Decision of the Enlarged Board of Appeal dated 5 December 1984 Gr 05/83

Composition of the Board:
Chairman: R. Singer
Members: P. Ford, O. Bossung, R. Kämpf, M. Prélot, G. Szabo, J. van Voorthuizen

Title of invention: Use of butoxybenzylhyoscyamine bromide in pharmaceutical compositions against deafness and tinnitus

Applicant: Eisai Co., Ltd.

Headword: "Second medical indication/EISAI"

EPC Article 52 (1), 52 (4), 54 (5), 57

Vienna Convention Article 31, 32

"Interpretation of the EPC / Vienna Convention" — "therapeutical use claims"

Headnote

I. A European patent with claims directed to the use may not be granted for the use of a substance or composition for the treatment of the human or animal body by therapy.

II. A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application.

Summary of the Procedure

I. In the course of examining seven separate appeals against refusal of European patent applications, the Technical Board of Appeal for Chemistry has referred the following question of law to the Enlarged Board of Appeal for decision, in accordance with Article 112 EPC: Can a patent with claims directed to the use be granted for the use of a substance or composition for the treatment of the human or animal body by therapy? The decision referring this question in the present case was dated 20 June 1983.

II. By a written communication from the Enlarged Board of Appeal, the appellants were given the opportunity to submit comments in writing to the Enlarged Board of Appeal on this question. It was indicated to each appellant that the Enlarged Board of Appeal was concerned with the same point of law in six other cases and that the Board would examine the point of law in each of the cases at the same time.

It was stipulated that comments should be confined to legal arguments on the point of law. The Board indicated that after the period for submitting comments had expired it would examine the comments received and inform the appellants whether it could give an unqualified affirmative answer to the point of law submitted. If that were not so, the Board would hold oral proceedings, if so requested.

III. The appellants made written submissions which were duly considered by the Enlarged Board of Appeal.

IV. By a further written communication, the Enlarged Board of Appeal indicated that, for stated reasons, it did not consider that an affirmative answer could be given to the question of law put by the Technical Board of Appeal for Chemistry. However, attention was drawn to a recently adopted statement of practice regarding "use claims" issued by the Swiss Federal Intellectual Property Office, in accordance with which (*inter alia*) a claim to the use of an active ingredient for the manufacture of a medicament ready for administration could be allowed even where it related to the second (or further) application for a known pharmaceutical composition. The Enlarged Board of Appeal stated that it considered that it was also necessary to decide whether this kind of claim was acceptable under the European Patent Convention.

All the appellants were invited to file observations with particular reference to the acceptability of this Swiss type of "use claim".

Oral proceedings were provisionally arranged to take place in November 1984, but, in inviting the appellants to file requests to be heard in such proceedings, the Enlarged Board of Appeal asked them to indicate whether they would still wish to be heard if, after considering their observations, the Board found that it could give a decision in favour of the Swiss type of "use claim". Summonses to oral proceedings were then duly issued.

V. Some appellants filed observations and others did not but all appellants indicated that they would not wish to be heard in oral proceedings if the Enlarged Board of Appeal found that it could give a decision in favour of the Swiss type of "use claim".

VI. The Enlarged Board of Appeal subsequently cancelled the oral proceedings.

Reasons for the Decision

Preliminary Observations: Interpretation of the European Patent Convention

1. As an international treaty, the European Patent Convention has to be interpreted in accordance with the rules of interpretation developed in the so-called "law of nations" or public international law. To the traditional kind of international treaty which regulates legal relations between States must today be added the treaty which directly creates and defines rights and duties for individuals and corporate bodies. According to the generally accepted opinion, the principles of interpretation to be applied to both kinds of treaty are identical.

2. Since this case is one of the first group of cases to come before the Enlarged Board of Appeal and since the question of interpretation of the European Patent Convention has been raised by two of the parties, the first matter to be settled by the Enlarged Board, without any reference to the specific question of law in this case, is the approach to interpretation of the European Patent Convention. The Legal Board of Appeal (cf. Case J 08/82: OJ EPO 1984, 155) and the Technical Board of Appeal for Chemistry (cf. Case T 128/82: OJ EPO 1984, 164) have already applied the principles of interpretation set out in The Vienna Convention on the Law of Treaties, concluded on 23 May 1969 (reprinted, in part, in OJ EPO 1984, 192).

