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Datasheet for the decision of 10 June 2008

Case Number: T 0733/05 - 3.3.02

Application Number: 97916143.7

Publication Number: 0906090

IPC: A61K 31/135

Language of the proceedings: EN

Title of invention:
Method for preventing and treating peripheral neurophathy by administering selegiline

Applicant:
SOMERSET PHARMACEUTICALS, INC.

Opponent:
-

Headword:
Selegiline for peripheral neuropathy/SOMERSET

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 56

Keyword:
"All requests - inventive step - (no): teaching of the state of the art put into practice"

Decisions cited:
-

Catchword:
-

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Case Number: T 0733/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 10 June 2008

Appellant: SOMERSET PHARMACEUTICALS, INC.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 7 January 2005 refusing European application No. 97916143.7 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 97 916 143.7 (publication No. WO 97/33572) was refused by a decision of the examining division on the basis of Article 97(1) EPC for lack of novelty.

Claim 1 of the main request before the examining division read as follows:

"Use of selegiline for the manufacture of a medicament for preventing or treating peripheral neuropathy, wherein the neuropathy is caused by a chemotherapeutic agent, a genetically-inherited condition or a systemic disease."

II. The following document was cited *inter alia* during the proceedings before the examining division and before the board of appeal:

(1) US 5 444 095

III. The examining division held the subject-matter of the application to be not new with respect to document (1). This document disclosed the use of selegiline for the treatment of Parkinson's disease and, since this disease always showed peripheric symptoms in the form of dysfunctions of the peripheric motoneuron system, the use of selegiline against the peripheric and central components of parkinsonism could not be distinguished.

IV. The appellant lodged an appeal against the decision of the examining division.

V. The board issued a communication dated 3 March 2008 drawing the applicant's attention to various amendments that, as examples, appeared to violate Article 123(2) EPC.

In addition to the objections raised by the examining division during the examination proceedings, new Article 54(5) EPC was mentioned with respect to the new formulation of second medical use claims under EPC 2000.

VI. By letter of 16 May 2008 the applicant filed four new sets of claims as main request and auxiliary requests 1 to 3.

The wording of claim 1 of the main request is:

"Use of selegiline for the manufacture of a medicament for preventing or treating peripheral neuropathy caused by a chemotherapeutic agent, genetically-inherited condition or a systemic disease."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in particular in a restricted definition of the "systemic disease"; instead of this term, the term "alcoholic polyneuropathy or diabetes" is inserted.

Claim 1 of auxiliary request 2 is restricted to the treatment of "peripheral neuropathy caused by a chemotherapeutic agent or a genetically-inherited condition".

Claim 1 of auxiliary request 3 reads:

"Use of selegiline for the manufacture of a medicament for preventing or treating peripheral neuropathy caused by a chemotherapeutic agent."

VII. Oral proceedings took place on 10 June 2008.

VIII. The arguments of the appellant in both the written procedure and the oral proceedings may be summarised as follows:

With respect to second medical use claims under new Article 54(5) EPC 2000, the appellant stated that although there was now a second manner open to draft such claims, it preferred to stay with the classical Swiss-type form.

In document (1), the highly artificial situation of axotomised neurons was disclosed for treatment with selegiline, while the teaching of the application was the treatment of metabolically induced disease peripheral neuropathy, which had nothing to do with motoneurons cut from their muscle. The situation of document (1) was far away from the real occurrence of the symptoms of peripheral neuropathy such as lack of sensation in the fingers or distorted movements. Thus it would not occur to the skilled person that axotomised motoneurons could lead in any way in the direction of the treatment of these symptoms.

The rest of document (1) concerned treatment of **central** neurons of the brain and the spinal cord which was not

in any way correlated to the treatment of **peripheral** neuropathy.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of the sets of claims filed as main request or auxiliary requests 1 to 3 with letter of 16 May 2008.

Reasons for the Decision

1. The appeal is admissible.

2. Claims 1 of the main request and of the auxiliary requests may be seen as being based on the claims and the description as originally filed (Article 123(2) EPC).

The board is satisfied that these claims also do not offend against the requirements of Articles 84 and 83 EPC.

3. *Novelty*

3.1 The subject-matter of claim 1 of the main request concerns the "Use of selegiline for the manufacture of a medicament for preventing or treating peripheral neuropathy", peripheral neuropathy caused for instance by a chemotherapeutic agent.

Following the definition of "peripheral neuropathy" on page 5, lines 2 to 5, of the application in suit (WO 97/33572), "abnormal function or pathological changes in nerves located outside of the brain or

spinal column" and the resulting symptoms, which "vary widely depending upon the cause of the peripheral nerve damage and the particular types of nerves affected" (page 6, lines 1 to 2), are included in this wording.

Consequently, in the application in suit, treatment of peripheral neuropathy is *inter alia* to be read as the treatment of particular "pathological changes in nerves" or, in wording used in a synonymous way, as the treatment of "peripheral nerve damage".

3.2 Document (1) relates to

"A method for rescuing damaged nerve cells in a patient, comprising: administering to a patient having damaged nerve cells an amount of deprenyl, … such that rescuing of damaged nerve cells occurs in the patient wherein the patient has damage resulting from a condition selected from the group consisting of hypoxia, ischemia, stroke and trauma" (claim 1) while in column 7, lines 56 to 58, application of the said method on "traumatic and nontraumatic peripheral nerve damage" is mentioned as a particular embodiment of claim 1.

Deprenyl and selegiline are synonyms for the same substance.

Thus, the teaching of document (1) comprises the use of selegiline in the manufacture of a medicament for the treatment of "traumatic and nontraumatic peripheral nerve damage".

3.3 Claim 1 of the main request, in accordance with the definitions in the application in suit, is directed to "preventing or treating symptoms based on peripheral nerve damage" with the only difference with respect to document (1) that the damage *inter alia* was to be "caused by a chemotherapeutic agent". In this context the chemotherapeutic agent is not the medicament preventing or treating symptoms, but a toxin causing peripheral neuropathy or peripheral nerve damage as a side-effect of the chemotherapy.

3.4 Since in document (1) the conclusion with respect to the concurrent experiments is "It (selegiline) may also be useful in stimulating muscle reinnervation in traumatic and nontraumatic peripheral nerve damage" and since these experiments are based on the use of selegiline for rescuing axotomised motoneurons without any prior influence of a chemotherapeutic agent, novelty of the corresponding subject-matter in suit is acknowledged (Text in brackets introduced by the board).

4. *Inventive step*

4.1 Document (1) represents the closest state of the art.

4.2 The technical problem underlying the application in suit can only be seen in finding a further use of selegiline.

4.3 According to claim 1 of the main request, one solution to this problem is the "Use of selegiline for the manufacture of a medicament for preventing or treating peripheral neuropathy **caused by a chemotherapeutic agent"** which includes "preventing or treating symptoms

based on peripheral nerve damage" **caused by a chemotherapeutic agent** (see point 3.1 of this decision; emphasis by the board).

4.4 Having regard to the study attached to the applicant's letter of 22 August 2001, setting out selegiline as reducing particular peripheral side-effects of cis-platin therapy, the board is convinced that the problem has been solved.

4.5 In document (1), however, as set out under point 3.2 of this decision, the use of selegiline in the manufacture of a medicament for the treatment of "traumatic and nontraumatic peripheral nerve damage" is disclosed without any respect to the cause of this damage.

Since, in the application and throughout the whole proceedings no particularity of peripheral neuropathy **caused by a chemotherapeutic agent** with respect to peripheral neuropathy in general or "traumatic and nontraumatic peripheral nerve damage" was pointed out, the teaching of the application in suit only puts into practice, what is already disclosed in document (1).

4.6 Consequently, the board can only conclude that the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

5. The same holds for the auxiliary requests 1, 2 and 3, since all of them comprise the same subject-matter: "Use of selegiline for the manufacture of a medicament for preventing or treating peripheral neuropathy caused by a chemotherapeutic agent".

6. In the circumstances of the case, the arguments of the appellant cannot succeed:

6.1 The appellant argued that in document (1), the highly artificial situation of axotomised neurons was disclosed for treatment with selegiline which was far away from the teaching of the application.

6.2 However, as in any model experiment on cell level, the model situation and the conclusions of the experiments are thought to be applied to a real pathologic situation represented by the model and they are intended to lead to the treatment of a correlated disease.

Starting from the knowledge that at least one way in which for instance the chemical substance MPTP causes parkinsonism is by axonal damage to neurons of the substantia nigra compacta (central nerve system), the authors of document (1) decided to investigate the action of selegiline on axotomised motoneurons. The experiments conducted in this context were aimed at answering the question whether other neurons, for instance motoneurons, would be rescued in the same way by selegiline as the neurons of the substantia nigra compacta (see document (1), column 5 line 65 to column 6, line 17, together with column 12, lines 66 to 68 and column 21, lines 64 to 66).

The general conclusion drawn from these experiments in document (1) was that selegiline may be useful in the treatment of peripheral nerve damage.

Since the model was to simulate nerve damage caused by a toxin, this conclusion clearly is not restricted to the model situation itself, namely axotomised motoneurons. It was rather intended to provide proof with respect to the target situation of the experiment, namely rescuing motoneurons damaged by a toxin. This includes also the situation of chemotherapeutic substances acting as a toxin with respect to side-effects caused by their use which are then to be treated by a medicament to be produced with selegiline as active component.

Thus, the teaching of document (1) is, that selegiline may be used for rescuing damaged peripheral nerve cells in the same way as this was possible with respect to neurons of the substantia nigra damaged by a toxin and the used model situation is representative for the teaching of the application in suit.

7. In these circumstances, there is no need to discuss whether Swiss-type claims under the new provisions of Article 54(5) EPC 2000 were still to be treated in the manner consequent upon the decisions of the Enlarged Board of Appeal with respect to second medical use (G 1, 5 and 6/83, OJ EPO 1985, 60, 64 and 67).

Even fully acknowledging the treatment of peripheral neuropathy as the feature to be taken into account as "any specific use" of selegiline in the sense of Article 54(5) EPC 2000, while only the wording of the claim remained in Swiss-type form, the Board concludes on the basis of the same arguments as set out above that the subject-matter of the application in suit, with reference to the main request and to auxiliary

requests 1 to 3, is obvious with regard to the state of the art (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald