European Federation of Pharmaceutical
Industries and Associations

To:
The European Patent Office
Enlarged Board of Appeal in the matter G 1/25 ("Hydroponics")

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Enlarged Board of Appeal referral G 1/25 ("Hydroponics") 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.

1. Summary

The EPO's practice for amending the description has become steadily stricter and more onerous over the past 6-7 years, despite a lack of legal basis in the EPC for this requirement. This practice introduces unnecessary complexity, delivers no tangible value, and lacks any demonstrated benefit for legal certainty. More critically, it erodes the quality of granted patents, leaving them vulnerable to unwarranted post-grant challenges.

The strict requirement to adapt the description to the claims does not result in higher quality patents. This stricter standard potentially leaves the patent more vulnerable to grounds of attack which are available post-grant, such as added matter and sufficiency. For example, if applicants are required to delete parts of the disclosure, a very careful assessment needs to be made in each instance not to introduce added matter by accidentally disclosing something in a new context or without a previous restriction (which was an issue in T1808/06). Further, if, in order to avoid introducing added matter issues by deleting parts of sentences or paragraphs, the applicant is forced to delete a longer piece of text, there is the potential to create lack of sufficiency issues by deleting information that was relevant. Thus, with more changes to the description than previously, more patents may later be found to have grounds of post-grant attack, decreasing quality and thereby also increasing the workload of the Opposition Divisions and the Technical Boards of Appeal.

Further, adaptation of the description to reflect the wording of amended claims, and hence to the claimed subject matter, presents risks of unintended consequences in subsequent infringement proceedings. This is because such adaptation does not take into account (and can negatively impact) the extent of protection conferred by a patent (application). The EPO is not required (or empowered)

to determine the extent of protection (except in the limited circumstances of Article 123(3) EPC). Indeed, a determination of the extent of protection involves "due account […] of any element which is equivalent to an element specified in the claims", which typically requires an alleged infringement as a reference point, and so cannot be performed by the EPO. As explained below, national courts and the UPC have taken into account whether there are teachings in the description that are "broader than the wording of the claim" when assessing whether a variant is an infringing equivalent. If the EPO insists that such broader teachings are amended or deleted simply to match the wording of the claims, then there is a risk of a detrimental effect on the extent of protection that will subsequently be determined by a national court or the UPC. In view of this, and in the absence of any clear legal basis or proven benefit, EFPIA believes that the EPO should not be requesting that patentees or applicants amend the description simply because it is broader than the claims.

Finally, a significant amount of time is spent by applicants, patentees and the EPO complying with increasingly strict requirements. This time and effort would be better spent on the core goal of issuing (and upholding in opposition proceedings) high quality patents that meet the requirements of the EPC. The strict requirements for description amendments also delay grant of patents, as it is not uncommon for communications under Article 94(3) EPC to be issued solely requesting adaptation of the description. This hinders the EPO's ability to achieve its goal of reducing the average time taken to conclude the examination procedure, which is also in the interests of users of the EPO.

Notably, adaptation of the description to match the allowed claims amended during prosecution is not required by any other major patent granting body. For example, the other members of the IP5 (KR, CN, JP and US) do not require such adaptations. In fact, many of the national patent offices of EPC-contracting states (e.g., the UKIPO) do not require this, yet UK courts have no difficulty assessing the validity and infringement of national UK patents in the absence of conforming the description to the granted claims.

In summary, this labour-intensive practice reduces the quality of European patents with **no demonstrable benefit** to any stakeholder.

2. Referred question 1

> *"If the claims of a European patent are amended during opposition proceedings or opposition-appeal proceedings, and the amendment introduces an inconsistency between the amended claims and the description of the patent, is it necessary, to comply with the requirements of the EPC, to adapt the description to the amended claims so as to remove the inconsistency?"*

Summary of EFPIA's position

The EPC and associated legislation nowhere deal with the situation where an amendment introduces a supposed inconsistency between the amended claims and the description. Therefore, it cannot be considered a requirement for EPC compliance to necessitate adaptation of the description to remove such inconsistency. In most cases, additional material in the description reflecting a breadth no longer present in the claims will not hinder compliance with the EPC, including the provisions discussed below, and can be retained.