3. The provisions of the Vienna Convention do not apply to the European Patent Convention *ex lege,* since the former Convention applies only to treaties which are concluded by States after the entry into force of the Vienna Convention with regard to such States (Article 4, Vienna Convention). At the time of conclusion of the European Patent Convention, the Vienna Convention was not in force at all.

4. Nevertheless, there are convincing precedents for applying the rules for interpretation of treaties incorporated in the Vienna Convention to a treaty to which in terms they do not apply. The International Court of Justice has already applied principles expressed in the Vienna Convention to situations to which the Convention strictly did not apply, whilst the European Court of Human Rights, the Federal German Constitutional Court and the House of Lords (England) have applied the principles of interpretation in Articles 31 and 32 of the Convention also to treaties to which strictly they do not apply (cf. Wetzel, Rausching "Die Wiener Vertragsrechtskonvention", Metzner, Frankfurt 1978 and *Fothergill v. Monarch Airlines* [1981] A.C. 251 (House of Lords (England)).

After a careful study of the whole subject, the Enlarged Board of Appeal concludes that the European Patent Office should do the same.

5. The text of Articles 31 and 32, Vienna Convention, has been reprinted in the Official Journal of the EPO, as noted above, and need not be repeated here. The effect of these provisions, so far as concerns interpretation of the EPC can, however, be summarised in the following rules:

(1) The treaty must be interpreted in good faith.

(2) Unless it is established that the Contracting States intended that a special meaning should be given to a term, the terms of the treaty shall be given their ordinary meaning in their context and in the light of the object and purpose of the EPC.

(3) The context, for this purpose, is

the text (including the Preamble and Implementing Regulations) *and*

any agreement made between all the parties in connection with the conclusion of the treaty (e.g. the Protocol to Article 69 EPC).

(4) There shall also be taken into account:

— any subsequent agreement between the parties regarding interpretation or application of the provisions.

— any subsequent practice which establishes the agreement of the parties regarding interpretation.

— any relevant rules of public international law.

(5) The preparatory documents and the circumstances of the conclusion of the treaty may be taken into consideration

— in order to confirm the meaning resulting from the application of the previous rules or

— to determine the meaning, when applying those rules either leaves the meaning ambiguous or obscure or leads to a manifestly absurd or unreasonable result.

6. In the interpretation of international treaties which provide the legal basis for the rights and duties of individuals and corporate bodies it is, of course, necessary to pay attention to questions of harmonisation of national and international rules of law. This aspect of interpretation, not dealt with by the provisions of the Vienna Convention, is particularly important where, as is the case with European patent law, provisions of an international treaty have been taken over into national legislation. The establishment of harmonised patent legislation in the Contracting States must necessarily be accompanied by harmonised interpretation. For this reason, it is incumbent upon the European Patent Office, and particularly its Boards of Appeal, to take into consideration the decisions and expressions of opinion of courts and industrial property offices in the Contracting States.

The question of law referred to the Enlarged Board of Appeal

7. This case is one of seven in which the same question of law has been referred to the Enlarged Board of Appeal. Without formally consolidating the cases, the Enlarged Board has nevertheless considered all the appellants´ submissions at the same time. These have been fully taken into account by the Enlarged Board, although specific reference will not be made to them in this decision.

8. In referring the question of law to the Enlarged Board of Appeal, the Technical Board of Appeal rightly stressed its importance, particularly for the pharmaceutical industry, and the fact that it is controversial. These matters are also clear from the reported cases on the subject before national courts and tribunals and the voluminous periodical literature.

9. The question of law referred to the Enlarged Board relates to therapeutic use claims for substances and compositions in general. The Enlarged Board is, of course, aware that the problem of the protection of inventions of the so-called "second medical indication" is the central one. For this reason, the Enlarged Board has considered it right to examine all aspects of that problem.

10. As generally understood, the concept of "therapy" includes treatment with chemical substances or compositions. Article 54 (5) EPC exempts from the operation of the earlier paragraphs of that Article any substance or composition comprised in the state of the art for use in a method according to Article 52 (4) EPC. Reading the two Articles together, in context, it is, therefore, clear that Article 52 (4) EPC embraces chemotherapy in the broadest sense of that term.

11. The European Patent Convention, in general, allows both method claims and use claims but whether any activity is claimed as a method of carrying out the activity (setting out a sequence of steps) or as the use of a thing for a stated purpose (the sequence of steps being implied), is, in the opinion of the Enlarged Board, a matter of preference. For the European Patent Office there is no difference of substance. In the context of the present case, this means that any artificial distinction according to which, when the invention concerns the employment of a substance or composition for therapy, a method claim excludes and a use claim includes at least the preparation of a pharmaceutical product, with instructions for use in the treatment of illness (which has been called in German the *"augenfällige Herrichtung"*), cannot be accepted, because in both cases the active substance or composition for therapy must be in a state capable of exerting its therapeutic activity and this necessarily means that the active material has been formulated and made up into doses.

