BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [X] To Chairmen and Members
(C) [ ] To Chairmen

D E C I S I O N
of 4 February 1999

Case Number: T 0863/96 - 3.3.2

Application Number: 89903719.6

Publication Number: 0404807

IPC: A61K 31/135

Language of the proceedings: EN

Title of invention:
Deprenyl for systemic transdermal administration

Patentee:
Somerset Pharmaceuticals, Inc.

Opponent:
Hexal-Pharma GmbH & Co. KG

Headword:
Deprenyl/SOMERSET PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 54, 123

Keyword:
"Disclaimer - exclusion of subject-matter from citation - highly questionable"
"Novelty - no - same use of the same drug for the same group of patients treated in the same application route with a drug having the same pharmaceutical effect"

Decisions cited:
G 0005/83, G 0002/88, T 0270/94, T 0143/94, T 0004/80, T 0170/87

Catchword:
The disclaimer to be formulated on the basis of a disclosure is only allowable if the cited document containing the said disclosure has no relevance for any further examination of the claimed invention and it must then disappear from the prior art field to be taken into consideration (see point 3 of the Reasons for the Decision).

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0863/96 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 4 February 1999

Appellant: (Opponent 01)
Hexal-Pharma GmbH
Industriestrasse 25
83607 Holzkirchen (DE)

Representative:
Boeters, Hans Dietrich, Dr.
Patentanwälte Boeters & Bauer
Bereiteranger 15
81541 München (DE)

Respondent: (Proprietor of the patent)
Somerset Pharmaceuticals, Inc.
777 S. Harbour Island Boulevard, Suite 880
Tampa, Florida 33602 (US)

Representative:
Hornby, John Richard
Clifford Chance
200 Aldersgate Street
London EC1A 4JJ (GB)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 19 July 1996 concerning maintenance of European patent No. 0 404 807 in amended form.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
R. E. Teschemacher

Summary of Facts and Submissions

I. European patent No. 0 404 807 was granted on the basis of seven claims in response to European patent application No. 89 903 719.6 corresponding to international application PCT/EP89/00291 with the international publication No. WO 89/09051.

Claim 1 as granted reads as follows:

"1. A pharmaceutical composition for systemic transdermal administration, incorporating as sole active agent N-methyl-N-(1-phenyl-2-propyl)-2-propinylamine in racemic or optically active form or a pharmaceutically acceptable acid addition salt thereof."

II. Two oppositions were filed against the granted patent. According to the grounds of opposition the patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step by the former Opponent 02, who withdrew the opposition on 10 November 1995, and for lack of inventive step by the Appellant (Opponent 01). Of the numerous documents cited during the opposition proceedings, only document

(1) EP-A-0 241 809

remains relevant to the present decision.

III. In an interlocutory decision under Article 106(3) EPC posted on 19 July 1996, the Opposition Division concluded that the patent in amended form and the invention to which it relates meet the requirements of the EPC.

The Opposition Division took the view that the subject-matter of the patent in suit was novel since document (1) did not disclose a separate formulation of deprenyl as sole active agent in combination with a transdermal application of that drug.

For the assessment of inventive step the disclosure in document (1) was considered to be of less relevance since it described the transdermal administration of deprenyl only in combination with amantidine and clearly indicated deprenyl alone being not sufficiently effective. Accordingly, inventive step of the subject matter of the patent in suit as amended was acknowledged.

IV. The Appellant lodged an appeal against the said decision and filed a statement of grounds.

In a communication pursuant to Article 11(2) of the Rules of Procedure of the Boards of Appeal, the parties were informed that the subject matter of the patent in suit appeared to lack novelty in the light of the prior art.

Oral proceedings took place on 3 February 1999.

During the oral proceedings the Respondent filed several sets of claims. Claim 1 of the last filed main request reads as follows:

"The use of N-methyl-N-(1-phenyl-2-propyl)-2-propinylamine in optically active (-)-form or a pharmaceutically acceptable acid addition salt thereof, as sole active agent in the manufacture of a

transdermal patch structure for systemic transdermal administration for the treatment of Parkinson's disease or depression in a patient not receiving a synergistic combination of amantadine and selegiline at all stages of the disease."

Claim 1 of the only auxiliary request which was maintained by the Respondent differs from that of the main request by the inclusion of the functional feature "...transdermal patch structure for systemic transdermal administration *for inducing a long lasting and constant inhibition of monoamine oxidase activity*..."

V. The Appellant took the view that claim 1 of the main request and that of the auxiliary request by the exclusion of the treatment of certain patients did not fulfil the requirements of Article 123(2) EPC. Furthermore, it was pointed out that disclaiming the treatment of a patient in any case was inadmissible since in accordance with Article 52(4) EPC such treatment of the human or animal body was excluded from patentable matter.

As regards the question of novelty it was particularly argued that document (1) disclosed for the treatment of Parkinson's disease the use of a selegiline formulation on one plaster and the sequential use of an amantadine formulation on another plaster. Since document (1) furthermore disclosed that selegiline alone was useful in the treatment of Parkinson's disease, claim 1 of the main request as well as that of the auxiliary request did not fulfil the requirements of Article 54 EPC. As regards the auxiliary request, it was particularly objected that the functional feature in claim 1 of **long**

lasting and constant inhibition of monoamine oxidase activity did not relate to the course of the disease but only to the duration of the effect after administration of one dosage of the drug.

VI. In the Respondent's view document (1) clearly represented a so-called accidental prior art in comparison with the subject matter of the patent in suit and therefore it was justified to disclaim parts of the disclosure of this document which could give rise to a novelty objection. The disclaimer left no doubt that document (1) in comparison with the patent in suit related to the use of selegiline for the manufacture of a different medicament for a different treatment of diseases.

The Respondent particularly emphasised that apart from the inclusion of the disclaimer the wording "*as sole active agent*" and "*for the treatment of Parkinson's disease*" had to be understood as limiting the scope of claim 1 such that a full treatment at all stages of the disease could be carried out by only using selegiline in a patch structure for systemic transdermal administration and excluding parallel or sequential treatments of the disease with other drugs. In accordance with decision G 5/83, OJ 1985, 64 such a new application route in the form of a monotherapy could establish novelty of the second medical indication.

It was inter alia argued that document (1) exclusively related to synergistic combinations of amantadine and selegiline and by clearly indicating insufficient anti-Parkinson activity of selegiline established a prejudice against using that drug alone. Accordingly, document (1) neither expressly nor implicitly disclosed the use of selegiline alone as the sole active agent and in no way could provide technical information how

to use that drug in the manufacture of a transdermal patch structure for a monotherapy of Parkinson disease at all stages of the disease. The mention of separate formulations according to document (1) at best could be regarded as a speculative disclosure. Moreover, since the worked examples of document (1) were focused on injection solutions and capsules and since the rest of the document described several other application routes such as suppositories, there was no reason to conclude that this prior art clearly and unambiguously disclosed - as would be required to destroy novelty in the present case - the use of selegiline alone in combination with a transdermal patch structure. In view of the long list of possibilities of administrating two different kinds of drugs and the further necessity to choose between the administration of selegiline and amantadine at the same time or sequential, by starting from document (1), it was only possible to arrive by a hindsight combination of selections at the subject-matter of the patent in suit. It was emphasised that the use of selegiline for a monotherapy of Parkinson's disease did not belong to the common general knowledge of a person skilled in the art. At the priority date of the patent in suit it was only common general knowledge that the racemat deprenyl was orally tested but without a final result whether or not it worked in practice and accordingly, there was no consistency by the skilled persons that deprenyl represented a useful product.

The inclusion of the technical feature **long lasting and constant inhibition of monoamine oxidase activity** in claim 1 of the auxiliary request more precisely defined that the transdermal administration according to the use of claim 1 allowed to raise the selegiline concentration to such an extent that monotherapy of Parkinson's disease was possible. As to the relevance of this feature as a new technical effect suitable for further establishing novelty of the claimed subject-

matter, reference inter alia was made to the situation in the so-called second non-medical use as underlying the decision G 2/88 OJ 1990, 93.

