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Datasheet for the decision of 19 April 2010

Case Number: T 1079/08 - 3.3.10

Application Number: 00920026.2

Publication Number: 1165487

IPC: C07C 215/64

Language of the proceedings: EN

Title of invention:
Derivatives of venlafaxine and methods of preparing and using the same

Patentee:
Sepracor Inc.

Headword:
Derivatives of venlafaxine/SEPRACOR

Relevant legal provisions:
EPC Art. 111(1)

Keyword:
"Remittal (yes): essential issue of sufficiency of disclosure not dealt with - technical effect in a use claim being a technical feature"

Decisions cited:
G 0001/03, T 0278/00, T 0087/08

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1079/08 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 19 April 2010

Appellant: Sepracor Inc.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 November 2007 refusing European patent application No. 00920026.2 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: R. Freimuth
Members: J.-C. Schmid
F. Blumer

Summary of Facts and Submissions

I. The appeal lodged on 23 January 2008 lies from the decision of the Examining Division posted on 27 November 2007 refusing European patent application No. 00920026.2 (International publication Number WO-A-00/59851).

II. The Examining Division refused the application on the ground of lack of inventive step considering that document

(5) Drug Development Research vol. 23, (1991), pages 191 to 199

represented the closest prior art and formulating the technical problem to be solved vis-à-vis this document as the provision of alternative uses for the known metabolites of venlafaxine. The Examining Division found that this problem was not credibly solved, since there was no evidence that the metabolites could be effective for the treatment of the diseases listed in claims 1 and 5 and, thus, without reformulating the problem and taking into account further prior art concluded that the claimed subject-matter lacked an inventive step.

III. In the communication of 25 January 2010 accompanying the summons to attend oral proceedings on 19 April 2010, the Board drew the Appellant's attention to the revised Article 54(5) EPC applicable to any European application pending at the time of EPC 2000 entry into force stipulating a new claim format for a purpose-related product claim directed to any further specific

use in a method referred to in Article 53(c) EPC, thereby superseding the Swiss-type claim format allowable under EPC 1973. The Board furthermore indicated that it intended to remit the case back to the first instance for further prosecution since the application was rejected for lack of inventive step for reasons only relevant to the question of sufficiency of disclosure under Article 83 EPC, the decision under appeal containing no assessment of obviousness with respect to the prior art and the issue of sufficiency of disclosure under Article 83 EPC being not addressed.

IV. Taking account of the observations of the Board, the Appellant (Applicant) filed on 24 March 2010 a fresh main request differing from the main request on which the decision of the first instance was based only by rewriting the claims having a Swiss-type claim format into purpose-related product claims according to Article 54(5) EPC and filed arguments with respect to the issue of sufficiency of disclosure. Independent claims 1 and 5 read as follows:

"1. A venlafaxine derivative, or a pharmaceutically acceptable salt or solvate thereof, for use in treating or preventing obesity, weight gain, Parkinson’s disease, epilepsy, a cerebral function disorder, pain, an obsessive-compulsive disorder, substance abuse, pre-menstrual syndrome, anxiety, an eating disorder, migraine, migraine headache, incontinence, or an affective disorder selected from attention deficit disorder, attention deficit disorder with hyperactivity, a bipolar condition or a manic condition, wherein the venlafaxine derivative is (±)-N-desmethylvenlafaxine, (±)-N,O-didesmethylvenlafaxine,

(±)-N,N-didesmethylvenlafaxine or
(±)-O-desmethyl-N,N-didesmethylvenlafaxine."

"5. A venlafaxine derivative, or a pharmaceutically acceptable salt or solvate thereof, for use in treating or preventing epilepsy, pain, an obsessive-compulsive disorder, substance abuse, migraine, migraine headache, incontinence, a bipolar condition or a manic condition, wherein the venlafaxine derivative is (±)-O-desmethylvenlafaxine."

V. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the Examining Division for further prosecution.

VI. Oral proceedings took place on 19 April 2010 in the absence of the Appellant, which had informed the Board with letter of 13 April 2010 that it would not attend. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. The Examining Division rejected the application for lack of inventive step merely by finding that the technical effect underlying the invention had not been credibly achieved.

The Examining Division arrived at this conclusion by considering that document (5) comparing the monoamine uptake inhibition activity of venlafaxine with that of

its metabolites represented the closest prior art and by defining the technical problem to be solved as the provision of alternative uses for the known metabolites of venlafaxine. The Examining Division found that this problem was not credibly solved, since there was no evidence provided showing that the metabolites were effective for the treatment of the diseases listed in claims 1 and 5.

3. However, claims 1 and 5 then pending had the format of a second medical use Swiss-type claim. The Board observes that the use of the metabolites of venlafaxine for the preparation of a medicament for the treatment of the diseases listed in then pending independent claims 1 and 5 is the solution proposed by the application and the purpose of preparing a medicament for the treatment of the diseases indicated in then claims 1 and 5 is a technical feature defining the subject-matter claimed.

Accordingly, being technical features of the use claims said preparation of a medicament for treating the listed diseases does not form part of the technical problem to be solved, but is the solution thereof.

4. Actually, the Examining Division rejected the application only because the prepared medicament was not shown to be suitable for the treatment of the diseases listed in then independent claims 1 and 5, i.e. because it was not shown that the technical effect underlying the claimed use was achieved.

In Decision G 1/03 (OJ, 2004, 413) the Enlarged Board of Appeal indicated that a lack of reproducibility of

the claimed invention is relevant under the requirements of sufficiency of disclosure if the technical effect is a technical feature of the claim, since then it is a feature characterising the subject-matter claimed (see point 2.5 of the reasons).

Hence the Examining Division rejected the application under Article 56 EPC for reasons relevant to the matter of sufficiency of disclosure pursuant to Article 83 EPC.

The same considerations and conclusions apply to the new format of present claims 1 and 5, i.e. purpose related product claims pursuant to Article 54(5) EPC 2000.

5. The application was refused by the Examining Division for lack of inventive step on the basis of reasons relevant to the matter of sufficiency of disclosure pursuant to Article 83 EPC (see point 4 above). However, the issue of sufficiency of disclosure had never been addressed during the examining proceedings before the first instance, although compliance with Article 83 EPC is normally a prerequisite to assess inventive step on a proper basis.

In reply to the communication of the Board, the Appellant made some submissions with respect to the requirement of sufficiency of disclosure, but requested the case to be remitted back to the Examining Division for consideration of that issue.

6. In order to have the essential issue of sufficiency of disclosure under Article 83 EPC be considered by two instances, the Board considers it appropriate to exercise the power conferred to it by Article 111(1) EPC to remit the case to the Examining Division for further prosecution.

7. When resuming examination proceedings the first instance should take into account that in the decision under appeal, it arrived at the conclusion that the subject-matter of the main request lacked inventive step (Article 56 EPC) merely by finding that the technical problem underlying the application had not been credibly solved without reformulating the problem in a less ambitious way and without assessing obviousness of the claimed solution to that reformulated problem in the light of the cited prior art. However, Article 56 EPC requires that "an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art". Thus, when it comes to the issue of inventive step pursuant to Article 56 EPC the Examining Division should assess obviousness vis-à-vis the state of the art (see T 278/00, OJ EPO, 2003, 546 and T 87/08; not published in OJ EPO).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the main request (claims 1 to 18) filed on 24 March 2010.

The Registrar: The Chairman:

C. Rodríguez Rodríguez R. Freimuth