Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 18 December 2014

Case Number: T 2279/10 - 3.3.01

Application Number: 03008911.4

Publication Number: 1331003

IPC: A61K31/135, A61K9/50

Language of the proceedings: EN

Title of invention:
Extended release formulation containing venlafaxine

Applicant:
Wyeth LLC

Headword:
Extended release of venlafaxine/WYETH

Relevant legal provisions:
EPC 1973 Art. 56, 84

Keyword:
Claims - clarity - main request (no)
Inventive step - auxiliary request (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2279/10 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 18 December 2014

Appellant: (Applicant)	Wyeth LLC 235 East 42nd Street New York, NY 10017-5755 (US)
Representative:	Laurent, Claire Pfizer European Pharma Patent Department 23-25 avenue du Docteur Lannelongue 75668 Paris Cedex 14 (FR)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 14 June 2010 refusing European patent application No. 03008911.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	C. M. Radke
	T. Karamanli

Summary of Facts and Submissions

I. European patent application No. 03 008 911.4 was published as EP-A-1 331 003 with the title "Extended release formulation containing venlafaxine".

II. The appeal of the patent applicant is directed against the decision of the examining division refusing the application.

III. The following documents were cited during the examination proceedings:

(D1) EP-A-0 654 264
(D2) EP-A-0 639 374
(D3) WO-A-94/27 589
(D4) EP-A-0 112 669.

IV. In particular, the examining division decided that
- the insertion of the term "for the treatment of depression" contravened the requirements of Article 123(2) EPC;
- claim 1 then on file defined the subject-matter in terms of the result to be achieved, namely in the form of pharmacokinetic parameters which varied from subject to subject, thus rendering the claim unclear;
- claims 1 and 3 then on file were unduly broad and not supported by the description;
- the subject-matter claimed could not be put into practice over the whole scope of the claims without inventive ingenuity;
- the subject-matter of the claims then on file lacked inventive step in view of documents (D1) to (D4).

V. The board enclosed a communication with the summons to oral proceedings. In this communication, it

- raised objections under Article 53(c) EPC and Articles 83 and 84 EPC 1973,
- introduced the following document into the proceedings:
  (D5) US-A-4 138 475, and
- gave reasons why it regarded document (D3) as the closest prior art, and document (D5) as relevant for the assessment of inventive step.

VI. The present claims are

- claims 1 to 8 of the main request submitted under cover of a letter dated 17 October 2014, and
- claims 1 to 8 of the auxiliary request submitted during the oral proceedings of 18 December 2014.

(a) Claims 1 and 2 of the main request read as follows:

"1. An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropylmethylcellulose coated with ethyl cellulose and hydroxypropylmethyl-cellulose for use in the treatment of depression."

"2. An encapsulated, extended release formulation of venlafaxine hydrochloride for use according to claim 1 wherein the spheroids are composed of 37.3% by weight of venlafaxine hydrochloride, 0.5% by weight of hydroxypropylmethylcellulose 2208, and 62.17% by weight of microcrystalline cellulose."

(b) Claim 1 of the auxiliary request is identical to that of the main request. Claim 2 of the auxiliary request reads as follows:

"2. An encapsulated extended release formulation of venlafaxine hydrochloride according to claim 1 wherein the spheroids are composed of 37.3% by weight of venlafaxine hydrochloride, 0.5% by weight of hydroxypropylmethylcellulose 2208, and 62.17% by weight of microcrystalline cellulose."

VII. The arguments of the appellant, as far as relevant for the present decision, may be summarised as follows:

The amended claims explicitly define the components of the formulation and thus overcome the objections under Articles 83 and 84 EPC 1973. They no longer contain the type of claims objected to under Article 53(c) EPC.

Document (D3) may be considered to be the closest prior art. The objective problem was to provide an alternative extended-release formulation of venlafaxine hydrochloride. Document (D3) is related to an entirely different release mechanism as it teaches the use of osmosis to deliver the drug. The person skilled in the art would not have combined the teaching of document (D3) with that of (D5) because the high solubility in water of venlafaxine hydrochloride used in (D3) may lead to premature release of the drug. This problem does not arise in document (D5), as propranolol used therein has a much lower solubility in water. Even the combined teaching of documents (D3) and (D5) does not teach the addition of hydroxypropylmethylcellulose (HPMC) when forming the spheroids.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request filed with letter dated 17 October 2014, or according to the auxiliary request filed during oral proceedings on 18 December 2014.

IX. At the end of the oral proceedings, the chairman announced the decision of the board.

Reasons for the Decision

1. The appeal is admissible.

2. Objections under Articles 83 and 84 EPC 1973

2.1 The objections raised by the board in its communication were based on the fact that the claims then on file were characterised only by the blood plasma concentration profile and the release profile of the drug, i. e. by the result to be achieved (see points 3 and 4 of the communication).

In the present claims, the features concerning the blood plasma concentration profile and the release profile have been replaced by features defining the form taken by the formulation (namely spheroids containing the drug which are coated and encased in a hard gelatin capsule) and specifying the chemical compounds contained in the formulation.

Hence, the objections raised in the communication no longer apply to the present claims.

2.2 However, the amended claims of the **main request** give rise to the following objection under Article 84 EPC 1973.

The term "for use according to claim 1" or "for use according to any one of claims ..." in claims 2 to 8 leaves doubt as to whether

- only the use as specified in the claim referred to is to be included in the respective dependent claims, or
- the respective claims are to be dependent on the claims referred to and thus contain all their features.

