# Enlarged Board of Appeal EPO, 11 December 1989, Bayer



## PATENT LAW

# Second non-medical indication: novelty of second use with same technical means of of execution

• A claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Article 54(1) EPC provided that such technical feature has not previously been made available to the public

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Case number: G 0006/88 Applicant name: Bayer

[...]

## **Summary of the Procedure**

I. In the course of examining and deciding upon the appeal in case T 208/88, Chemical Board of Appeal 3.3.1 of its own motion in its Decision dated 20 July 1988 referred the following question of law to the Enlarged Board of Appeal under Article 112(1)(a) EPC: Is a claim to the use of a chemical compound or class of compounds for a particular non-medical purpose novel within the meaning of Article 54 EPC, having regard to prior art which discloses the use of that compound (class of compounds) for a different non-medical purpose, if the two teachings are carried out by identical technical means and the only novel feature in the claim is the use itself? The subject-matter of this question had already been discussed in the Statement of Grounds of Appeal filed on 19 March 1988. In a communication dated 7 October 1988, the Appellant's attention was drawn to the fact that in copending appeal G 2/88, essentially the same question had already been referred to the Enlarged Board, and further supplementary observations were invited. In replies dated 7 March, 1 June and 9 June 1989, the Appellant filed further submissions. Oral proceedings were held on 26 June 1989, during which the Appellant presented additional submissions.

- II. The Appellant's case in connection with the referred question of law can be summarised as follows:
- 1. The discovery of new and surprising properties in a compound, which are industrially applicable, can properly form the basis for a patentable invention. In the

case of the application in suit, for example, the technical teaching of the invention is not restricted to the mechanical means of application, but must be considered as a totality: if the teaching for technical action in its totality is not within the state of the art, there is novelty. In this connection, the technical features of "use" and "process" inventions should be recognised as different.

- 2. Decision G 1/83 (OJ EPO 1985, 60) is not applicable to the present case, and passages from that decision taken out of context should not be applied against the present Appellant. In this appeal the EPC is directly applicable in favour of the Appellant, the exclusions of Article 52(4) EPC not being applicable. The EPC should be interpreted to provide equal treatment for inventors of all types of invention.
- 3. The evaluation of novelty does not depend upon the purely intellectual information content but upon concrete teaching for technical action. A use patent is not granted for the means of realisation of the use, but for the previously unknown use itself. Methods of use are to be distinguished from methods of manufacture. A new purpose of use represents a functional indication which is a technical feature of the invention. For novelty it is decisive whether the content of the claims as a whole is contained in the state of the art.
- 4. To refuse claims to a use invention as in the present case would cause disharmony between the EPC and most Contracting States, who normally grant patents for a new use of a known product.
- III. During oral proceedings which took place on 26 June 1989, the Appellant emphasised the following points in particular:
- 1. There should be no discrimination between further medical and non-medical uses.
- 2. A use claim should not be equated with a process claim, but is a separate category.
- 3. Use claims of the type in question should be allowed in the interests of international harmony.
- 4. The novel technical feature in a use claim of this type is functional in nature. At the conclusion of the oral proceedings, the Board reserved its decision.
- IV. By letter dated 3 August 1989, the President of the European Patent Office presented to the Chairman of the Enlarged Board of Appeal a written reasoned request to be invited to comment upon some questions of general interest which arose in connection with the referred question, pursuant to Article 11a of the Rules of Procedure of the Enlarged Board of Appeal, which came into force on 7 July 1989 (OJ EPO 1989, 362). By letter dated 13 September 1989, the Chairman replied to the President that the Enlarged Board had decided not to invite him to comment, particularly having regard to the fact that the relevant question of law was first referred to the Enlarged Board on 26 April 1988, that oral proceedings took place on 26 June 1989, and that the Enlarged Board was at an advanced stage in its deliberations preceding the issue of its decision.

## **Reasons for the Decision**

1. Having regard to the purpose for which questions are referred to the Enlarged Board as set out in Article 112

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EPC, it is appropriate that the Enlarged Board should not take too narrow a view of the question which has been referred but should consider and answer it in such a way as to clarify the points of law which lie behind it. 2. Prior to the entry into force of the EPC in 1978, the role of patent claims in determining the protection conferred by a patent had developed differently within the national patent systems of the countries that are now Contracting States. Such different developments reflected somewhat different national philosophies underlying the concept of patent protection. In particular, the extent to which the wording of the claims determined the scope of protection varied considerably from country to country, and this factor significantly affected drafting practice. In some countries, in particular Germany, in practice the protection conferred by a patent depended more upon what was perceived to be the inventor's contribution to the art, as disclosed in the patent, by way of the general inventive concept, than upon the wording of the claims. In other countries, in particular the United Kingdom, the precise wording of the claims was regarded as crucial, because the claims were required to define the boundary between what was protected and what was not, for purposes of legal cer-

