Amicus Curiae Brief by the Intellectual Property Advisory Committee (IPAC) of the BioIndustry Association (BIA), in the Enlarged Board of Appeal (EBA) proceedings G1/25

For the attention of Mr. Nicolas Michaleczek

These submissions are made pursuant to Article 10 of the Rules of the Procedure of the Enlarged Board of Appeal, and under the following headings:

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1. Introduction and Interest of the Amicus

[001] These submissions are made by the UK BioIndustry Association (BIA) and its Intellectual Property Advisory Committee (IPAC).

[002] The BIA is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation. We have over 600 members spanning human health and non-health biotech, including start-ups, scale-ups and established global companies. Our membership also encompasses the full UK ecosystem, including non-commercial research institutions and service providers.

[003] The IPAC of the BIA brings together senior in-house and private practice IP professionals and practitioners with extensive experience in the creation, prosecution, enforcement and defence of patent rights in Europe and globally. IPAC advises the BIA on IP policy issues of strategic importance to the life sciences sector.

[004] BIA members are highly research-intensive and operate in a global innovation ecosystem. Effective, predictable and proportionate patent protection is therefore critical to supporting continued investment in research and development, technology transfer and commercialisation.

[005] The referral in G1/25 raises an issue of substantial practical importance for BIA members, namely whether the European Patent Convention (EPC) requires mandatory adaptation of the description to align with allowed or granted claims. The outcome will directly affect the cost, risk profile and legal certainty of European patent protection for life sciences innovators.

[006] On behalf of BIA members, IPAC would like to provide the Enlarged Board of Appeal with the **practical and policy perspectives of innovator life sciences and biotechnology companies** and respectfully submits this amicus curiae brief.

2. Executive Summary

[007] IPAC submits that the questions referred in G1/25 should be answered as follows:

- **Question 1:** No. The EPC does not require mandatory adaptation of the description to be consistent with amended claims.
- **Question 2:** Not applicable.
- **Question 3:** No. The answer should not differ depending on whether amendments arise in examination or opposition proceedings.

[008] Mandatory description adaptation is not supported by the text or structure of the EPC and, more importantly from the perspective of BIA members, imposes significant and unjustified costs and introduces unnecessary risks.

[009] In particular, mandatory adaptation of the description:

- Disproportionately and unfairly impacts the life sciences sector, which operates globally and is characterised by exceptional technical and legal complexity;
- Increases prosecution and opposition costs without corresponding benefit. Rather, it simply introduces risks and uncertainty;
- Wastes resources and prolongs proceedings;
- Has a negative impact on enforcement and commercial certainty; and
- Places European patent practice out of step with other major jurisdictions.

[010] IPAC emphasises that it is not opposed to amendments to the description per se. Voluntary description amendments may be appropriate in specific cases. The concern is with compulsion: a mandatory requirement to adapt the description in cases where claims are amended during prosecution or opposition.

3. Policy Considerations Supporting a Negative Answer to Question 1

[011] A mandatory burden on applicants and proprietors to amend the description imposes significant but unnecessary disadvantages for all parties, including third parties.

3.1. Disproportionate Impact on the Life Sciences Sector

[012] Whilst all sectors are affected by a mandatory description amendment requirement, the life sciences sector is an outlier in terms of technical complexity, regulatory overlay and development timelines. By necessity, patent applications are often drafted many years before the ultimate commercial product is finalised and launched, and hence they must accommodate evolving scientific understanding and regulatory requirements. This results in long and complex patent applications in this sector that can be very difficult to accurately amend in response to a narrowed set of claims.

[013] As a result, the life sciences sector is not only disproportionately affected by the immediate disadvantages of a mandatory requirement to amend the description (including cost and procedural burden) but is also disproportionately exposed to the downstream risks discussed herein, particularly in national and UPC litigation.

[014] In addition, the amendment of claims during prosecution, for example to address emerging prior art, does not reflect a change in the underlying technical teaching, yet it may trigger demands for extensive description adaptation.

[015] Because life sciences applications are drafted globally and at an early stage, they are not written with later mandatory description amendment in mind. Requiring such amendments retrospectively imposes an unfair and disproportionate burden on this sector, where applicants often maintain very large global portfolios and must navigate the many competing legal requirements imposed on it by different patent offices.

[016] Furthermore, given the scale of investment required to bring life sciences products to market, even incremental increases in cost and uncertainty can have a significant adverse effect on innovation. This is particularly problematic in a sector where patent protection underpins the development of medicines, diagnostics and biologics that serve the public interest.

3.2. Mandatory Adaptation Only Introduces Risk and Uncertainty

[017] Mandatory adaptation of the description is often presented as a purely formal or administrative exercise. In practice, however, description amendments are rarely simple, and never litigation-neutral. Far from improving legal certainty, mandatory adaptation of the description often introduces new and unnecessary legal risks. Any amendment is an opportunity to challenge, either before the EPO or in national proceedings, and thus amendments to the description increase uncertainty (for all parties) rather than reduce it.