The EPO is not required and is not empowered to determine the "*extent of protection*" under Article 69 EPC (except in limited circumstances under Article 123(3) EPC). Therefore, the EPO cannot fully assess whether an amended description has been adapted appropriately. It also cannot decide whether a patentee or applicant has a legitimate interest in retaining subject matter in the description not covered by the claims. Rather, the current strict requirements to amend the description can interfere with these legitimate interests.

There is no legal basis for this requirement

Consideration of the various provisions cited as legal basis for the requirement that the description be adapted to the claims reveals that there is no legal basis whatsoever in the EPC for this requirement. Digging into the analysis in more detail, the requirement is generally set up as a desideratum without concrete justification, then various provisions of the EPC are cited as post-hoc support based on assumptions about what they implicitly mean or were intended to mean.

The referring decision lists the following subcategories of decisions finding legal basis for the requirement to adapt the description[1]:

1. Article 84 EPC alone
    a. Decisions citing T1024/18
    b. Decisions not citing T1024/18
2. Article 84 EPC and other provisions e.g., T1452/21
    a. Article 84 EPC, Article 94(3) EPC and Rules 42, 48 and 71(1) EPC
    b. Article 84 EPC and Rule 42 EPC
3. Rule 42 EPC alone e.g., T140/19
4. The requirements of the EPC as legal basis e.g., T250/20
5. For reasons of consistency (general rule of law) e.g., T1571/22

Article 69 EPC has also been considered in decisions on this point. However, none of these provide legal basis for this requirement.

Article 84 EPC alone

Article 84 EPC is entitled "*Claims*" and recites that "*[t]he claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.*" Article 84 does not specify any requirements for the content of the description beyond supporting the scope of the claims, and certainly does not specify that the description should be limited in any way.

The case law considering whether it is necessary to adapt the description to the claims has looked at the requirement under Article 84 EPC for the claims to be clear and the requirement under Article 84 EPC for the claims to be supported by the description. Neither of these requirements necessitates the present practice of adapting the description to remove any subject matter broader than the claims. Using Article 84 EPC as justification for such a strict requirement is inconsistent with the intention of the legislators, who did not include Article 84 EPC as a ground of opposition in Article 100 EPC or revocation in Article 138 EPC to safeguard the needs of third parties.

Clarity

T1989/18 rightly found that "*if claims are clear in themselves and supported by description, their clarity is not affected if the description contains subject matter which is not claimed*" (reasons 5).

Under G1/24, the description and drawings should always be consulted to interpret the claims when assessing patentability. However, the presence in the description of unclaimed subject matter does not necessarily lead to a lack of clarity when interpreting the claims[2], because in many cases it will be clear to the skilled reader that the description contains subject matter that is not encompassed by the literal wording of the claims. In such cases it is not necessary to amend the description because the additional subject-matter does not give rise to a lack of clarity. The decisions that used

[1] Point 14.3 of the referring decision. The referring decision notes in point 12 that, to have a complete picture, it also surveyed decisions in examination-appeal cases. This is why legal provisions are listed that would not seem relevant to question 1, which relates to opposition proceedings.

[2] For this reason, the reasoning in T1989/18, which is limited to the situation where the claims are themselves clear, is still relevant even in view of G1/24.

clarity as justification for requiring adaptation of the description did not properly consider whether additional subject-matter in the description necessarily leads to a lack of clarity.

By contrast, in some cases it might not be clear whether specific subject matter is encompassed by the wording of the claims, and this may give rise to a lack of clarity. G1/24 provides guidance to overcome this situation: the correct response to any such lack of clarity in a claim – whether based on the claims on their face or when the description and drawings are consulted – is amendment of the claim[3]. For example, where a term in the claims is not clear on its face, the claim might be amended to incorporate a definition from the description to ensure that this lack of clarity is removed. This is different from the situation where there is additional subject matter in the description: additional subject matter in the description does not give rise to a lack of clarity.

Support

T1024/18, which was identified as a key case by the referring board, notes in point 3.1.7 that the requirement to adapt the description to the claims is justified by the requirement for support in the description, not for requirements for the claims to be clear and concise.

However, points 3.1.1 and 3.1.2 of T1024/18, also cited in the referring decision, merely refer to established practice without explaining why Article 84 EPC should be interpreted as requiring consistency between the claims and the description. The reasoning in point 3.1.9 of T1024/18 is also not persuasive: it simply emphasises that the provisions of Article 84 EPC are important because the claims are used after grant to determine infringement; it does not explain why any perceived inconsistency between the claims and the description would prevent this.