VII. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained on the basis of claims 1 and 2, in the version of the main request or of the auxiliary request as submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. The Board notes that the Opposition Division in its decision took up the novelty objection raised by the former Opponent 02 and gave a substantiated reasoning why the claims as granted fulfilled the requirements of Article 54 EPC in the light of document (1).

Moreover, having regard to the requirements under Article 113 EPC none of the parties involved in the proceedings can be excluded from taking up arguments presented by another party. The act of filing oppositions by different Opponents using different grounds of opposition does not lead to parallel opposition proceedings but establishes one common opposition procedure for each of the parties (see decision T 270/94, dated 22 January 1998, not in OJ EPO).

Accordingly, novelty under Article 54 EPC is at issue in the present appeal proceedings and the Board has, the Respondent's objections notwithstanding, allowed the Appellant to comment on this question.

3. The Board notes that in an attempt to overcome the novelty objection raised in the light of the disclosure of document (1), the Respondent has filed amended claims which comprise in addition to the features as granted on the one hand features relating to a positive definition of the subject-matter for which protection is sought and on the other hand features in the form of a so-called disclaimer intended to exclude subject-matter from the said prior art document.

Thus, the claims are of narrower scope than granted and satisfy Article 123(3) EPC.

3.1 As regards the positive features claim 1 of the main request is based on claim 6 as originally filed in combination with page 6, fourth and fifth paragraph of the description as originally filed.

The positive features of claim 1 of the auxiliary request can be derived from the same passages in the description as originally filed as those referred to for the main request and additionally are based on page 3, last full paragraph of the description as originally filed.

3.2 As regards the exclusion of the subject matter known from document (1), the Board has strong doubts whether such a formulation with a view to install not only novelty but also inventive step is admissible.

In accordance with the case law of the Boards of Appeal, it would be allowable under Article 123(2) EPC to formulate a disclaimer which is precisely defined

and limited to the prior art disclosure, provided this disclosure is an accidental novelty-destroying disclosure. From the jurisprudence of the Boards of Appeal dealing with this exceptional means for reinstalling novelty, it clearly appears that the disclaimer to be formulated on the basis of this disclosure is only allowable if the cited document containing the said disclosure has no relevance for any further examination of the claimed invention and it must then disappear from the prior art field to be taken into consideration. By way of example, reference can be made to decision T 4/80, (OJ 1982, 149), where the relevant document did not belong to the state of the art under Article 54(2) EPC, and to decision T 170/87 (OJ 1989, 441), where the disclaimer was not allowed because the subject-matter to be disclaimed was considered relevant to the assessment of inventive step.

In the present case document (1) undisputedly relates to the same field as that of the claimed invention. The fact that it deals with the drug of the claimed invention and its use for the same therapeutic indication makes document (1) relevant with or without the disclaimer in claim 1. In such circumstances, it is the view of the Board that a disclaimer should normally not be allowed under Article 123(2) EPC, but in the present case in view of the conclusions under point 4 below, the admissibility of the disclaimer could be left aside.

4. For the question of novelty of the subject-matter of claim 1 according to the main and auxiliary request, it is necessary to analyse in detail the disclosure of document (1).

4.1 This prior art relates to a combination of the active substances amantadine and selegiline for example for the treatment of Parkinson's disease in all stages and for the treatment of depression (see column 1, lines 15/16; column 3, lines 51 to 54). According to column 4, lines 42/43 and column 5, lines 13 to 15, the dosage unit of the combination can be applied as a pharmaceutical formulation on the skin or mucous membranes in the form of a plaster. In the same context it is then indicated that the individual active substances of the combination may be present in separate formulations each containing one of the individual substances (see column 5, lines 45 to 50, "Die *Einzelwirkstoffe* der Kombination können aber auch in *jeweils getrennten* Formulierungen vorliegen,..."; **emphasis added**). Further confirmation for this application route by separate formulations is given in column 8, lines 40/41 and 48 to 53 as well as column 9, lines 1 to 3, again indicating that the application can be to the skin or mucous membrane and that the combination may also be present in the form of a product in which the two individual components are each present in separate formulations so that even a separate administering or even an administering at different intervals is possible and that in case of a separate use it is even possible that both combination partners not be administered at the same time ("Die...Kombination kann auch als Erzeugnis vorliegen, bei dem *jeweils die beiden Einzelwirkstoffe* in getrennten Formulierungen vorliegen, so daß auch eine *getrennte oder auch zeitlich abgestufte Verabreichung* möglich ist."; "Bei getrennter Anwendung ist es auch möglich, daß beide Kombinationspartner *nicht gleichzeitig verabreicht* werden.", **emphasis added**).

