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G1/23		FK23180-02-ACT	+49 6172 608-6343	2023-11-29

Fresenius Kabi - Amicus Curiae brief relating to case G 1/23 "Solar cell"

Dear Members of the Enlarged Board of Appeal,

We appreciate the opportunity to provide comments to the pending referral G 1/23. Please find our detailed position attached.

Best regards,

Fresenius Kabi Deutschland GmbH

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Enclosure
Fresenius Kabi - Amicus Curiae brief relating to case G 1/23

G 1/23 "Solar Cell" - Amicus brief by Fresenius Kabi

A Summary

A product that is available to the public must not be artificially – i.e., by legal fiction - excluded from being prior art under Art. 54(2) EPC. The question of how and with which effort, skill level and to what extent the product can be reproduced is a question of extent of disclosure, not its existence.

Written disclosure must be taken at face value, until proven otherwise. No artificial distinction must be made depending on its nature (manual, scientific article, a rare copy of a PhD thesis in a foreign language).

The extent of any disclosure is governed by the "Gold Standard". Prior art disclosures other than patent literature can only be removed from the prior art if proven incorrect or if it is prima-facie obvious that they run contrary to the laws of nature. (Balance of probabilities)

Reproducibility of a prior art disclosure without undue burden is only relevant for the claimed technical contribution of an invention over the prior art as a prerequisite for granting a monopoly (patent).

The questions referred to the Enlarged Board of Appeal must be answered:

1. **No**
2. **Yes**
3. Not applicable

B Detailed discussion

B.1 Referred Questions and proposed answers

The below questions were referred to the Enlarged Board of Appeal:

Question 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?

Question 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?

Question 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 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?

We propose that these questions be answered as follows:

Question 1

***No**. Such a product should not 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.*

Question 2

***Yes.** 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) is 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.*

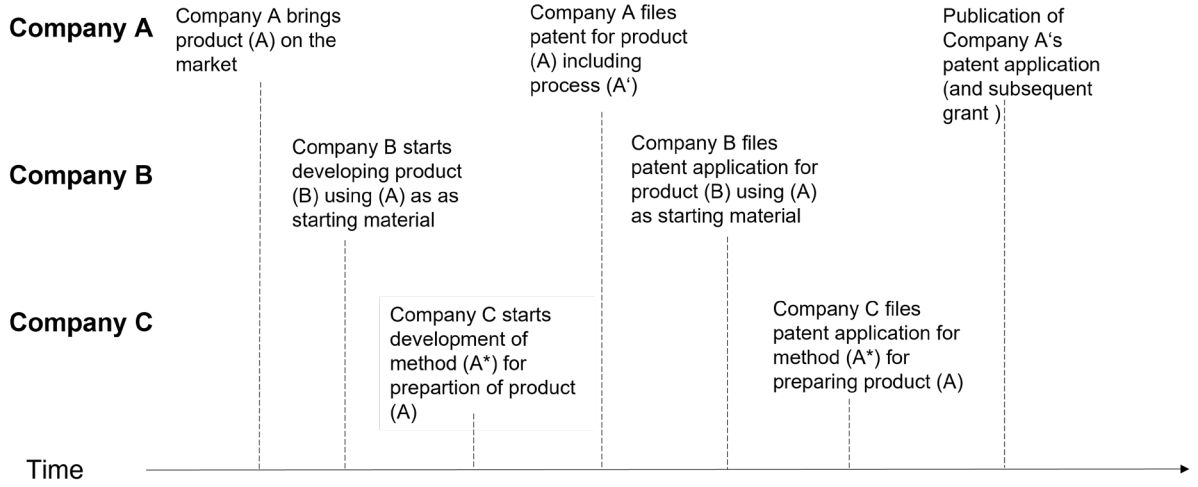
Question 3

Not applicable

B.2 Introductory remarks

In the first part of our brief, we would like to invite the Members of the Enlarged Board of Appeal to take the hypothetical scenario presented below into consideration (see B.3). This scenario highlights some of the - as we think - undesirable consequences should the referred questions not be answered as proposed above. In the second and third part of our brief, we will discuss the relevant legal provisions in the EPC (see B.4) and our understanding of G1/92 in view of these provisions (see B.6).

B.3 Scenario



Company A places product (A) on the market, thereby making it available to the public. Company A does not intend to provide the public with any technical teaching other than that the product exists, can be used for certain purposes, and, most importantly, is available for sale. Product (A) cannot be prepared by applying commonly known methods. Company A has – somewhat ill-advised, perhaps - decided against filing a patent application prior to bringing the product on the market. It does not provide any information to the public on how the product is prepared, as it intends to rely on keeping this know-how secret to protect the product from being copied by competitors. In the accompanying marketing materials, the product's structure and specific properties are disclosed.

Company B buys product (A) and uses it as a starting material in the development of its own product (B).