12. Whilst, therefore, there can be no objection to "use claims" in general, the obvious objection to a patent "with claims directed to the use" being granted for "the use of a substance or composition for the treatment of the human or animal body by therapy" is that it seems to be in direct conflict with the provisions of Article 52 (4) EPC, in accordance with which "methods for treatment of the human or animal body by therapy ... shall not be regarded as inventions which are susceptible of industrial application" within the meaning of Article 52 (1) EPC.

13. For the reasons already given, in the considered opinion of the Enlarged Board, a claim directed to the "use of a substance or composition for the treatment of the human or animal body by therapy" is in no way different in essential content from a claim directed to "a method of treatment of the human or animal body by therapy with the substance or composition". The difference between the two claims is one of form only and the second form of claim is plainly in conflict with Article 52 (4) EPC. Since this is so, no patent can be granted including any such claims: Article 97 (1) EPC.

14. Claims directed to substances or compositions for use in any methods for treatment of the human or animal body, on the other hand, are unquestionably directed to inventions which are susceptible of industrial application within the meaning of Article 52 (1) EPC. This is not only expressly made clear in Article 52 (4) EPC, last sentence, but also to be deduced from the definition of "susceptible of industrial application" in Article 57 EPC, namely, that the invention "can be made or used in any kind of industry, including agriculture". The last sentence of Article 52 (4) EPC, indeed, appears to be a statement of the self-evident, made out of an abundance of caution.

15. Furthermore, Article 54 (5) EPC provides that the general rules of law relating to novelty (Article 54 (1) to (4) EPC) shall not exclude the patentability of any substance or compositions, comprised in the state of the art *for use in* a method referred to in Article 52 (4) EPC, provided that its use for any such method is not comprised in the state of the art. Thus the inventor of a "first medical indication" can obtain purpose-limited product protection for a known substance or composition, without having to restrict himself to the substance or composition when in a form technically adapted to a specified therapeutic purpose. The appropriate protection for him is, therefore, in its broadest form, a purpose-limited product claim. No problem arises over its susceptibility of industrial application, within the meaning of Article 57 EPC.

16. Claims directed to the use of a substance or composition for the preparation of a pharmaceutical product are equally clearly directed to inventions which are susceptible of industrial application, within the meaning of Article 57 EPC.

17. At the time the question of law was referred to the Enlarged Board of Appeal in this case, the X Civil Chamber of the German Federal Court of Justice (*Bundesgerichtshof*, hereinafter referred to as "the Federal Court of Justice") had not decided the appeal in Case No. X ZB 4/83 *Hydropyridine* (OJ EPO 1984, 26). The Court has, however, decided that, in German national law, the subject-matter of a claim directed to the use of a chemical substance to treat an illness extends beyond the treatment of the illness to the *"augenfällige Herrichtung"*, which, as has been said, includes at least the packaging of the substance with instructions for use in the treatment of the illness. Such a claim can be used in German national law to protect the "second (or further) medical indication". The basis for this decision was the earlier national case law in the *Benzene sulfonyl urea* (68 BGHZ 156; GRUR

1977, 652; Bl.f.PMZ 1977, 198; in English 9IIC 42) and *Sitosteryl glycoside* (GRUR 1982, 548; Bl.f.PMZ 1982, 300; in English, 14IIC 283) cases. In the *Sitosteryl glycoside* case, in 1982, the Federal Court of Justice took the view that the use of a known substance to treat an illness was susceptible of industrial application because the *"augenfällige Herrichtung"* of the substance for therapeutic purposes in accordance with the invention could be performed in the industrial sector.

In the *Hydropyridine* decision, the Federal Court of Justice acknowledged that there was disagreement in the literature both in the Federal Republic of Germany and elsewhere whether a provision in the terms of Article 52 (4) EPC stands in the way of patent protection in respect of an invention involving the use of a substance, already known as a medicament, to treat an illness not previously treated by means of that substance. The Federal Court of Justice considered that it did not. It thought that the provision of German national law equivalent to Article 52 (4) EPC only excluded from patentability "methods for treatment of the human body by therapy which take place wholly outside the industrial sector".