4.2 As argued by the Respondent, document (1) is indeed related to a synergistic combination of amantadine and selegiline in the treatment of Parkinson's disease and according to numerous passages in this document reference is made to a synergistic effect to be achievable at different stages of the disease (see for example column 3, lines 16 to 50, particularly lines 16 to 20 and 40 to 42). However, passages indicating for example that after the simultaneous giving of amantadine, the relatively weak effect of the selegiline is increased synergistically (see particularly column 3, lines 28 to 30, "..., daß nach gleichzeitiger Gabe von Amantadin die relativ schwache Wirksamkeit des Selegilins synergistisch gesteigert wird (...)."") explicitly confirms an individual, even if weak, activity of selegiline. Moreover, claim 9 of document (1) relating only to the use of selegiline for the preparation of a formulation with 1 to 50 mg of selegiline for the treatment of Parkinson's disease and depression, independent from any other simultaneous or successive treatment, makes clear that this prior art also envisages the use of selegiline as the sole active agent. Although disclosing a synergistic effect of the combined use of selegiline and amantadine, this prior art as a whole discloses also the anti-Parkinson effect of selegiline when used alone and leaves the choice to the user whether he is satisfied with this weak effect in the individual case.

4.3 Having regard to the content of document (1) analysed above, it can be summarised that this prior art clearly discloses:

(i) the use of a separate plaster containing selegiline as the sole active agent and

(ii) that the plaster containing selegiline is used in a separate step for the treatment of Parkinson's disease and

(iii) in the form of an independent claim the use of selegiline for the preparation of a medicament for the treatment of Parkinson's disease without any relationship or reference to a further treatment of Parkinson's disease by amantadine or any other drug.

In the light of these known facts, it is clear that independently from its allowability under Article 123(2) EPC, in the circumstances of the present case, the disclaimer relating to the treatment of Parkinson's disease or depression in a patient not receiving a synergistic combination of amantadine and selegiline at all stages of the disease cannot establish novelty of subject matter of a claim relating to the **same use** of selegiline for the **same group of patients** treated in the **same application route** with a drug having the **same pharmaceutical effect** as already known from the prior art.

Although it is not decisive in view of the clear disclosure in document (1), the Board notes that the patent in suit as originally filed did not exclude the use of more than one active substance in the treatment of Parkinson's disease and that contrary to the Respondent's point of view, the wording ***"for*** the treatment of Parkinson's disease" instead of ***"in*** the treatment of Parkinson's disease" can be interpreted as covering both a monotherapy and a sequential therapy of Parkinson's disease using different drugs and thus this change of the wording had in no way influence on the comparison of the teaching of the patent in suit with document (1). Since the specific term plaster clearly

falls under the more general definition transdermal patch structure, the Board can only conclude that the subject matter of claim 1 of the main request lacks novelty in the light of the disclosure in document (1).

The same reasoning applies to claim 1 of the auxiliary request since the insertion **for inducing a long lasting and constant inhibition of monoamine oxidase activity** represents only an explanation of what already happened when using selegiline alone on a plaster for the treatment of Parkinson's disease according to document (1). In this respect, the Board notes that claim 9 of document (1) discloses the same unit dosage of selegiline as proposed in the patent in suit on page 4, lines 21/22.

4.4 For the reasons set out above, it is also clear that the Respondent's argument that by starting from document (1) the mere omission of the simultaneous or subsequential amantadine treatment of Parkinson's disease automatically would establish novelty by way of a new second medical indication in the form of a so-called second medical use claim as proposed by decision G 5/83 is no more relevant and need not be considered by the Board.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

P. Martorana P. A. M. Lançon