Amicus Curiae

PETER DE LANGE

in referral to the Enlarged Board of Appeal of the EPO

G 1/23 - Enablement

Dear Chair and Members of the Enlarged Board of Appeal,

The following questions were referred by decision T 438/19 (OJ 2023 A72):

> 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?
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> 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?
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> 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?

1. A recent statement of the general rule on novelty is that a claim is not novel if the skilled person would directly and unambiguously derive an embodiment falling within the ambit of the claim from the cited prior art document (adapted from T 890/17 r.1.2).[1] The disclosure must inevitably lead to subject-matter falling within the scope of the claim (T 2160/18 r.31). In addition, the teaching of the cited prior art document has to be enabling (see T 206/83).

2. Because lack of novelty can be based not only on (explicitly or implicitly) disclosed features but also on inherent features, this statement of the rule can be refined: the disclosure in the state of the art must, *when reduced to practice*, inevitably lead to a product (or process) that falls within the scope of the claim. In the context of the present referral, this means that the cited prior art document must directly and unambiguously provide a specific teaching that meets two requirements: (i) the skilled person can reduce it to practice, and (ii) when reduced to practice, it gives inevitably an embodiment falling under the scope of the claim, i.e. an embodiment that exhibits all features that are specified in the claim under examination.

3. It follows that a lack of an enabling teaching for an embodiment that is formally disclosed in a prior art document does not disqualify that document as prior art but

[1] As explained in T 890/17, this rule can be derived from the uniform concept of disclosure (as established and reaffirmed by G 3/89, G 11/91, G 1/03 and G 2/10) when applied in the context of novelty.

causes the document to be not novelty-destroying for a claim directed to or encompassing that embodiment.

4. For inventive step, the requirement is that the combination of prior art documents relied upon provides, in an obvious manner, a teaching that the skilled person can reduce to practice and that, when reduced to practice, provides an embodiment that falls under the scope of the claim. It is therefore possible that the teaching of a cited document is non-enabling and that this deficiency is repaired by another cited document, for inventive step.

   See, in this respect, e.g. T 1203/19, T 699/19, T 1123/16, and T 1018/21, all in connection with the prior art for a second medical use claim. In each decision, a non-enabled prior art document was considered for inventive step.

   By way of further illustration, T 595/90 r.5 (OJ 1994 p.695) can be cited, which concerns inventive step of products that are envisaged as desirable in the prior art. In that decision, the prior art technical report B(1), which suggested the claimed product as an unobtainable desideratum with the then available grain growth inhibitors, was cited in the inventive step analysis in combination with other documents (including a more recent document B(3) where a new grain growth inhibitor was presented) and inventive step was denied.[2]

5. To conclude, the effect of non-enablement of a prior art document is not to exclude a pre-existing and public document from the state of the art in the sense of the prior art basis.

6. The headnote of Opinion G 1/92 should not be an obstacle to adopting the above analysis. G 1/92 can be understood with a focus on its holding that an opponent does not need to show that the skilled person had particular reasons for analysing the chemical composition of a prior art product, in view of the questions referred by the President of the EPO and in view of decision T 93/89 which was overruled by said Opinion. This, in fact, seems to be settled case law since T 952/92 (OJ 1995 p.755).

7. A possible interpretation of Article 54 EPC is, therefore, that Article 54(2) EPC defines a set of *documents* that form the prior art basis (and similarly for other types of publications). In other words, Article 54(2) EPC specifies when a document belongs to the state of the art in the sense of a set of documents, i.e. the prior art basis.[3]

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[2] See also *Raytheon Techs. Corp. v. Gen. Elec. Co.*, 993 F.3d 1374 (Fed. Cir. 2021): “To render a claim obvious, the prior art, taken as a whole, must enable a skilled artisan to make and use the claimed invention. (…) In general, a prior art reference asserted under § 103 does not necessarily have to enable its own disclosure, i.e., be "self-enabling," to be relevant to the obviousness inquiry.” (internal citations omitted)

[3] The same applies to Article 54(3) EPC.

In contradistinction, Article 54(1) EPC should not be interpreted in the literal sense, as specifying that an invention (i.e. subject-matter) can be a member of the collection of documents constituting the state of the art, because subject-matter and documents are different categories. Therefore, Article 54(1) EPC should not be interpreted as stipulating that "if an invention forms part of the prior art basis, it shall be considered not new". Rather, the phrase 'does [not] form part' in Article 54(1) EPC needs interpretation.

8. The interpretation of Article 54(1) EPC should not exclusively focus on the grammatical method of interpretation (see, recently, J 5/23 r.2.3.2). In the present case, the systematic and the teleological methods favour an interpretation that enablement does not affect the prior art basis, as speculative disclosures in the prior art can still make subject-matter obvious when combined with later documents. Hence, I propose that a suitable interpretation of Article 54(1) EPC is the requirement for lack of novelty as outlined in §2 hereinabove.[4]

This interpretation is supported by the *travaux préparatoires*, as observed in point 10 of the referral decision, in particular in point 10.2. As shown therein, the relevant committee did not intend to specify a detailed rule for the enablement aspects of novelty in the wording of Article 54 EPC.

9. Hence, the proposed answer to the first question is no, the answer to the second question is yes, and the third question does not need to be answered.

10. Tentatively, the above conclusions could be summarised as follows:

> 1. A prior art disclosure is not to be excluded from the state of the art in the sense of Article 54(2) and (3) EPC on the ground that one or more of its teachings are not enabled.
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> 2. Lack of novelty and lack of inventive step both require that the skilled person arrives, respectively would arrive, at an embodiment which exhibits the features of the claim under examination and which the skilled person could reduce to practice at the relevant date.
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> 3. The holding of Opinion G 1/92 should be understood as follows: information about a structural or compositional property of a product belongs to the state of the art in the sense of Article 54(2) EPC when the product as such is available to the public and the property can be analysed by the skilled person without undue burden, irrespective of whether or not particular reasons can be identified for analysing the composition in respect of said property.

[4] Similarly, Article 56 EPC can be understood to specify that an invention shall be considered as involving an inventive step if, having regard to the prior art basis, it is not obvious to a person skilled in the art; wherein obviousness of an invention requires (at least) that cited prior art documents make obvious a technical teaching that meets two requirements: (i) the skilled person can reduce it to practice, and (ii) when reduced to practice, it gives an embodiment falling under the scope of the claim.

11. Proposed point 3 is the application of the general principle that the theoretical possibility of having access to information renders it available to the public in the sense of Article 54(2) EPC (T 444/88 and T 381/87) to the structural and compositional properties of products as prior art, as is already implied in the Case Law of the Boards of Appeal, 10th edition, paragraph I.C.3.1. For completeness' sake, this principle does not extend to functional properties of products, such as, e.g., therapeutic effects and specific interactions that can be measured with binding assays.

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12. If the questions are answered as proposed herein, the remaining issue to be decided in the underlying appeal is whether the claimed subject-matter was obvious or not having regard to all the relevant prior art on file; in particular, whether example 3 of D1 alone, or in combination with common general knowledge or other documents, provides, in an obvious manner, a teaching that the skilled person can reduce to practice without undue burden and that, when reduced to practice, provides an embodiment that exhibits all features specified in the claim under examination. This issue appears to be chiefly a fact-specific question.

This enquiry, however, involves no requirement for an exact reproduction of the commercial polymer used in example 3 of D1. Instead, the required degree of similarity between D1 and the embodiment reduced to practice is defined by the breadth of the claim under examination.

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13. The question may arise whether the skilled person, when trying to reduce to practice a prior art teaching in the field of chemistry, such as D1 – an international patent application on which a European patent was granted – can start from any commercially available chemical product, or, roughly speaking, from mineral oil only. The latter seems an extreme position; the former would imply that a patent application could meet the requirements of Article 83 EPC even if it involves, as an essential element of its technical teachings, a non-divulged trade secret.

This question could arise both under point 2 as proposed above, and under the original headnote of G 1/92. The question is, moreover, touched upon in points 19 and 20 of the referral decision.

14. To address this question, it may be observed that T 206/83 r.2 already held that the enablement requirement is *identical* under Article 54(2), Article 54(3) and Article 83 EPC.[5] This principle is to be upheld in my view. It is a hallmark of the case law of the EPO that uniform concepts are applied throughout the substantive patent law requirements of the EPC (cf. the uniform concept of 'disclosure' as emphasized in G 2/10). It can be appreciated that such an approach demands a rigorous analysis

[5] The enablement requirement under Article 87 EPC is logically the same (see G 1/15).

of the concepts involved and serves to strike a fair balance between the interests of patent proprietors and the principles of free trade.

15. However, a strict approach to enablement for commercial products may have repercussions for the drafting of patent applications, as already observed in T 206/83 r.3 in connection with Article 83 EPC:

> "the skilled person is therefore left to his own resources to find a route to those precursors before he can prepare the end-products. Such situation is not uncommon in chemistry, since many applications start from basic materials which are assumed by the Applicant to be readily available on the market or by "standard" methods. There is a risk that the inventor or the draftsman of the specification is unduly influenced by his excessive experience in the relevant field, so as to neglect providing all the detailed instructions in the specification which are necessary for carrying out the invention without difficulties."

16. On the other hand, a liberal approach could invite attempts of applicants to unduly combine patent protection with trade secrets to protect the same technology, for instance, by patenting uses of a product X, which product is commercially available from the patent proprietor only, without divulging the trade secrets involved in its manufacture. In this way, the proprietor could avoid dedicating product X to the public after the end of the patent term. However, one of the legitimising principles of patent law is that a patented invention becomes a common good, benefitting society, at the latest when the patent term expires.

17. At this stage, I prefer not to draw any conclusions on this dilemma beyond agreeing with the conclusion of T 206/83 that the concept of enablement should be uniform under the EPC.

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The above observations are my personal views only.

Respectfully submitted,

/ *Peter de Lange* /

c/o V.O. Patents & Trademarks
Utrecht, The Netherlands

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