In fact, the support for the claims is not necessarily affected by the presence of unclaimed subject matter in the description[4]. Article 84 EPC requires that the claims be supported by the description, but there is no obligation in the EPC for a patentee to claim every embodiment that is disclosed. In other words, the only requirement is that the subset of subject matter that is in the claims can find support in the description; the inverse is not a requirement.

Indeed, unclaimed subject matter may give additional support by, for example, explaining variants that are not claimed but help the invention to be understood, detailing variants that led to development of the specific subject matter claimed, or explaining e.g. ways of using a claimed product. Where unclaimed subject matter in the description does not hinder understanding of the technical context, there is no basis for requiring its removal from the description.

T1024/18 concludes that the requirement for support under Article 84 EPC necessitates adaptation of the description because;

> "*to provide only support for the claims in one single passage of the description while the rest of the description might give a different or even contradictory meaning to the claims, would in essence negate the general meaning of the words "support by the description" and in fact would allow it to be reduced to a de minimis requirement of e.g. repetition of the claim wording while allowing the entire remaining description to be left to explain an entirely different invention to the one claimed.*"[5]

However, as explained in T1989/18, there is **no problem with support in the description being a de minimis requirement**. See point 5 of the reasons which explains that "*under [the requirement of support in the description], the subject-matter of the claim must be taken from the description, it being inadmissible to claim any subject-matter which is not described*". **There is no basis for extending the requirement of support in the description further** to require that any subject matter inconsistent with the claims be removed.

[3] See point 20 of G1/24, which does not refer to inconsistencies – a term that does not appear in the EPC – but to unclarity.
[4] This is contrary to the discussion in point 3.1.9 of T1024/18, which in fact seems to refer to clarity rather than support, since it deals with the interpretation of the claims.
[5] Point 3.1.8.

Articles 84 and 94(3) EPC and Rules 42, 48 and 71(1) EPC, or Article 84 EPC and Rule 42 EPC

None of the provisions cited in combination with Article 84 EPC provide legal basis for the requirement to adapt the description. The key case cited by T697/22 in this regard is T438/22 and, in finding that the EPC requires adaptation of the description, T438/22 in fact does not identify any explicit legal basis. Rather, it finds implicit basis for removal of subject matter where "*the description manifestly impedes a common understanding*". This is simply a matter of the requirement of Article 84 EPC, which should be assessed on a case-by-case basis and does not justify a blanket rule for strict description amendments as currently practised by the EPO.

Considering the additional provisions relied on, Article 94(3) and Rule 71(1) EPC deal with examination proceedings and cannot inform the requirements during opposition and opposition-appeal proceedings (hereinafter referred to together as "*opposition proceedings*"). These provisions have corollaries for opposition proceedings in at least Rules 79(1) and 80 EPC, but these simply indicate that the relevant EPO body shall invite the applicant to amend the application (in Rule 79(1) EPC, "*give [the proprietor] opportunity to […] amend the description, claims and drawings*"). These provisions may be relevant if there were a requirement to adapt the description to remove perceived inconsistencies with the claims. However, they do not themselves create such a requirement because they do not address that issue.

With regard to Rule 42 EPC[6], there is very little reasoning in T697/22. Rule 42(1)(c) EPC has previously been cited as legal basis for the requirement to adapt the description, but again, this provision has been extrapolated to situations to which it does not apply. It is possible for more general subject matter to remain in the application as filed without hindering the understanding of the technical problem and its solution, and any advantageous effects of the invention with reference to the background art[7].

In support of Rule 42 EPC providing legal basis for the requirement to adapt the description, T697/22 referred to T348/22. However, T348/22 simply concedes that "*Rule 42 EPC may not appear to provide a legal basis for removing matter from the description*" (point 5.7.1). Additional useful guidance on Rule 42 EPC was provided in T2194/19, which stated that Rule 42(1)(c) EPC "*cannot be the legal basis for establishing such a general and broad requirement for an adaptation of the description to the claims. It is simply not what this provision says*". This is a common theme in the decisions and commentary that attempt to use various provisions of the EPC to support this requirement: there is simply no language in the EPC that actually sets out this requirement.