In the meantime, product (A) becomes commercially successful in the market. The management of Company A gets second thoughts, whether its strategy of keeping the know-how on how to prepare product (A) secret will be sufficient to keep others from copying the product for much longer. Company A is especially concerned about Company C, one of Company A's close competitors. And indeed, Company C, having noticed that the commercially available product (A) and its synthesis are not protected by patents, has decided to invest considerable financial means into the development of a process for the preparation of said product (A) with the aim of participating in the commercial success of product (A). Company C's product is to be a 1:1 copy of product (A).

Company A now applies for a patent to protect product (A), irrespective of the fact that the product has been available on the market for a considerable time, already. The patent application includes composition claims covering product (A) as such and claims directed at the inventive preparation of product (A).

Shortly afterwards, Company B applies for a patent for its new product (B), identifying Company A's product (A) as a starting material and stating in the description of the patent application that this starting material (A) can be commercially obtained from Company A.

Before Company A's patent application is published, Company C files a patent application claiming the method (A*) it developed for the preparation of product (A). This method turns out to be inventive over the method disclosed in Company A's patent application.

During examination of Company A's patent application, a third-party observation is filed by Company C citing Company A's marketing materials disclosing the product's structure and specific properties as prior art.

Company A responds to this third-party observation by arguing that all previously sold products and the public marketing materials are non-enabling disclosures which do not qualify as prior art under Article 54(2) EPC. Company A argues that the preparation described in the now published patent application represented secret know-how up to the publication day of its patent application and that the product could not be prepared by applying commonly known methods. This contention is supported by the experimental data provided in Company A's patent application demonstrating that applying standard methods used for the preparation of related products fail to provide product A. In its response to Company C's third-party observation, Company A refers to point 1.4 of G1/92 and requests grant of the patent.

If the first question of the referral of G1/23 was answered with "*yes*", accepting that a product available to the public becomes prior art under Article 54(2) EPC only if the product can be prepared by commonly known methods, a patent would have to be granted to Company A, including the composition claims directed at product (A) as such.

Company A's patent would then block Company C from selling its product (A), irrespective of the facts that the process Company C uses for the preparation does not infringe the process claim in Company A's patent and that at the filing date of Company C's patent application, product (A) had been commercially available. Although Company C had disclosed to the public its own proprietary process, it would be denied any benefit from such a disclosure. Its investment in the development of a commercially viable preparation method (A*) of the already commercially available product (A) would go unrewarded.

Answering the first question of the referral of G1/23 with "*yes*" would lead to situations in which products, although being commercially available to the public, would have to be disregarded as prior art, in effect "artificially removing" readily available products from the public domain.

Similarly, answering the second question of the referral of G1/23 with "*no*" would lead to situations in which technical information about a product, although made available to the public in form of published marketing materials, would have to be disregarded as prior art, again "artificially removing" readily available technical information from the public domain.

Both would run contrary to the fundamental principles of the patent system and create a great deal of legal uncertainty.

If the first question of the referral was answered with "*no*" and the second question with "*yes*", Company A could still obtain a patent for the process of making product (A) (and for the product directly obtained via this specific process). Company C could obtain its own process patent, providing protection for the process (and the product directly obtained via this process).

Continuing with the outlined scenario, Company B's patent application has in the meantime been accepted for grant. Sufficiency of disclosure was not an issue during examination as Company A's product (A), used as a starting material for Company B's product (B), was commercially available and the structure and specific properties of product (A) are disclosed in the accompanying marketing materials.

Applying the rationale that removes Product (A) from the public domain to the question of sufficiency of disclosure of Company B's patent application on product (B), i.e., that the public disclosure of a product qualifies as prior art only if its preparation is disclosed at the same time or is possible by applying commonly known methods, Company B's patent could be invalidated by raising objections under sufficiency of disclosure. At the time of filing of company B's patent application, it was not possible to prepare the starting material, i.e., product (A), without inventive effort which would remove product (A) from the public domain. Any process relying on this starting material would therefore have to be considered insufficiently disclosed.

Answering the first question of the referral with "*yes*" and the second question with "*no*", would therefore cause a lot of additional work for patent applicants when preparing a patent application, and - even more importantly - generate legal uncertainty. To ensure that the own patent application meets the requirements of sufficiency of disclosure, the applicant would have to determine whether any commercially available product used, e.g., as a starting material in the preparation of the claimed product, can be prepared without undue burden. It does not take much to imagine that such assessments might also be contested during opposition.

If the first question of the referral was answered with "no" and the second question with "yes", no issues would arise regarding sufficiency of disclosure for Company B's patent utilizing product (A) as a starting material for the products claimed therein.

The above scenario is particularly relevant in the field of chemistry, e.g., where product A is a complex organic molecule which can only be prepared using a previously unknown multistep synthesis comprising at least one inventive reaction step.