[018] Any amendment to the description carries an inherent risk of introducing added subject-matter issues under Article 123(2) EPC. This risk is particularly acute in the life sciences, where disclosures are highly technical, interrelated and frequently drafted to support a wide range of potential (but legitimate) claim strategies.

[019] In national enforcement and validity proceedings, the description is routinely scrutinised by courts and defendants as part of claim interpretation and as evidence of the patentee's understanding of the invention. Amendments to the description — particularly those made under procedural compulsion rather than for substantive reasons — can therefore have material and unintended consequences in later litigation.

[020] In the context of infringement proceedings, mandatory description adaptation creates a risk that amendments made solely to satisfy EPO formal requirements will later be relied upon by alleged infringers to argue for a narrower interpretation of the claims. For example, it may be argued that: the patentee intentionally disclaimed certain embodiments by removing or qualifying them in the description; the amended description reflects the patentee's definitive understanding of the invention; or the claims should be interpreted restrictively to remain consistent with the amended description.

[021] However, where such amendments were made under compulsion rather than as part of a considered enforcement strategy, this can unfairly prejudice patentees and distort the assessment of claim scope.

[022] Mandatory adaptation also increases the risk of creating inconsistencies within the patent itself or between related applications and patents in the same family, further undermining predictability for both proprietors and third parties.

3.3. Increased Cost and Waste of Resources

[023] Mandatory adaptation of the description imposes additional and recurring costs on applicants and proprietors, both during examination and in opposition proceedings. These costs arise from repeated drafting, internal review, outside counsel time, translation, and negotiation of description amendments that often have no material impact on the scope of protection or the clarity of the claims. Further, the subjective nature of mandatory description adaptation leads to inconsistent requests and acceptance between different Examiners[1] and Opposition Divisions, resulting in uncertainty for proprietors when considering the extent of amendments that should be made. Such deliberations increase both time and monetary costs.

[024] In life sciences and biotechnology cases, claim amendments are of course frequently required to address complex patentability issues arising from dense and evolving prior art landscapes. Each such amendment may trigger renewed demands to adapt the description, multiplying costs throughout prosecution and during the patent's term (e.g. during post-grant opposition proceedings).

[025] These additional costs are not marginal. For SMEs and start-ups, which form a significant proportion of the BIA's membership, they can represent a meaningful barrier to maintaining robust

[1] It must be emphasised that the existing Guidelines are not enforced in a consistent manner, because by its nature amending a description is a highly complex matter. As a result, Representatives must contend with objections that vary hugely in nature and severity from Examiner to Examiner, rending many of the description amendment objections raised and requirements placed on applicants pointless. If something is acceptable in one description, why is it not acceptable in another?

European patent protection. Even for larger organisations, the cumulative effect across extensive patent portfolios is significant.

[026] Mandatory description adaptation also represents a waste of resources at the level of the EPO. Examiner and Opposition Division time must be spent reviewing and debating description amendments that do not alter claim scope, time that would be better devoted to substantive examination issues. According such a burden would improve procedural efficiency and allow more timely resolution of cases.

3.4. Negative Impact on Enforcement and Commercial Certainty

[027] For BIA members, patents are core commercial assets relied upon to secure investment, partnerships, licensing opportunities and market exclusivity.

[028] Description amendments made under compulsion, rather than as part of a considered enforcement strategy, may later unfairly prejudice the proprietor in national litigation. Opponents may seek to use such amendments to argue for a narrower interpretation of the claims or to cast doubt on the proprietor's original technical contribution. Conversely, third parties may be adversely impacted if an amendment to a description implies the actual scope of protection afforded by the claims is different to how the claims will be construed (and enforced) in practice during litigation.

[029] These concerns are heightened by recent jurisprudence in G1/24 emphasising the importance of the description in claim interpretation (see also section 4.2 below). Mandatory adaptation therefore has a direct and negative impact on the enforceability and perceived strength of European patents.

[030] The resulting uncertainty as to how claims may be construed in national litigation undermines commercial certainty, making it more difficult for life sciences companies to attract investment and to make long-term R&D commitments.

3.5. Europe as an International Outlier

[031] To the best of IPAC's knowledge, the EPO is unique among major patent offices in systematically requiring applicants or proprietors to adapt the description to align with amended claims.

[032] Life sciences companies typically draft patent applications from a global perspective, seeking to maintain consistency across jurisdictions such as Europe, the United States, and other key markets. A global drafting approach is essential for efficient portfolio management and coherent enforcement strategies.

[033] Mandatory, Europe-specific description adaptation forces divergence within global patent families. Such divergence increases complexity, cost and the risk of inconsistent interpretations across jurisdictions, complicating enforcement and licensing discussions.

[034] By placing Europe out of step with other major patent systems, mandatory adaptation also risks reducing the attractiveness of the European patent system for globally operating innovators. To the best of IPAC's knowledge, the lack of a requirement to make mandatory description amendments in other territories has not directly resulted in an increased lack of claim clarity in those jurisdictions as compared to Europe.

4. Legal Considerations Supporting a Negative Answer to Question 1

[035] While IPAC's primary concerns are policy-driven, those concerns are firmly supported by the legal framework of the EPC. We provide some very brief comments below.