With regard to Rule 48 EPC, T438/22 – after considering the *Travaux Préparatoires* - concedes that this rule cannot be directly understood to mean subject matter not covered by the claims. There is no reason why such subject matter, where it was relevant to the disclosure of the application as filed, should be "*obviously irrelevant or unnecessary*". Although it is more general than the claim, there is a sound reason for its presence (because the application as filed covered more general subject matter). In addition, as explained in T1989/18, there are no legal consequences provided for non-compliance with Rule 48(1)(c), unlike subparagraphs (a) and (b), so to extrapolate this provision to justify refusal of an application or revocation of a patent does not seem to reflect its intent. See T1989/18 – "*[i]t is therefore difficult to conceive that the legislator intended to impose more severe sanctions on less offensive matter*"[8] (reasons 11) – and T56/21 – "*the wording and history of this provision suggest that this was not its intended purpose*" (point 95 and subsequent discussion).

Other legal basis proposed in T697/22: Rule 42 EPC alone, the requirements of the EPC as legal basis, and for reasons of consistency (general rule of law)

The decisions cited in T697/22 regarding subcategories of legal basis 3, 4 and 5 include no discussion of the legal requirements they point to. For example, T1571/22 merely states "*the*

[6] Rule 42 deals with applications not patents (see title of Chapter II) so cannot impose any requirement in opposition-appeal proceedings. However, the referring decision deals with this provision in its discussion under question 1 so this submission also deals with this provision in this section.

[7] This was the case in the patent in suit in T1989/18: see point 8 of the reasons.

[8] The Board in T1444/20 agreed with this analysis, see reasons 3.3.3.

requirement of consistency between the claims and the description is met" (point 5.2.4) and T140/19 merely has a title "*Anpassung der Beschreibung (Regel 42 EPÜ)*" before a section determining that the case would be remitted to first instance to adapt the description[9] (point 13). These decisions therefore cannot provide the answer to the first referred question and seem rather to simply reflect established practice.

Article 69 EPC

The referring decision does not contain a standalone section that deals with the relevance of Article 69 EPC. Instead, this provision is addressed solely within quotes from two conflicting decisions, T1024/18 and T56/21. As explained below, EFPIA believes that the characterisation of Article 69 EPC in T56/21 is correct. Furthermore, it follows from this understanding of Article 69 EPC that the EPO should not require adaptation of the description. In brief, in order to adapt the description appropriately, the description amendments would need to take into account the "*extent of protection*" conferred by a European patent (or patent application). However, the EPO is not required and is not empowered to determine the "*extent of protection*". Therefore, the EPO cannot fully assess whether an amended description has been adapted appropriately. Indeed, per Article 2 of the Protocol on the Interpretation of Article 69 EPC, a determination of the "*extent of protection*" involves "*due account […] of any element which is equivalent to an element specified in the claims*". This assessment typically requires an alleged infringement as a reference point, and so cannot be performed by the EPO.

Adapting the description to the claims without consideration of the full extent of protection can have unintended consequences for subsequent infringement proceedings. In view of this, and in the absence of any clear legal basis for requiring description amendments, EFPIA believes that the EPO should not be requiring patentees or applicants to make description amendments.

The EPO is not required and is not empowered to determine the "extent of protection"

The Board in T56/21 correctly decided that there was no legal basis for a "*requirement to bring the description into agreement with claims intended for grant by deleting or disclaiming subject-matter in the description which is not claimed*". In doing so, the Board rejected the notion that Article 69(1) EPC provided a guiding principle for interpreting Article 84 EPC. In particular, the Board "*saw an important distinction between the functions of Articles 84 and 69(1) EPC […] and observed: "In fact, the assessment of patentability, which is a task entrusted to the examining divisions of the EPO alone, should be kept separate from the determination of the extent of protection conferred by a patent, which is a matter for consideration by national courts in infringement proceedings*" (point 15.1.3, last two sub-paragraphs).

Indeed, there is a clear difference between: (i) the invention that an applicant has sought to protect in a patent (application) and (ii) the protective effects conferred by the patent (application) in the Contracting States. This difference was acknowledged by the EBA in G2/12:

> "*A distinction needs to be made between, on the one hand, the aspects of patentability and, on the other hand, the (protective) effects of European patents or patent applications. The EPC clearly provides for such a clear division, as the requirements for patentability are governed by Articles 52 to 57, 76, 83, 84 and 123 EPC whereas the extent of protection and the rights conferred by European patents or patent applications are specified in Articles 64(2) and 69 EPC in particular*"[10].