18. The European Patent Office has the task of granting patents which have the same effect as national patents in all Contracting States, even though, at the present time, not all of them have completely harmonised patent laws or outlooks on patent matters. It is particularly important to bear in mind that Article 64 (3) EPC leaves questions of infringement to be dealt with by national law.

When a national court which is competent to consider both questions of law relating to the allowability of claims and questions of law relating to infringement considers the former, it is likely to be influenced in its thinking by the national rules and doctrines of infringement law with which the court is familiar.

It is therefore difficult for the Office to follow the practice of a superior court of only a single Contracting State in a matter which has a bearing on questions of infringement and which is regarded as controversial, however eminent that court may be. It is to be regarded as unfortunate that the appellant in the *Hydropyridine* case withdrew an appeal to the English Courts against a refusal of the United Kingdom Patent Office to grant a patent for the same invention. The decisions of the national courts of two Contracting States tending in the same direction might have had great weight.

Indeed, if other superior courts in Contracting States show that they are prepared to follow the line taken by the Federal Court of Justice in respect of national patent applications, the way may be open for the Enlarged Board of Appeal to reconsider the question so far as the European Patent Office is concerned.

For the time being, however, the Enlarged Board of Appeal adheres to its view that a claim directed to the use of a substance or composition for the treatment of the human or animal body by therapy is to be regarded by the European Patent Office as confined to the step of treatment.

19. As indicated in the Enlarged Board of Appeal´s communication dated 31 July 1984, having regard to the statement of practice of the Swiss Federal Intellectual Property Office, the Enlarged Board has also given careful consideration to the possibility of protecting second (and subsequent) medical indications by means of a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application. Such claims do not conflict with Article 52 (4) EPC or Article 57 EPC but there may be a problem concerning the novelty of the invention.

20. Where the medicament itself is novel in the sense of having novel technical features — e.g. a new formulation, dosage or synergistic combination — the ordinary requirements of Article 54 (1) to (4) EPC will be met and there will in principle be no difficulty over the question of novelty, whether the claim be directed to the medicament *per se* or to the use of the active ingredient to prepare the medicament. The critical case is, however, that in which the medicament resulting from the claimed use is not in any way different from a known medicament.

21. As is rightly recognised by the Federal Court of Justice, Article 52 (1) EPC expresses a general principle of patentability for inventions which are industrially applicable, new and inventive and it is clear that in all fields of industrial activity other than those of making products for use in surgery, therapy and diagnostic methods, a new use for a known product can be fully protected as such by claims directed to that use.

This is in fact the appropriate form of protection in such cases as the new and non-obvious use of the known product constitutes the invention and it is the clear intention of the European Patent Convention that a patent be granted for the invention to which a European patent application relates (cf. Articles 52 (1), 69, 84 and Rule 29 EPC read together). Article 54 (5) EPC provides an exception to this general rule, however, so far as the first use of medicaments is concerned, in respect of which the normal type of use claim is prohibited by Article 52 (4) EPC. In effect, in this case the required novelty for the medicament which forms the subject-matter of the claim is derived from the new pharmaceutical use.

It seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament and this irrespective of the fact whether any pharmaceutical use of the medicament was already known or not. It is to be clearly understood that the application of this special approach to the derivation of novelty can 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.

22. The intention of Article 52 (4) EPC, again as recognised by the Federal Court of Justice, is only to free from restraint non-commercial and non-industrial medical and veterinary activities. To prevent the exclusion from going beyond its proper limits, it seems appropriate to take a special view of the concept of the "state of the art" defined in Article 54 (2) EPC. Article 54 (5) EPC alone provides only a partial compensation for the restriction on patent rights in the industrial and commercial field resulting from Article 52 (4) EPC, first sentence. It should be added that the Enlarged Board does not deduce from the special provision of Article 54 (5) EPC that there was any intention to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim. The rule of interpretation that if one thing is expressed the alternative is excluded (*expressio unius (est) exclusio alterius*), is a rule to be applied with very great caution as it can lead to injustice. No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention: nor can it be deduced from the legislative history of the articles in question. On this last point, after conducting its own independent studies of the preparatory documents, the Enlarged Board finds itself also in accord with the conclusion of the Federal Court of Justice.

23. For these reasons, the Enlarged Board considers that it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient.

ORDER

For these reasons

It is decided that the question of law referred to the Enlarged Board of Appeal is to be answered as follows:

1. A European patent with claims directed to the use may not be granted for the use of a substance or composition for the treatment of the human or animal body by therapy.

2. A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application.