The appellant did not provide any counter-argument as to this objection raised by the board during the oral proceedings.

The board concludes that the terms mentioned above render the claims of the main request unclear, contrary to the requirements of Article 84 EPC 1973.

3. The board can only decide on a request as a whole. Therefore, the main request is not allowable.

4. Auxiliary request

4.1 Article 84 EPC 1973

The above clarity objection has been overcome in the auxiliary request by deleting the words "for use" in claims 2 to 8. The claims of this request do not give rise to additional objections under Article 84 EPC 1973.

4.2 Article 123(2) EPC

Present claim 1 is based on original claim 1 and page 1, lines 32-33, of the application as originally filed. Claims 2 and 6 are based on original claim 2, claims 3 to 5 on original claims 3 to 5, and claims 7 and 8 on page 3, lines 19-26, of the application as originally filed.

Therefore, the amended claims of the auxiliary request meet the requirements of Article 123(2) EPC.

4.3 Novelty

It was not disputed that the subject-matter of the claims is novel, due to the fact that

- document (D3) discloses an extended-release formulation of the same drug, which however does not contain the remaining components as defined in present claim 1; and
- document (D5) is restricted to an extended-release formulation of a different drug.

4.4 Inventive step

4.4.1 The board concurs with the appellant that document (D3) represents the closest prior art, as this document is the only one of the cited documents to disclose extended-release dosage forms of venlafaxine (see claims 4 and 6 of (D3)). In contrast to the invention according to claim 1 of the auxiliary request, which concerns coated spheroids in a hard gelatin capsule, document (D3) relates to "an osmotic dosage form that delivers a drug by osmotic action over an extended period of time" (see page 8, lines 12-14). It has the form of a tablet containing a wall 12 which is

substantially impermeable to the drug apart from the at least one exit port 13 (see Figures 1 to 3 and page 9, lines 3-15).

4.4.2 The board concurs with the appellant that the problem to be solved in view of document (D3) was to provide an alternative extended-release formulation of venlafaxine hydrochloride.

4.4.3 Tables 2 and 3 on pages 8 and 9 of the application as filed show that this problem has been solved.

4.4.4 In view of the fact that the claimed dosage form is quite different from that of document (D3), this document alone cannot render the subject-matter of the present claims obvious.

4.4.5 Thus, it remains to be assessed whether the subject-matter of the present claims is obvious in view of document (D3) in combination with any other piece of prior art.

The only other cited document relating to extended-release formulations is document (D5).

This document discloses a sustained-release composition consisting of a hard gelatin capsule containing film-coated spheroids (see claims 1). The disclosure of document (D5) is, however, restricted to formulations of the drug propranolol or of its salts; the respective hydrochloride was used in the only example.

A combination of documents (D3) and (D5) could render the subject-matter of the present claims obvious only if the person skilled in the art would have taken into account the teaching of document (D5) when looking for

an alternative extended-release formulation of venlafaxine hydrochloride. The person skilled in the art would have taken document (D5) into account only if he could reasonably expect to achieve a satisfactory extended-release formulation by replacing the propranolol hydrochloride in the formulation disclosed in document (D5) by venlafaxine hydrochloride.

Document (D3) discloses that the "high solubility of **570 mg per ml** at a body temperature of 37°C ... can lead to a premature release of the drug from the dosage form" (see page 4, lines 18-21; emphasis added by the board). The term "drug" in this context apparently refers *inter* alia to the drug used in the examples of document (D3), namely to venlafaxine hydrochloride (see page 23, line 6, page 24, lines 17 and 24, and page 25, line 8).

Document (D5) gives no indication that the formulation disclosed therein might be useful for drugs which are highly water-soluble. Moreover, as the appellant noted, the solubility of propranolol hydrochloride in water is about **50 mg/ml**, i. e. considerably lower than that of venlafaxine hydrochloride. Therefore, the person skilled in the art had no reason to believe that a formulation similar to that of document (D5) might be useful for venlafaxine hydrochloride. Hence, the person skilled in the art would not have modified the formulation disclosed in document (D3) according to that disclosed in document (D5) in order to solve the problem posed.

Moreover, document (D5) does not teach or suggest the presence of HPMC within the spheroids, as required by the present claims. Therefore, the person skilled in the art would not arrive at the subject-matter of the

present claims even if he did combine the teachings of documents (D3) and (D5).

In consequence, the subject-matter of claim 1 and of the respective dependent claims 2 to 8 involves an inventive step.

4.5 Amended description

During the oral proceedings before the board, the appellant presented an amended description page 2 adapted to the claims of the auxiliary request. The board is satisfied that this amendment to the description merely adapted the text to the amended claims.

4.6 The board is not aware of any other requirements which might prevent the application as amended according to the auxiliary request from proceeding to grant.

5. Summary

The board considers the main request unallowable, as its claim 1 is not clear, contrary to the requirements of Article 84 EPC 1973. The board concludes that the auxiliary request, including the description adapted thereto, meets the requirements of the EPC.

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 with the order to grant a patent in the following version:

Claims: Nos. 1 to 8 according to the auxiliary request filed during oral proceedings on 18 December 2014;

Description: pages 1, 3 to 10 as originally filed and page 2 filed during oral proceedings on 18 December 2014.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated