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Registry of the Enlarged Board of Appeal FAO Mr Nicolas Michaleczek Case number G 1/23

By email: <a>EBAamicuscuriae@epo.org

Thursday 30th November 2023

About the Chartered Institute of Patent Attorneys (CIPA)

The Chartered Institute of Patent Attorneys is the UK's largest intellectual property organisation. We are the professional and examining body for patent attorneys in the UK, representing virtually all the 2,600 registered patent attorneys in the UK, whether employed in industry or private practice. Total membership is over 4,500 and includes trainee patent attorneys, judges, barristers and other professionals with an interest in protecting innovation through the use of intellectual property rights (patents, trade marks, designs and copyright). We represent members' interests to government and a wide range of stakeholders at home and abroad. The profession is one of the UK's most export intensive technical / legal services, generating around £1 billion for the economy in gross value added, and approaching £750 million in exports.

1. Background

1.1. Three questions have been referred to the Enlarged Board of Appeal (EBA) by Technical Board of Appeal 3.3.03 (the Referring Board) in case T 438/19. The questions that have been referred are:

1. Is a product put on the market before the date of filing of a European patent application to be excluded from the state of the art within the meaning of Article 54(2) EPC for the sole reason that its composition or internal structure could not be analysed and reproduced without undue burden by the skilled person before that date?

2. If the answer to question 1 is no, is technical information about said product which was made available to the public before the filing date (e.g. by publication of technical brochure, non-patent or patent literature) state of the art within the meaning of Article 54(2) EPC, irrespective of whether the composition or internal structure of the product could be analysed and reproduced without undue burden by the skilled person before that date?

3. If the answer to question 1 is yes or the answer to question 2 is no, which criteria are to be applied in order to determine whether or not the composition or internal structure of the product could be analysed and reproduced without undue burden within the meaning

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of opinion G 1/92? In particular, is it required that the composition and internal structure of the product be fully analysable and identically reproducible?

2. Summary

- 2.1. If a product has been placed on the market, and it is not possible to determine the composition or internal structure of that product before the earliest effective date of a patent or patent application, without undue burden, it follows that it cannot be ascertained what has been disclosed, directly and unambiguously, to the skilled person and what forms part of the state of the art.
- 2.2. One should not ignore the fact that a disclosure in some form has taken place. The features of the product that have been directly and unambiguously disclosed should be deemed to form part of the state of the art for assessing patentability. For example, ancillary information relating to the product, such as publications, including but not limited to technical brochures, non-patent and patent literature, would form part of the state of the art for assessing patentability. The usefulness of that information would be determined by the scope of the disclosure.
- 2.3. It is not necessary to provide commentary in relation to question 3, in view of the above.

3. The Relevant Law

- 3.1. Article 54(2) EPC states that "[t]*he state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application"*.
- 3.2. The EBA considered a similar issue in G 1/92, and it concluded that "where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art".
- 3.3. The Referring Board has identified a divergence in the application of G 1/92 in relation to the following, as set out in point 11 of the Reasons:
 - interpretation of the requirement made "available to the public" leading to the exclusion from the state of the art within the meaning of Article 54(2) EPC of the product itself (including its chemical composition/internal structure) or only of its chemical composition/internal structure;
 - ii) the degree of detail required for the analysis of the product; and
 - iii) the requirements for reproducibility.



- 3.4. Thus, a product could be "available to the public" and part of the state of the art, even if its structure and functional features could not be analysed and reproduced without "undue burden". Alternatively, if the structure and functional features could not be reproduced, then the product may not form part of the state of the art.
- 3.5. The Referring Board notes differing approaches that have been taken when determining whether a product has been put on the market could be analysed or reproduced. For example, as noted in point 12 of the Reasons, the Referring Board noted that the earlier decisions have decided that:
 - i) its chemical composition (or internal structure) was not state of the art (T 946/04 or T1666/16), adopting the wording of the conclusion of G 1/92; or

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- ii) the product itself was not state of the state, including its chemical composition or internal structure (T 370/02, T 2045/09, T 1833/14, T 23/11), adopting the wording in point 1.4 of the Reasons of G 1/92.
- 3.6. The Referring Board also notes that a complete analysis of a product was required in T 952/92, whereas missing structural information was not an impediment to a product being part of the *"state of the art"* in T 2458/09. Thus, additional clarity would be welcome in relation to the data that are needed in order to ascertain whether aspects of a particular disclosure are enabled.

4. What is made available to the public?

- 4.1. In G 1/92, the EBA took the view that a compound is "*made available to the public*" only when it could be analysed and reproduced by the skilled person (G 1/92, point 1.4 of the Reasons). Although this statement was made in relation to a composition, it is equally applicable to products. Thus, the commentary provided by the EBA in G 1/92 provides guidance in relation to answering question 1 that has been referred to the EBA. This appears to be suggested by the Referring Board in point 8.2.
- 4.2. There are many hypothetical examples that could be advanced to demonstrate absurd results when a product has been disclosed, but it is not possible to determine the composition and internal structure without undue burden in a reproducible fashion. However, once a disclosure has taken place, it becomes state of the art (in accordance with Article 54(2) EPC), but the scope of what has been disclosed may be limited to the technical information relating to the product, *e.g.* its technical effect or specific technical data.
- 4.3. The usefulness of any additional information relating to the product that was made available to the public before the effective date of the patent or patent application, may be limited by the fact that the composition and the internal structure of the product cannot be determined or the disclosure of the additional internal information may not be complete to allow the skilled person to determine, directly and unambiguously, what has been disclosed. That is a matter that will need to be considered on a case-by-case basis.



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4.4. Although an answer to question 3 is not required based on the analysis above. The challenge that rights holders will need to overcome in the future is determining when the "undue burden" requirement has been satisfied. Given the facts of each particular case will differ, it does not appear to be appropriate for the EBA to set a threshold test, specific criteria or rule to ascertain whether a particular act, or acts, would constitute an "undue burden". The absence of a concrete test could lead to differing outcomes from the Technical Boards of Appeal based on a subjective assessment on whether the "undue burden" requirement has been satisfied for each case that they consider. However, there is a body of case law already in this area that clarifies the approach that the Technical Boards are likely to take.

5. Conclusion

- 5.1. The questions that have been referred to the EBA deal with an interesting point of law, and the answers may impact other areas of technology where is it not apparent or it cannot be characterised how a product functions and a result is being achieved, *e.g.* Al. However, removing a product from the state of the art because its composition or internal structure cannot be analysed could lead to evergreening and known products being patented after the date on which they were known and disclosed.
- 5.2. CIPA is of the view that it would be beneficial to applicants and proprietors for the EBA to adopt a pragmatic approach when considering whether a disclosure forms part of the state of the art. The scope of what forms state of the art will be determined by the information that can be directly and unambiguously derived from that disclosure.
- 5.3. It would be of assistance to rights holders if they were provided with some guidance on meeting the *"undue burden"* requirement, but there is already a body of case law that deals with this issue. The factual matrix of each case is different, and so it appears appropriate that the existing case law should be applied on a case-by-case basis.