Consistent with this view, the EBA previously rejected the suggestion that there was a connection between the "*protection conferred*" by a claim and the patentability assessment of such a claim. In particular, in G1/98, the EBA referred to:

[9] As an aside, this is a further example of unnecessary prolongation of procedure as a result of this requirement.

[10] G2/12 point VIII.2.(6)(b) (fourth paragraph) of the reasons.

> "*the established case law according to which the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable per se*"[11].

The EBA's comments in G2/12 and G1/98 confirm that the "*extent of protection*" in Article 69 EPC is a different concept from the "*invention*" that the EPO is required to assess for patentability.

Similarly, in G1/24, the EBA did not accept that Article 69 EPC provides a basis for claim interpretation when assessing patentability. This was because Article 69 EPC relates to infringement actions before national courts and the UPC, not the EPO's assessment of patentability.[12] This conclusion was partly based on the wording of Article 69 EPC (and the Protocol) and the drafting history of these provisions. In addition, the EBA highlighted that Article 69 EPC is found in Part II, Chapter III of the EPC (Substantive Patent Law – Effects of the European patent and the European patent application), which is a distinct section of the EPC from that concerned with the assessment of patentability (Part II, Chapter I, which contains Articles 52-57 EPC).

The Boards of Appeal have long appreciated the fact that determining the "*extent of protection*" is a matter for the courts in the Contracting States, not the EPO.[13] As correctly noted in T56/21: "*it is not the task of the EPO as a patent examining authority, but for the national courts (and other authorities) of the Contracting States, which are responsible for patent infringement proceedings, to determine the extent to which protection is to be conferred*"[14]. This view was partly based on some foundational case law from the early years of the EPO. Excerpts from three exemplary TBA decisions are provided below:

> "*further determination of how this claim is to be interpreted with regard to definition of the extent of protection conferred in accordance with Article 69 EPC and the relevant Protocol is not a matter for the examining, opposition and appeal bodies of the European Patent Office*"[15].

> "*In opposition proceedings, the EPO deals with the scope of protection of a patent only within the framework of Article 123(3) EPC. Moreover, interpretations of the scope of a patent are not the responsibility of the EPO, but of the national courts responsible for patent infringement proceedings in accordance with Articles 64 and 69 EPC. The EPO will, of course, take great care in determining the wording of the allowable claims, since their content determines the scope of protection of the European patent under Article 69(1) EPC and, if necessary, clarifies how terms used in the claims are to be understood; beyond that, however, the EPO does not have to give any additional interpretations as to the future scope of protection of the granted or maintained patent, to which, moreover, no national infringement judge would be bound*"[16].

> "*the appellant's intention was to obtain from the Board an opinion with respect to the extent of the protection of claim 1 […] However, the extent of the protection of a patent is examined by the EPO in the opposition proceedings only within the framework of Article 123(3) EPC […]. In principle interpretation of the extent of the protection of a patent is not the task of the EPO, but is, according to Articles 64 and 69 EPC, that of the national Courts competent in procedures on infringement cases*"[17].

[11] G1/98 reasons 4 (fourth sentence).

[12] G1/24 reasons 6 and 7.

[13] The one exceptional circumstance is that Article 123(3) EPC (and related Article 138(1)(d) EPC) requires the EPO to ensure that the scope of protection is not broadened after grant in opposition or limitation proceedings. Even in this narrow context, the EPO is not tasked with determining the scope of protection per se, but is instead required to consider whether a post-grant amendment has a broadening impact on the scope of protection.

[14] T56/21 reasons 32 (last sentence).

[15] T175/84 reasons 5.2.

[16] T442/91 reasons 3.

[17] T740/96 reasons 3.3.

Accordingly, if the EPO were to provide opinions on the "*extent of protection*", this would be contrary to the established case law.

Furthermore, the understanding that the EPO would not opine on the "*extent of protection*" was also clearly held by stakeholders when Article 69 EPC was in draft form. For example, several associations (ICC, COPRICE, CEIF, UNICE, UNEPA and FICPI) submitted a joint suggestion for a "*text to achieve a more uniform interpretation of Article [69]*", noting that: "*it would be futile to attempt a definition ensuring absolute identical interpretation by the courts of law in all Contracting States*"[18]. Similarly, the Standing Conference of CPCCI filed comments suggesting that "*the expressions used in the three – English, French, German – version of the Draft [of Article 69] do not have the same meaning and are likely to encourage the adherence by the States in question to traditions of interpretation which are very different from one another. Since national courts will be responsible for the interpretation of the European patent, there is a danger that, even if they observe the letter of Article [69], they will persist in their previous habits*"[19]. Accordingly, the "*extent of protection*" was clearly understood to be a matter for the exclusive consideration of the courts in the Contacting States.