The above outlined consequences arising within this exemplary scenario, in our opinion, demonstrate that the first of the referred questions should be answered with "no" and the second with "yes".

As it is our position that the first of the referred questions should be answered with "no" and the second question with "yes", we will refrain from discussing question 3 in detail. Nonetheless, we would like to point out that - should the third question become relevant - analysability and reproducibility of a prior art product can only matter for specific features of the product if the product is cited as prior art against the claims of a patent/patent application comprising such specific features. Lack of analysability or reproducibility of features not forming part of a disputed claim cannot remove the entire product from the prior art, particularly if other claimed features are readily derivable from the product.

B.4 Relevant legal provisions of the EPC

For the referred questions, Articles 54 and 83 need to be discussed.

Article 54(2) EPC Novelty

> *(1)* …
>
> (2) *The 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) …

Article 83 EPC *Disclosure* of the invention

> *The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.*

Article 54 EPC is part of Chapter I "*Patentability*" of Part II "*Substantive Patent Law*" of the EPC. Contrary to this, enablement is dealt with in Article 83 EPC, "*Disclosure of the invention*" in Chapter I "*Filing and requirements of the European Patent application*" of Part III "*The European Patent Application*" of the EPC.

Systematically, the EPC differentiates between "disclosures" forming the prior art at a specific date and the "disclosure" of an invention in a patent application.

Article 54(2) EPC defines the relevant date applicable for disclosures to qualify as prior art and provides a non-limiting list of potential means of disclosure, i.e., written or oral descriptions, use, or **any other way**.

Article 54(2) EPC formulates no additional requirements other than "*making available to the public*" prior to the date of filing of the European patent application, for such a disclosure to qualify as prior art. Consequently, it has been established in the Case Law of the Boards of Appeal that it is not necessary that an applicant took notice of such a disclosure, e.g., a doctoral thesis in a foreign language available in a university library abroad, for it to qualify as prior art. It is sufficient that the skilled person could have obtained the thesis.

Article 83 EPC requires the disclosure in a **patent application** to be sufficiently clear and complete for it to be carried out by the person skilled in the art.

This requirement is justified by the basic rationale underlying the patent system, i.e., the "deal" that an applicant who provides the public access to the know-how of an invention (thereby potentially accelerating technical progress in society) is granted a temporary monopole on the commercial use of the claimed invention in return.

No such "deal" exists when a product is made available to the public by simply placing it on the market, and certainly, no obligation exists that a product may only be commercialized if the public is at the same time provided with the technical teaching of how the product is made. Very often, secret know-how forms part of the intellectual property owned by companies.

The respective rationales behind Articles 54(2) EPC and 83 EPC are different. While Article 54(2) EPC defines which disclosures qualify as prior art for a given patent application, Article 83 EPC defines which standard a disclosure of an invention in a patent application must meet to justify the reward of a temporary monopole to the disclosing company. Consequently, the standards established for sufficiency of disclosure of a patent application cannot be applied in identical manner to any form of disclosure.

"Gold Standard", "Undue burden", and "Standard of proof"

In the Case Law of the Boards of Appeal of the EPO the extent of information conveyed to the skilled person via "*any kind*" of disclosure in the sense of Article 54 EPC must be assessed by applying the "*Gold Standard*", i.e., by assessing what is "*directly and unambiguously derivable*" for the skilled person from such a disclosure (**G2/10**).

For the assessment of reproducibility in the context of sufficiency of disclosure of an invention in a patent application, the Case Law has developed the requirement that such reproducibility must be achievable by the skilled person without "*undue burden*".

These standards are not identical and, according to our understanding, only the "*Gold Standard*" is applicable to the public disclosure of a product as such. Public disclosure of a product is an act taking place in the real world and cannot be undone once it happened. It might be difficult to prove that such a disclosure took place, but if this is possible, the disclosure cannot be ignored. The public disclosure of the product itself proves that at least someone was able to produce the product at the time of its disclosure.

This distinguishes the public disclosure of a product from a written or oral disclosure of a product. In the latter cases, not the product "*as such*" is disclosed, but only a description thereof. For such a written disclosure the standard assumption must be that the disclosure contained therein is correct and therefore forms prior art under Article 54 EPC.

There are only two situations where such written disclosures must be disregarded. The first one concerns the disclosure of obviously impossible or incorrect information, e.g., disclosures that run contrary to established technical or scientific principles. The disclosure of a "*perpetuum mobile*" constitutes such a case.

The other situation arises where disclosures that can be proven incorrect in the sense that their content had not been made available to the public as a matter of technical reality (see e.g., **T 412/91** and **T 230/01**). Examples of such disclosures are publications claiming to have achieved energy production via "*cold fusion*" of atoms or publications on the stereoselective syntheses of chemical compounds solely by means of magnetic fields. According to our knowledge, all publications claiming to have achieved these goals have subsequently been proven not to work, the alleged achievements described therein until today not having become a matter of technical reality. Such disclosures must be removed from the prior art under Article 54 EPC. In proceedings at the EPO, the burden of proof for such a claim must be with the party trying to remove the disclosure from the prior art.