4.1. Consistency with the Legal Framework of the EPC

[036] There is no provision in the EPC that expressly requires the description to be amended whenever the claims are amended, whether during examination or opposition proceedings. In particular:

- **Article 84 EPC** requires that *the claims* be clear, concise and supported by the description. Its focus is on the quality and clarity of the claims themselves. It does not impose a **reciprocal obligation** to rewrite the description following claim amendments, nor does it require the excision of disclosed embodiments that fall outside the final claim scope.
- **Rule 42 EPC** specifies the content of the description at the filing stage. It does not provide a legal basis for imposing compulsory post-filing or post-grant amendments to the description as a consequence of claim amendments.

[037] A general obligation to adapt the description whenever claims are amended is not grounded in the text or structure of the Convention and risks imposing a substantive obligation by implication rather than by law.

4.2. The relevance of G1/24

[038] In **G1/24**, the Enlarged Board confirmed that the description and drawings must always be consulted when interpreting the claims. This decision reaffirmed the interpretative role of the description in understanding the technical teaching of the invention.

[039] Some have suggested that this principle supports a stricter requirement to align the description with the claims. IPAC respectfully submits that **the opposite conclusion follows**. G1/24 does not impose, or imply, an obligation to rewrite the description to mirror the final claim scope. Rather, it confirms that the description provides **context**, **technical explanation** and **background understanding** against which the claims are interpreted.

[040] The principle established in G1/24 strengthens the case against mandatory description adaptation for several reasons:

- **Interpretation does not require conformity**
  The fact that the description is consulted for interpretation does not mean it must be purged of all disclosed subject-matter that is broader than, or different from, the final claims. Patent interpretation has always involved assessing claim scope in light of the description as a whole, including embodiments that may not fall within the claims.

- **Risk of distortion of the technical teaching**
  Compulsory removal or re-characterisation of disclosed embodiments risks distorting the original technical teaching of the invention, particularly in complex fields such as life sciences. This is contrary to the interpretative function emphasised in G1/24.

- **Litigation uncertainty**
  If the description is always consulted, then compelled amendments to the description — made for formal rather than substantive reasons — carry heightened risk of being unfairly used against the proprietor in litigation (unfair at least for the reason the description amendments were imposed on the proprietor, rather than voluntary). G1/24 therefore underscores the danger of forcing amendments that were never intended to affect interpretation.

- **G1/24 addresses interpretation, not procedure**
  G1/24 is concerned with *how claims are interpreted*, not with *procedural obligations during prosecution or opposition*. Extending its reasoning to justify mandatory description adaptation would conflate two distinct legal questions.

[041] Properly understood, G1/24 supports a system in which:

- the description retains its role as a full and faithful account of the invention as originally disclosed;
- claim scope is determined by the claims, interpreted in that context; and

- applicants and proprietors retain discretion to amend the description, where doing so serves a legitimate purpose.

[042] It does **not** support a rigid requirement to rewrite the description whenever claims are amended, nor does it justify imposing additional procedural burdens not grounded in the EPC.

5. Voluntary Description Amendments as a Proportionate Alternative

[043] IPAC wishes to emphasise that it does not oppose description amendments in principle. Voluntary amendments to the description may be appropriate where they serve a clear and substantive purpose, for example to clarify technical teaching or to address genuine inconsistencies that could mislead the skilled reader.

[044] The EPC of course already provides applicants and proprietors with the ability to make such amendments where justified. Introducing a mandatory requirement removes flexibility and compels amendments even where they are unnecessary or detrimental.

[045] A system based on voluntary, case-specific amendments strikes a more appropriate balance between legal certainty, procedural efficiency and innovation policy.

6. Consistency with Other Amicus Curiae Submissions

[046] IPAC notes that a number of amicus curiae briefs already filed in these proceedings raise similar concerns, including the lack of a clear legal basis in the EPC for mandatory description adaptation and the risk of conflating claim interpretation principles with formal amendment requirements; and

[047] While IPAC does not seek to duplicate those submissions, it aligns with the shared view that **legal certainty is best served by a clear and limiting ruling** that confines mandatory requirements to those expressly provided for in the EPC. The additional, but highly valid, policy concerns set out in these submissions further support a position that mandatory adaptation of the description should not be required.

7. Answers Requested from the Enlarged Board of Appeal

[048] For the reasons set out above, IPAC respectfully submits that the referred questions should be answered as follows:

- **Question 1:** The EPC does not require the description to be adapted to be consistent with amended claims.
- **Question 2:** Not applicable.
- **Question 3:** The answer to Question 1 does not depend on whether amendments arise in examination or opposition proceedings.

8. Conclusion

[049] The life sciences and biotechnology sector depends on a patent system that is predictable, proportionate and aligned with global innovation practices. Mandatory adaptation of the description imposes significant cost and risk without delivering commensurate benefits in legal certainty. It places Europe at odds with other major patent systems and disproportionately impacts a sector of strategic importance to public health and economic growth.

[050] IPAC therefore urges the Enlarged Board of Appeal to provide a clear decision that mandatory description adaptation is not required under the EPC, while preserving the ability for voluntary amendments where appropriate.

Respectfully submitted,

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