Following stakeholder submissions, the Protocol on the Interpretation of Article 69 EPC was ultimately adopted to regulate the "*extent of protection*" analysis that would be performed by national courts. As explained in T 56/21: "*During the preparatory work for the EPC, interested non-governmental organisations expressed their concern that Article 69(1) EPC 1973 (at that time Article 20 of the draft) gave the national courts too broad a latitude in its interpretation and, consequently, also in determining the extent of protection. The ensuing discussions led to the Protocol on the Interpretation of Article 69 EPC 1973*"[20].

Subsequently, the Protocol on the Interpretation of Article 69 EPC was amended in 2000. The underlying motivation was explained in the Administrative Council's Basic Proposal for Revision of the EPC. In brief, the Administrative Council was concerned with the divergence in how equivalents and file wrapper estoppel were being treated by the national courts of the Contracting States. The Administrative Council noted:

> "*In applying these provisions in litigation concerning the infringement of European patents, the national courts of the EPC contracting states have tried since the beginning to develop as harmonised a practice as possible. However, despite some progress, not least due to regular European Patent Judges' Symposia, case law has failed so far to develop Europe-wide uniform criteria and rules for the interpretation of European patents and the assessment of their extent of protection. […]*
>
> *In order to strengthen and clarify the extent of protection under Article 69 EPC, and to contribute to a more uniform court practice in Europe, the Protocol on its interpretation should be supplemented by a few rules regarding the significance of equivalents and limiting statements in assessing the extent of protection*"[21].

As would be expected from the original purpose of Article 69 EPC, the Basic Proposal does not refer to this provision being applied by the EPO. It is clear that the legislators did not envisage Article 69 EPC being applied to the EPO's activities (beyond assessing compliance with Article 123(3) EPC), and doing so was certainly not an established EPO practice when the Protocol was revised in 2000.

In summary, the assessment of the "*extent of protection*" has been entrusted to the courts in the Contracting States and the UPC, not the EPO.

[18] BR/165/72.

[19] M/18, 162, paragraph 7.

[20] T56/21 reasons 23.

[21] MR/2/00, 59.

Since the EPO is not empowered to determine the "extent of protection", the EPO cannot fully assess whether an amended description has been adapted appropriately

Referred question 1 addresses "*an inconsistency between the amended claims and the description of the patent*". However, the referred question does not acknowledge the fact that a description may appear to be 'inconsistent' with the amended claims, and yet be wholly appropriate in view of the "*extent of protection*" conferred by the patent. A couple of illustrative examples are provided below.

As noted above, "*the protection conferred by a process patent is extended to the products obtained directly by the process*"[22]. Thus, it would be wholly appropriate for a process patent to contain statements regarding products, even though the claims exclusively recite processes. However, applicants (and patentees) are frequently required by EPO examiners to amend (or delete) statements and embodiments of the invention that do not conform to the format of the allowable claims. This is potentially problematic because deleting such statements or embodiments could subsequently have an impact on the patentee's ability to rely on the full extent of protection that they would have had without the deletions.

More significantly, the description amendments requested by the EPO cannot take into account "*equivalents*" per Article 2 of the Protocol on the Interpretation of Article 69 EPC. This is because an assessment of "*equivalents*" would generally require an alleged infringement as a point of reference. However, the EPO does not have that point of reference, and so cannot pre-empt how the "*extent of protection*" would be determined in the context of subsequent infringement proceedings.
As a result, requiring description amendments to remove a perceived inconsistency between the description and the claims can have unintended consequences for infringement proceedings. In particular, in connection with whether a national court deems a variant to be an infringing equivalent.

