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Datasheet for the decision of 4 May 2010

Case Number: T 0279/07 - 3.3.02

Application Number: 99924625.9

Publication Number: 1083904

IPC: A61K 31/565

Language of the proceedings: EN

Title of invention:
Pharmaceutical compositions and uses for androst-5-ene-3 beta, 17 beta-diol

Patentee:
ENDORECHERCHE INC.

Opponent:
-

Headword:
5-diol/ENDORECHERCHE INC.

Relevant legal provisions:
EPC Art. 84

Relevant legal provisions (EPC 1973):
-

Keyword:
"Clarity - no: unreasonable burden"

Decisions cited:
T 0068/85

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0279/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 4 May 2010

Appellant: ENDORECHERCHE INC.
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Representative: Bogensberger, Burkhard
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 26 September 2006 refusing European patent application No. 99924625.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 99 924 625.9 was refused by a decision of the Examining Division dated 14 September 2006 under Article 97(1) EPC with regard to Articles 54 and 56 EPC.

II. The decision was based on the set of claims faxed and received on 11 August 2006.

Independent claim 1 of this set of claims reads as follows:

"1. Use of androst—5—ene—3ß,l7ß—diol or prodrug thereof, for the manufacture of a pharmaceutical composition for treating or reducing the likelihood of acquiring, in a female patient in need thereof or benefitting therefrom, an indication where an estrogenic effect is desired to a greater extent than is an androgenic effect and in which lower androgenic activity than provided by DHEA is desired, the indication selected from the group consisting of hypogonadism, skin atrophy, skin dryness, vaginal atrophy, and urinary incontinence."

III. The documents cited in the Examining Division's decision included the following:

(1) WO 9416709
(2) WO-A-9856386
(5) FR 672 M
(19) US-A-5641768.

IV. The Examining Division considered that the claimed subject-matter was anticipated by the disclosure in document (5) and in the interfering document (2), which disclosed the use of a compound according to claim 1 for the same indication as in the application, namely the treatment of menopausal conditions.

The Examining Division was also of the opinion that the request was not inventive, for instance, vis—à—vis document (1) in combination with (19), which suggested that treatment with 5—Diol (Androst-5-ene-3ß,17ß-diol) avoided many of the androgenic side effects that occur when the precursor DHEA (Dehydroepiandrosteron) is administered.

V. The appellant (applicant) lodged an appeal against the said decision.

The appellant's written submissions can essentially be summarised as follows:

As to novelty, it held that document (2) did not qualify as a prior art reference document under Article 54(3) EPC because it had not entered the regional phase before the European Patent Office.

It further considered that the general disclosure of "menopause syndrome" in document (5) could not regarded as an anticipation of the specific conditions recited in the present claim 1.

Concerning inventive step, the appellant was of the opinion that the combination of documents (1) and (19) could not lead to the present invention, as nothing in

those documents, or in the remaining prior art provided information on the activity profiles of 5-Diol and DHEA and on the ratio regarding estrogenic vs. androgenic effect of 5-diol.

VI. In a communication dated 21 April 2010, the Board expressed its preliminary view that the term "prodrug" in claim 1 rendered the claimed subject-matter unclear contrary to the requirements of Article 84 EPC and that the unfavourable conclusions of the Examining Division's decision as to inventive step would have to be confirmed.

VII. Oral proceedings were held before the Board on 4 May 2010.

The appellant did not attend.

VIII. The appellant requested in writing that the decision under appeal be set aside and that the patent be granted on the basis of the set of claims filed on 11 August 2006.

Reasons for the Decision

1. The appeal is admissible.

2. Main and sole request

2.1 Article 84 EPC

Under Article 84 EPC the claim(s) shall define the matter for which protection is sought.

Thus, the question to be answered with respect to clarity under Article 84 EPC is whether it is possible to determine if an embodiment falls within the scope of the claims or not.

In the present case, the chemical structures in independent claim 1 are mainly defined by a functional feature, namely "androst-5-ene–3ß,17ß-diol or **prodrug** thereof" (emphasis added).

According to the description, "prodrugs" of 5-Diol are defined as compounds "converted thereto *in vivo*", and two specific structures, i.e. the 3-acetylated derivative of 5-Diol and a 3,17-succinic ester of 5-Diol, and 5-Diol fatty acids are disclosed (page 4, line 19; page 20; page 7, lines 17–20).

The Board has no doubt that the skilled person is perfectly able in most cases to decide whether or not a steroid derivative will be converted to 5-diol *in vivo,* in particular when the chemical entity differs from the 5-diol skeleton merely by the presence of usual hydrolysable hydroxyl protecting groups such as esters, carbonate esters, phosphate esters, acyloxyalkyl ethers a.s.o..

However, the Board is also convinced that, in order to establish whether a structurally more remote steroid derivative constitutes a prodrug of 5–diol, in other words in order to clearly establish the scope of protection of the claims, the skilled person would sometimes have no other choice than to synthesize a labeled sample of the steroid to be tested and to

follow its biochemical transformations *in vivo* to determine whether or not the chemical structure under consideration is a biological precursor of 5-diol. In addition, toxicological studies might also be necessary.

According to the Case Law of the Boards of Appeal (e.g. T 0068/85, OJ 6/1987, 228), clarity demands not only that a skilled person be able to understand the teaching of the claim but also that he be able to implement it. In other words, the feature must provide instructions which are sufficiently clear for the expert to reduce them to practice without unreasonable burden, if necessary with routine experiments.

The clarity requirement is therefore not met in the present case since, as shown above, the skilled person would have to find out in some cases merely by trial and error whether a steroid derivative meets the functional requirement set out in the claim, i.e. by making his own investigations, similar to a research programme.

Under these circumstances, the Board concludes that claim 1 of the main request does not fulfill the requirement of Article 84 EPC.

2.2 As the appellant neither replied to the Board's communication regarding the deficiency discussed under point 2.1 above nor attended the oral proceedings, the Board sees no reason now to differ from the above unfavorable conclusions.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

N. Maslin U. Oswald