The applicable standard of proof is the "*balance of probabilities*", which is different from both the "*Gold Standard*" and the standard applicable for *"reproducibility without undue burden"*. Demonstrating that a disclosure includes matter that does not form part of the technical reality may require skills going beyond those attributable to the skilled person. This because, the standard "*reproducibility without undue burden*" is only applicable for inventions disclosed in patent literature forming part of a special legal system. This system attributes rights to the applicant/patentee which are not obtainable via other forms of disclosure. For this reason, the technical contributions forming the inventions disclosed in patent applications/patents must be reproducible without undue burden to qualify as prior art.

However, as a rule, considering only technical information as prior art that can be analysed and reproduced without undue burden would cause an unacceptable degree of legal uncertainty. In our understanding, sufficiency of disclosure and law of evidence and should not be confused.

For an uncontested public disclosure of a product, only the extent to which information is derivable from the product can be a matter of discussion ("*Gold Standard*"). The reproducibility of a publicly available product can only be an issue for preparation-related aspects of the product but not for the product itself. Likewise, analysability can only be an issue with respect to certain properties or inherent features of the product that may need to be shown/proven or analysed experimentally as they are not apparent via simple inspection. In such cases, the disclosure provided by a publicly available product does not include any inherent features, e.g., features whose analysis requires the skilled person to

invent a suitable method of analysis or to apply a known method of analysis in an inventive way to identify such inherent features ("*undue burden*").

B.5 Interpretation of G 1/92

The questions referred to the Enlarged Board of Appeal in **G1/92** were:

> "*(1) Is the chemical composition of a product made available to the public by virtue of the availability to the public of that product, irrespective of whether particular reasons can be identified to cause the skilled person to analyse the composition?*"
>
> *and, if the answer to this first question is positive,*
>
> "*(2) Does the principle extend to the more general case whereby all information which can be obtained from a product is made available to the public by virtue of the availability of that product, irrespective of whether particular reasons exist to cause the skilled person to search for that information*?"

The questions did not at all refer to whether a product made available to the public must be disclosed in a manner that the person skilled in the art is able to reproduce the product without undue burden. Instead, they focused on whether the skilled person needed reasons to analyse a publicly available product, especially a chemical composition, for the information gained about the product to be considered as prior art.

The issue of reproducibility was raised only under 1.4. of the reasons for the decision, where it is discussed what "*made available to the public*" (according to Article 54(2) EPC) means.

Reason 1.4 of **G1/92** reads:

> "*1.4 An essential purpose of any technical teaching is to enable the person skilled in the art to manufacture or use a given product by applying such teaching. Where such teaching results from a product put on the market, the person skilled in the art will have to rely on his general technical knowledge to gather all information enabling him to prepare the said product. 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.*"

The Enlarged Board says that where the skilled person - without undue burden – can reproduce the product and is able to determine its composition or internal structure, these additional features, too, become state of the art under Article 54(2) EPC.

In **G1/92** the Enlarged Board did, however, not address the situation where the product as such is not reproducible without undue burden.

Therefore, there is no basis for reversely concluding that where a product cannot be reproduced without undue burden the (commercially available!) product as such must be "artificially removed" from the prior art. It can also not be reversely concluded that where certain specific features of the product cannot be analysed all other features of the product must be excluded from the prior art, too.

Consider the following example: The commercially available product is a medicament comprising the active ingredient X in a specific crystalline form ("polymorph A") in a capsule. If the active ingredient X, its crystalline form ("polymorph A"), and the capsule can be reproduced without undue burden, according to the Enlarged Board in G1/92 the medicament (a capsule comprising the active ingredient X as "polymorph A") is prior art under Article 54(2) EPC.

However, it goes without saying that if the skilled person was not able to reproduce "polymorph A" without undue burden, the medicament as such, i.e., a capsule containing the active ingredient X as "polymorph A" would remain prior art, if the crystalline form could be analysed without undue burden.

If the skilled person was not able to analyse the crystalline form of the active ingredient X, the medicament would remain prior art. It would just lack the information on the crystalline form ("polymorph A"). The medicament could then only be considered to disclose a capsule comprising the active ingredient X.

In summary, the lack of disclosure of certain features or the lack of reproducibility cannot remove the entire disclosure from the public domain, and in our opinion, the Enlarged Board of Appeal in G1/92 cannot be interpreted otherwise.

C Conclusion

Therefore, the questions referred to the Enlarged Board of Appeal should be answered:

1. **No**
2. **Yes**
3. Not applicable