expected. Because pursuing each substance in a separate application is a costly proposition, the applicant may decide to seek protection for only a few substances.

If the application as filed discloses no activity or purpose of the substances, the applicant may face an Article 52 EPC objection that the substances are a mere discovery and/or that the substances lack any credible industrial applicability under Article 57 EPC. Also, if the application as filed proposes an entire laundry list of undemonstrated activities or purposes, the very same grounds may be invoked. A lack of industrial applicability objection may then be more opportune in order to maintain the low threshold character of the technicality inquiry pursuant to Article 52 EPC.

If the application as filed mentions only one activity or a limited number of related activities, say an activity as an antibiotic, then the aforementioned Article 52 or Article 57 EPC objections may be inappropriate. The inventive step inquiry may then proceed, for each of the novel substances, starting from the closest prior art document disclosing a structurally similar substance having antibiotic activity. The technical difference will correspond to the structural feature or features that distinguish(es) the novel substance from the prior art one.

If the application contains no data proving the antibiotic activity of the new substance, then the EPO should assert that the objective technical difference is not linked to any technical effect and the objective technical problem is to provide an alternative to the prior art substance, whether or not it

retains antibiotic activity. Modifying the prior art substance in such a way that it does not even need to retain its antibiotic activity will in all likelihood be obvious.

Absent post-published proof of the compound's antibiotic activity, the application should therefore fail for lack of inventive step.

If the applicant is able to provide post-published data showing that the substance does have activity as an antibiotic, then the objective technical problem can be to provide an alternative to the prior art substance, because the antibiotic activity is preserved. This will increase the chances of an inventive step being acknowledged, especially if the structural difference between the new and prior art substances is relatively large. Importantly, in inherently unpredictable technical fields, the chances that the applicant can generate such evidence may be close to zero if the activity was proposed based solely on random speculation rather than on some form of informed prediction.

If the applicant is able to provide post-published data showing that the substance also displays an unexpected technical effect within the spirit of the stated invention (i.e. bearing some relevance to the use of the substance as an antibiotic) compared to the prior art substance, then the objective technical problem can be to modify the prior art substance to achieve that technical effect, further increasing the chances of the invention being found to entail an inventive step. However, the applicant's chances to collect evidence of such an advantageous technical effect are even lower if he was only randomly speculating at the filing date.

In both cases, the post-published data will endow the public, before the patent is granted or upheld in an opposition, with the knowledge of a compound having proven antibiotic activity and potentially also some advantageous effect as an antibiotic. The public can act on this information, by researching and building on the invention while the patent is in force, and by exploiting the invention freely commercially once the patent expires or lapses.

Also, if the application alleges that the compounds do all have an antibiotic effect, but the applicant is unable to prove that any of them do, then Article 83 EPC can be applied to prevent grant of the application.

For completeness, if the inventor later discovers that a particular combination of two of the substances has an advantageous effect (e.g. some synergistic antibiotic effect), this will not provide proof of the effect for the broad scope of "any combination of the substances" but only for that particular combination of substances. Article 123(2) EPC will, however, prevent the applicant from claiming this specific combination because it would have been constructed by making a selection from two lists of substances, which selection was not unambiguously disclosed by the generic "any combination" language. A new application for this combination will typically be preferred.

An added "plausibility" requirement would distort this balance because the applicant can be expected to file the application only later, once proof of the antibiotic effect has been generated. This is because "plausibility" is a vague and complex criterion, while assessing the existence or absence of proof is much more straightforward and a rational applicant will favour certainty over uncertainty. The public will thus receive the information about the substance later, since the application will be filed and published later. The public will receive the proof of the antibiotic activity at about the same time as in the first scenario, namely once it has been generated and presented either in the post-published evidence (first scenario) or in the later-filed application (second scenario). The public's free access to the invention will be hindered for longer, since the patent term will be calculated from the later filing date of the application. The public will be relatively worse off.

For at least these reasons, it can be concluded that the European patent system already contains enough features and tools to mitigate effectively against the supposed problem of arbitrary speculation and that no further "plausibility" requirement is necessary. The fact that, on a rare occasion, an application may pass the problem-and-solution analysis relying on a technical effect that was put forward based on a truly arbitrary (but lucky, correct and subsequently proven) speculation by the inventors is an adequate price for ensuring the public's early access to inventions, not held up by applicants' concerns about whether their applications as filed do or do not render the technical effect "plausible" for most of the disclosed aspects and embodiments.

Because the problem-and-solution approach, which underpins the inventive step evaluation in the EPO, involves the determination of technical effects displayed by the claimed invention relative to the closest prior art, which may change, even repeatedly, during prosecution of the application and opposition against the granted patent, the European patent system must remain flexible enough to allow the applicant to prove the existence of a technical effect vis-à-vis the closest prior art by post-published evidence, the only precondition being that this technical effect is within the spirit of the invention as originally disclosed. As established above, the public is not disadvantaged by this flexibility, but instead benefits by receiving additional useful information about the invention.

ANSWERS TO THE REFORMULATED QUESTIONS

For these reasons, the answer to the reformulated Question 1 should be "yes, provided that the technical effect is within the spirit of the invention, according to the current satisfactory approach". This means that Questions 2 and 3 do not need to be answered. However, in the event that Question 1 is answered "no", Questions 2 and 3 should be answered "yes".

THE REFERRED QUESTIONS

Were the Enlarged Board to consider that the referred questions are appropriate, **epi** would answer the referred questions as follows. It is **epi**'s view that there can be no clear "yes" or "no" answer to any of the question because of the way the questions are drafted and because each case will depend on its own facts.

Question 1 must be answered in the negative

Question 1 should be answered in two parts. The answer to the first part is that there should be no exception to the rule that there should be free evaluation of evidence.

Any evidence must be evaluated freely and fully since, otherwise, one cannot even conclude whether the evidence actually provides proof of the technical effect. Moreover, once the conclusion has been made that the evidence either does or does not substantiate the technical effect, its role has ended. If the effect has been demonstrated, the problem-and-solution approach could in principle continue by formulating the objective technical problem as being to adapt the closest prior art to provide the technical effect. If the technical effect has not been demonstrated, the problem-and-solution approach can continue by formulating the objective technical problem as being the provision of an alternative to the closest prior art.

Any inquiry whether the technical effect would have been plausible or at least not implausible at the filing date of the application is entirely separate and can logically only ensue after the free and full evaluation of the post-published evidence has established that the technical effect does occur (if no effect occurs, no plausibility analysis is required at all). However, the post-published evidence can play **no** role in the evaluation of plausibility at the filing date, simply because it is post-published and by definition not available at the filing date.

The answer to the second part is that, insofar the technical effect proven for the first time by the post-published evidence has not been mentioned in the application as filed, the applicant or proprietor can only rely on the technical effect in the examination of inventive step if that technical effect is within the spirit of the invention disclosed in the application as filed.

Questions 2 and 3

If the Enlarged Board were to answer Question 1 in two parts, as set out above, the answers to Questions 2 and 3 should be "yes". However, **epi** considers that Question 3 should over-ride Question 2. The lower requirement of Question 3, which should provide a low bar, should be adopted.

Yours sincerely

Christopher Mercer
Chair of EPPC