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D E C I S I O N
of 27 September 2005

Case Number: T 0605/02 - 3.3.01

Application Number: 97201712.3

Publication Number: 0823436

IPC: C07J 73/00

Language of the proceedings: EN

Title of invention:
Polymorphic forms I and II of finasteride

Applicant:
MERCK & CO.INC.

Opponent:
-

Headword:
Finasteride/MERCK

Relevant legal provisions:
EPC Art. 54(2), 76(1), 111(1), 123(2)

Keyword:
"Main request: novelty (yes)"
"Remittal to first instance for further prosecution"

Decisions cited:
G 0010/93, T 0206/83

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0605/02 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 27 September 2005

Appellant: Horgan, James Michael Frederic
Merck & Co., Inc.
European Patent Department
Terlings Park
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Harlow, Essex CM20 2QR (GB)

Representative: -

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 18 January 2002 refusing European application No. 97201712.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: A. Nuss
Members: P. P. Bracke
S. Perryman

Summary of Facts and Submissions

I. The appeal lies from the Examining Division's decision refusing European patent application No. 97 201 712.3, which is a divisional application of European patent application No. 93 203 163.6, due to lack of novelty of the claimed polymorphic forms I and II of 17 β-(N-tert-butyl carbamoyl)-4-aza-5 α-androst-1-en-3-one (Finasteride) over documents

(1) American Institute of Chemical Engineers, Symposium Series 284, vol. 87, 1991, pages 58 to 63, and

(2) EP-A-0 428 366.

In particular, the Examining Division was of the opinion, that, although document (1) did not contain an enabling disclosure for preparing the polymorphic forms of Finasteride, it was nevertheless novelty destroying, since both crystal forms were characterised by spectral and physicochemical data and both crystal forms were accessible by means of any known crystallisation method. Moreover, since the crystals resulting from the crystallisation step of the example of document (2) were prepared according to a method described in the present application, also document (2) was novelty destroying for the claimed polymorphic forms.

II. With telefax dated 25 August 2005, the Appellant filed sets of claims according to a main request and a first and second auxiliary request.

The two claims according to the main request read:

"1. 17 β-(N-tert-butyl carbamoyl)-4-aza-5 α-androst-1-en-3-one polymorphic form I, characterized by characteristic absorption bands obtained from X-ray powder diffraction spectral d-spacings of 6.44, 5.69, 5.36, 4.89, 4.55, 4.31, 3.85, 3.59 and 3.14; a differential scanning calorimetry curve, at a heating rate of 20°C/min, that exhibits a minor endotherm with a peak temperature of about 232°C and an extrapolated onset temperature of about 223°C with an associated heat of about 11 joules/gm and that exhibits a major melting endotherm with a peak temperature of about of 261°C and an extrapolated onset temperature of about 258°C with an associated heat of about 89 joules/gm; an FT-IR spectrum (in KBr) showing bands at 3431, 3237, 1692, 1666, 1602 and 688 cm-1; and solubilities in water and cyclohexane at 25°C of 0.05+0.02 and 0.27+0.05 mg/gm, respectively."

"2. 17 β-(N-tert-butyl carbamoyl)-4-aza-5α-androst-1-en-3-one polymorphic Form II. characterized by characteristic absorption bands obtained from X-ray powder diffraction spectral d-spacings of 14.09, 10.36, 7.92, 7.18, 6.40, 5.93, 5.66, 5.31, 4.68, 3.90, 3.60 and 3.25; a differential scanning calorimetry curve, at a heating rate of 20°C/min, that exhibits a single melting endotherm with a peak temperature of about 261°C and an extrapolated onset temperature of about 258°C with an associated heat of about 89 joules/gm; an FT-IR spectrum (in KBr) showing bands at 3441, 3215, 1678, 1654, 1597, 1476 and 752 cm-1; and solubilities in water and cyclohexane at 25°C of 0.16+0.02 and 0.42+0.05 mg/gm, respectively."

III. The Appellant submitted that, since no method for preparing polymorphic form I of Finasteride was described in document (1), it was not an enabling disclosure of any polymorphic form of Finasteride. Therefore, document (1) could not be novelty-destroying for the claimed polymorphic forms. Additionally, it could not be deduced from document (2) that the white crystals obtained from the crystallisation procedure described therein are in any particular polymorphic form.

IV. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the claims according to the main request or according to the first or second auxiliary request, all filed with telefax of 25 August 2005, and indicated that his request for oral proceedings would not apply if the Board came to the conclusion that the claims according to the main request filed with telefax of 25 August 2005 were novel and remitted the application to the Examining Division for further prosecution.