2.1 The manner in which claims were drafted naturally developed differently in the different countries, depending upon the relative importance of their function. Clearly in a country such as the United Kingdom, the wording of a claim had to provide a much more precise definition of what was sought to be protected than in countries such as Germany, where a statement of the essence of the inventive concept was more appropriate. 2.2 There are basically two different types of claim, namely a claim to a physical entity (e.g. product, apparatus) and a claim to a physical activity (e.g. method, process, use). Various sub-classes are possible (e.g. a compound, a composition, a machine; or a manufacturing method, a process of producing a compound, a method of testing, etc.). Furthermore, claims including both features relating to physical activities and features relating to physical entities are also possible. There are no rigid lines of demarcation between the various possible forms of claim.

2.3 The question which has been referred to the Enlarged Board is concerned with "use" claims: that is, with claims defining a "use of compound X for a particular purpose", or similar wording. The recognition or discovery of a previously unknown property of a known compound, such property providing a new technical effect, can clearly involve a valuable and inventive contribution to the art. In countries such as Germany, such inventions have for many years commonly been sought to be protected by means of "use" claims. In countries such as the United Kingdom, prior to 1978 such use claims were rarely found in patent applications and patents, a claim to an invention of such a character would normally have been defined in terms of the essential physical steps comprising the "activity" to be protected.

2.4 Despite the entry into force of the EPC, European

patent applications originating in the different Contracting States have continued commonly to include claims drafted in accordance with the traditional practices of such Contracting States discussed above. However, the requirements for drafting claims in respect of inventions which are the subject of European patent applications and patents, and the patentability of such inventions, are all matters which must be decided upon the basis of the law under the EPC. The function of the claims is central to the operation of the European patent system.

2.5 Article 84 EPC provides that the claims of a European patent application "shall define the matter for which protection is sought". Rule 29(1) EPC further requires that the claims "shall define the matter for which protection is sought in terms of the technical features of the invention". The primary aim of the wording used in a claim must therefore be to satisfy such requirements, having regard to the particular nature of the subject invention, and having regard also to the purpose of such claims. The purpose of claims under the EPC is to enable the protection conferred by the patent (or patent application) to be determined (Article 69 EPC), and thus the rights of the patent owner within the designated Contracting States (Article 64 EPC), having regard to the patentability requirements of Articles 52 to 57 EPC. It follows that the technical features of the invention are the physical features which are essential to it. When considering the two basic types of claim referred to in paragraph 2.2 above the technical features of a claim to a physical entity are the physical parameters of the entity, and the technical features of a claim to an activity are the physical steps which define such activity. A number of decisions of the Boards of Appeal have held that in appropriate cases technical features may be defined functionally (see e.g. T 68/85, OJ EPO, 1987, 228; T 139/85 EPOR 1987, 229).

3. For the purpose of determining their technical features, the claims must be interpreted in accordance with Article 69(1) EPC and its Protocol. The Protocol was adopted by the Contracting States as an integral part of the EPC in order to provide a mechanism for harmonisation of the various national approaches to the drafting and interpretation of claims discussed in paragraph 2.1 above. The central role of the claims under the EPC would clearly be undermined if the protection and consequently the rights conferred within individual designated Contracting States varied widely as a result of purely national traditions of claim interpretation: and the Protocol was added to the EPC as a supplement primarily directed to providing an intermediate method of interpretation of claims of European patents throughout their life, as a compromise between the various national approaches to interpretation and determination of the protection conferred ("... so as to combine a fair protection for the patentee with a reasonable degree of certainty for third parties"). The object of the Protocol is clearly to avoid too much emphasis on the literal wording of the claims when considered in isolation from the remainder of the text of the patent in which they appear; and also to avoid

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too much emphasis upon the general inventive concept disclosed in the text of the patent as compared to the relevant prior art, without sufficient regard also to the wording of the claims as a means of definition.

4. The legal problems associated with the patentability of claims to the new use of a known compound provided the subject-matter for the first seven Decisions to be issued by the Enlarged Board of Appeal, namely G 1-7/83 (three of which, G 1/83, G 5/83 and G 6/83 in German, English and French respectively, are published in OJ EPO 1985, 60, 64, 67). Such Decisions were all concerned with the patentability of further medical uses for a substance already known to have one medical use; and with the appropriate form of claim in respect of such an invention. All such Decisions have essentially the same content. In this Decision, it is only necessary to refer to the relevant German language Decision, G 1/83. The present Enlarged Board has considered how far the reasoning there set out bears upon the point of law to be decided in the present case. The question of law which was referred to the Enlarged Board in G 5/83 arose essentially because of the particular exclusion from patentability in relation to "methods of treatment of the human or animal body" set out in the first sentence of Article 52(4) EPC, and the exception to that exclusion set out in Article 54(5) EPC. The reasoning in G 5/83 is therefore primarily directed to answering a question of law concerning the allowability of claims whose subject-matter is a particular kind of medical or veterinary invention. The ratio decidendi of that Decision is essentially confined to the proper interpretation of Articles 52(4) and 54(5) EPC in their context. In that field of technology, the normal type of use claim is prohibited by Article 52(4) EPC, but Article 54(5) EPC expressly provides for an exception to the general rules for novelty (Articles 54(1) to (5) EPC) in respect of the first medical or veterinary use of a substance or composition, by allowing a claim to the substances or compositions for that use. G 1/83 applied this to cases of second and subsequent therapeutic use, but expressly indicated that such a special approach to the derivation of novelty could only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC. The present Enlarged Board of Appeal endorses that view. G 1/83 has the effect of giving to the inventor of a new use for a known medicament a protection analogous to but restricted in comparison with the protection normally allowable for a new non- medical use. The patentability of a second non-medical new and non-obvious use of a product is clearly recognised in principle (see Reasons 21). The patentability of "the (second or subsequent) use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application" was accepted, because although the exclusion of therapeutic methods from patentability provided in Article 52(4) (on the ground that then these are not susceptible of industrial application) has the effect of excluding from patentability a claim directed to the use of a substance for therapy (see Reasons 13), this type of claim would be clearly allowable (as susceptible of industrial application) for a non-medical use. Compare: "The use of X for treating disease A in mammals" (not allowed), with "The use of X for treating disease B in cereal crops" (allowed). In contrast, the question of law which has been referred to the Enlarged Board in the present case is not related to medical inventions but is of a general nature, being primarily concerned with the question of interpretation of Article 54(1) and (2) EPC.

5. The question referred assumes that the only novel feature in the claim under consideration is the purpose for which the compound is to be used. However, insofar as the question of interpretation of Article 54(1) and (2) EPC and the question of the allowable scope of protection (if any) of inventions concerning a further non-

for which the compound is to be used. However, insofar as the question of interpretation of Article 54(1) and (2) EPC and the question of the allowable scope of protection (if any) of inventions concerning a further non-medical use are matters of general importance, it will be appropriate for this Board to consider the question raised more generally, and in particular to consider other possible constructions for such use claims.

6. As discussed at paragraphs 2 to 2.5 above, the claims

6. As discussed at paragraphs 2 to 2.5 above, the claims of a European patent should clearly define the technical features of the subject invention and thus its technical subject-matter, in order that the protection conferred by the patent can be determined and a comparison can be made with the state of the art to ensure that the claimed invention is inter alia novel. A claimed invention lacks novelty unless it includes at least one essential technical feature which distinguishes it from the state of the art. When deciding upon the novelty of a claim, a basic initial consideration is therefore to construe the claim in order to determine its technical features.

7. In relation to a claim whose wording clearly defines a new use of a known compound, depending upon its particular wording in the context of the remainder of the patent, the proper interpretation of the claim will normally be such that the attaining of a new technical effect which underlies the new use is a technical feature of the claimed invention. In this connection, and with reference to the discussion in paragraphs 2.1 and 2.2 above, it is necessary to bear in mind the Protocol to Article 69 EPC, as discussed in paragraph 4 above. Thus with such a claim, where a particular technical effect which underlies such use is described in the patent, having regard to the Protocol, the proper interpretation of the claim will require that a functional feature should be implied into the claim, as a technical feature; for example, that the compound actually achieves the particular effect.

7.1 An example of such a claim which should be so interpreted can be given by reference to the facts in Decision T 231/85 (OJ EPO 1989, 74). The claims in question define "Use of (certain compounds) ... for controlling fungi and for preventive fungus control" - and the application contained teaching as to how to carry this out so as to achieve this effect. Prior published document (1) described the use of the same compounds for influencing plant growth. In both application T 231/85 and document (1), the respective treatments were carried out in the same way (so the means of realisation was the same). The Examining Division held that the claimed invention lacked novelty, apparently

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on the basis that the means of realisation was the same in document (1), and so the claimed effect underlying the use for fungus control must have been achieved in the treatment described in document (1). The Board of Appeal on the other hand held that the claimed invention was novel, on the basis that the technical teaching ("Lehre") in the application was different from that in document (1), and that the use was hitherto unknown, even though the means of realisation was the same. In the view of the Enlarged Board, with reference to the discussion concerning the interpretation of claims in paragraph 7, the claim in question should properly be construed, having regard to the Protocol to Article 69 EPC, as implicitly including the following functional technical feature: that the named compounds, when used in accordance with the described means of realisation, in fact achieve the effect (i.e. perform the function) of controlling fungus. Such a functional feature is a technical feature which qualifies the invention: and the use claim is properly to be considered as a claim containing technical features both to the physical entity (the compound and its nature), and to a physical activity (the means of realisation). In other words, when following the method of interpretation of claims set out in the Protocol, what is required in the context of a claim to the "use of a compound A for purpose B" is that such a claim should not be interpreted literally, as only including by way of technical features "the compound" and "the means of realisation of purpose B"; it should be interpreted (in appropriate cases) as also including as a technical feature the function of achieving purpose B (because this is the technical result). Such a method of interpretation, in the view of the Enlarged Board, is in accordance with the object and intention of the Protocol to Article 69 EPC. If the proper construction of such a claim in the context of a particular patent is such as to include such a functional technical feature, the question which remains to be considered is whether such claimed invention is novel. 8. Article 54(2) EPC defines the state of the art as comprising "everything made available to the public by means of a written or oral description, by use, or in any other way." Thus, whatever the physical means by which information is made available to the public (e.g. written description, oral description, use, pictorial description on a film or in a photograph etc., or a combination of such means), the question of what has been made available to the public is one of fact in each case. The word "available" carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection. In the case of a "written description" which is open for inspection, what is made available in particular is the information content of the written description. Furthermore, in some cases, the information which the written description actually contains, teaching the carrying out of a process for example, also makes available further information which is the inevitable result of carrying out such teaching (see in this respect Decision T 12/81 Diastereomers, OJ EPO 1982, 296, Reasons paragraphs 7 to 10, Decision T 124/87, Copolymers EPOR 1989, 33 and Decision T 303/86 Flavour concentrates, EPOR 1989, 95 for example). In each such case, however, a line must be drawn between what is in fact made available, and what remains hidden or otherwise has not been made available. In this connection the distinction should also be emphasised between lack of novelty and lack of inventive step: information equivalent to a claimed invention may be "made available" (lack of novelty), or may not have been made available but obvious (novel, but lack of inventive step), or not made available and not obvious (novel and inventive). Thus, in particular, what is hidden may still be obvious.

8.1 In cases where, for example, a compound has previously been described as having been used, but for a different purpose from the claimed use, and the previously described use had inherently had the same technical effect as the claimed use, the question arises as to whether there is a lack of novelty. In this connection problems in relation to infringement can also arise if there is no finding of lack of novelty in such circumstances, since a user of the previously described use would risk infringement of a later filed patent. In respect of this submission, the Enlarged Board would emphasise that under Article 54(2) EPC the question to be decided is what has been "made available" to the public: the question is not what may have been "inherent" in what was made available (by a prior written description, or in what has previously been used (prior use), for example). Under the EPC, a hidden or secret use, because it has not been made available to the public, is not a ground of objection to validity of a European patent. In this respect, the provisions of the EPC may differ from the previous national laws of some Contracting States, and even from the current national laws of some non-Contracting States. Thus, the question of "inherency" does not arise as such under Article 54 EPC. Any vested right derived from prior use of an invention is a matter for national law (see, in this connection, e.g. Article 38 of the Community Patent Convention, not yet in force). Furthermore, as to the suggested problems concerning infringement referred to above, it is to be noted that analogous problems would result from G 1/83 in the medical area.

8.2 This point may be illustrated by a further reference to the facts of Decision T 231/85. If the claims are interpreted as discussed in paragraph 7.1, the question in relation to novelty is whether document (1) made available to the public the technical feature that the compounds, when used as described, achieved the effect of controlling fungus. The Board of Appeal there referred in its decision to the "hitherto unknown" use of such compounds for controlling fungi and the "unnoticed protective effect" (even though the means of application of such compounds to plants (the "technical realisation") was the same). Thus, although document (1) described a method of treating plants with compounds in order to regulate their growth which, when carried out, would inevitably have been inherently a use of such compounds for controlling fungi, neverthe-

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less it appears that the technical feature of the claim set out above and underlying such use was not "made available" to the public by the prior written description in document (1).

9. The answer to the question referred may therefore be summarised as follows: with respect to a claim to a new use of a known compound, such new use may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim (e.g. the achievement in a particular context of that technical effect). If that technical feature has not been previously made available to the public by any of the means as set out in Article 54(2) EPC, then the claimed invention is novel, even though such technical effect may have inherently taken place in the course of carrying out what has previously been made available to the public.

## **ORDER**

## For these reasons, it is decided that:

The question of law which was referred to the Enlarged Board of Appeal is answered as follows: A claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Article 54(1) EPC provided that such technical feature has not previously been made available to the public.

Remarks: Referral by the Board of Appeal 3.3.1 T 0208/88 of 20 July 1988, unpublished

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