In *Actavis v Lilly* ([2017] UKSC 48), the UK Supreme Court established a three-step test for determining infringement by equivalents. As explained below, there is a clear risk of description amendments having unintended consequences with respect to a patentee's position on step (iii). The three steps are as follows:

> i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e., the inventive concept revealed by the patent?
>
> ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
>
> iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

Description amendments have an impact on the content of a patent and so can influence what "*a reader of the patent [would] have concluded*" regarding whether a patentee "*intended […] strict compliance with the literal meaning of the relevant claim(s)*". Indeed, this is clear from the Supreme Court's analysis of whether pemetrexed dipotassium was an infringing equivalent of pemetrexed disodium in the claims of the patent under consideration. In that regard, the Supreme Court stated explicitly that "*if the specification had not referred to anti-folates but had only referred to pemetrexed disodium, that would have been a more powerful indication that the patentee was intending to limit himself to pemetrexed disodium*".[23] Thus, if the patentee had deleted statements that related to the anti-folate class, to align with the recitation of the specific anti-folate in the claims (pemetrexed disodium), it is clear that their enforcement position could have been undermined in the UK.

There is similarly potential for description amendments having unintended consequences for the determination of infringement by equivalents at the UPC. In *Plant-e v Arkyne* (UPC_CFI_239/2023,

[22] G1/98 reasons 4 (fourth sentence).

[23] Point 73 of *Actavis v Lilly* ([2017] UKSC 48).

22 November 2024), the Hague Local Division applied a four-step test. Step 3 of the test is similar to step (iii) of the UK test above ("*does the skilled person understand from the patent that the scope of the invention is broader than what is claimed literally?*"). The Hague Local Division's application of Step 3 involved a consideration of whether "*the skilled person understands that the patent claim leaves room for equivalents because the teaching of the patent is (clearly) broader than the wording of the claim*".[24] If a teaching in the description that is "*broader than the wording of the claim*" is viewed by the EPO as being an inconsistency that should be addressed by amendment (or deletion), then this could have a detrimental impact on patentees' enforcement positions before the UPC.

In view of the risk of unintended consequences in infringement proceedings, and in the absence of any clear legal basis or proven benefit, EFPIA believes that the EPO should not be requesting patentees or applicants to make description amendments to address a perceived inconsistency with the claims.

3. Referred question 2

> *"If the first question is answered in the affirmative, which requirement(s) of the EPC necessitate(s) such an adaptation?"*

The first question should be answered in the negative, because no requirement of the EPC necessitates such an adaptation. Therefore, the second question does not need to be answered.

4. Referred question 3

> *"Would the answer to questions 1 and 2 be different if the claims of a European patent application are amended during examination proceedings or examination-appeal proceedings, and the amendment introduces an inconsistency between the amended claims and the description of the patent application?"*

The answer to referred question 3 is no

If the answer to the first referred question is "*no*", then the answer to the third referred question should also be "*no*". There is no legal basis for such a requirement during examination and examination-appeal proceedings (hereinafter referred to together as "*examination proceedings*") because all the arguments set out under question 1 above apply equally in examination proceedings.

In addition, a requirement for description amendment in examination but not in opposition would result in inconsistently amended patents. Consider a situation in which the description was adapted as a result of claim amendments during examination, and the patent was maintained as amended after opposition but no amendment of the description was required. In this case, the description of the resulting upheld patent would have been amended away from its original disclosure (to correspond to the claims as granted) but would not correspond to the final claims upheld following opposition. This would not be beneficial for third party certainty. This would also result in a divergent approach across European patents, with those where the claims were amended in examination having a description adapted to the amended claims, and those where the claims were amended only in opposition having a description not adapted to the amended claims.

Therefore, because the answer to the first question is no, the answer to the third question should also be no.

Claim-like clauses

Examining Divisions often require applicants to delete claim-like clauses from the description during examination proceedings. However, the EPO should not view the inclusion of claim-like clauses as presenting an inconsistency with the claims that should be addressed by deletion. It will be clear to the skilled reader that claim-like clauses are not the claims. The wording of the claims is not made

[24] Point 100 of *Plant-e v Arkyne* (UPC_CFI_239/2023, 22 November 2024)

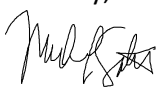
unclear simply because there are claim-like clauses in the description, even if those claim-like clauses recite additional subject matter that is not encompassed by the wording of the claims. As confirmed in T1426/21, "*Rule 42 EPC does not rule out claim-like clauses in the description. These claim-like clauses do not change or impair the understanding of the technical problem and the solution defined in the description. Therefore there is no reason to require their deletion*" (reasons 2.6).

5. Conclusion

In summary, the first and third questions should be answered in the negative. Referred question 2 therefore does not need to be answered. This finding will have significant benefits for stakeholders in the European patent system.

Thank you in advance for your time and consideration.

Sincerely,



Michael Swita, Director IP Policy - EFPIA