Reasons for the Decision

1. The appeal is admissible.

2. *Scope of examination on appeal*

While Article 111(1) EPC gives the Boards of Appeal the power to raise new grounds in ex-parte proceedings where the application has been refused on other grounds, proceedings before the Boards of Appeal in ex-parte cases are primarily concerned with examining the

contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), other objections normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be considered without loss of an instance.

In the present case, the Board restricts itself to examining the basis for the sole ground for refusal of the application, namely whether the claimed subject-matter meets the requirement of novelty pursuant to Article 54(2) EPC over documents (1) and (2).

3. *Main request*

3.1 Articles 76(1) and 123(2) EPC

Claims 1 and 2 correspond with Claims 12 and 13 respectively of the divisional application as filed and with Claims 28 and 29 respectively of the parent application as filed. Thus the requirements of Articles 76(1) and 123(2) EPC are fulfilled.

3.2 Novelty

3.2.1 Document (1)

Document (1) is concerned with the detection and characterisation of polymorphic forms in four pharmaceutically active compounds, one of them being Finasteride, designated therein as Prosac. It is not contested that the paragraph bridging pages 60 and 61 and Figures 3 and 4 unambiguously teaches that Finasteride exists in two polymorphic modifications,

namely forms I and II, of which the solid state differences are demonstrated by X-ray powder diffraction (XRPD) and differential scanning calorimetry (DSC) and of which the solubility in cyclohexane and in water are given, and that the lower temperature stable form I is converted to the higher temperature stable form II at the transition point whereas no conversion of form II to form I occurs upon cooling.

As it has never been contested that forms I and II of Finasteride disclosed in document (1) correspond with both presently claimed polymorphic forms, the question arises, whether such disclosure destroys the novelty of present Claims 1 and 2. Namely, according to the jurisprudence of the Boards of appeal of the EPO, as represented in decision T 206/83 (OJ EPO 1987, 5) a description of a product does not render the product "available to the public", and thus does not destroy the novelty of such a claim, if a skilled person is unable to make the product, using his common general knowledge and "without undue burden" (in other words, in the absence of an "enabling disclosure").

The only information that can be obtained from document (1) is how form II may be obtained from form I (see point 3.2.1 above). However, in the absence of any indication of how form I may be obtained, a skilled reader cannot get any information from document (1) on how either of the claimed forms may be prepared.

Since, thus, document (1) is not an enabling disclosure of how to prepare either claimed form of Finasteride,

document (1) is not a novelty-destroying disclosure for present Claims 1 and 2.

The Examining Division submitted that both crystal forms were accessible by means of any known crystallisation method so that a skilled person would not have had any difficulty in finding out under which crystallisation circumstances either of forms I and II could be obtained. That submission, however, which was not supported by any evidence, was disputed by the Appellant.

Since, as a general rule, the onus is on the party or the instance making a submission to furnish proof of the submitted facts, in so far as such facts are disputed, the Examining Division's unsupported submission cannot be accepted.

3.2.2 Document (2)

Document (2) describes on page 7, lines 23 to 26, a crystallisation process wherein Finasteride, defined as MK906, was dissolved in acetic acid and water was added slowly, whereby the product gradually crystallised out of the solution, the mixture was aged at room temperature for 10 hours with agitation and the crystals were filtrated and dried.

Since the present application disclosed a similar crystallisation process for preparing the polymorphic form I or II, the Examining Division was of the opinion that the compound obtained according to the method described on page 7, lines 23 to 26, of document (2)

must be identical with the claimed polymorphic form I or II of Finasteride.

However, according to the jurisprudence of the Boards of Appeal, in order to be novelty-destroying, all features in the claimed combination must be directly and unambiguously derivable from the teaching of one single document.

Since document (2) and, in particular, the passage on page 7, lines 23 to 26, is completely silent about the nature of the crystals, let alone, whether the obtained crystalline products are in a pure polymorphic form, the presently claimed polymorphic forms are not directly and unambiguously derivable from document (2). Therefore, independently thereof whether the crystallisation method described in document (2) is similar to the one described in the present application, document (2) itself does not disclose all features of Claim 1 or 2 and, thus, does not destroy the novelty thereof.

4. In view of the outcome of the decision there is no need to deal with the novelty of the auxiliary requests (see point II above).

5. Since the contested decision only concerns the novelty of the claimed subject-matter over documents (1) and (2) and having regard to the fact that the function of the Boards of Appeal is primarily to give a judicial decision upon the correctness of the earlier decision taken by the first instance, the Board makes use of its power under Article 111(1) EPC and remits the case to the first instance for further prosecution.

6. Since Appellant's requirements for withdrawing his original request for oral proceedings are met, oral proceedings are superfluous.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The claims according to the main request filed with telefax of 25 August 2005 are novel over the disclosure of each of documents (1) and (2).

3. The case is remitted to the Examining Division for further prosecution.

The Registrar: The Chairman

N. Maslin A. Nuss