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**Datasheet for the decision
of 9 August 2007**

Case Number: T 0323/05 - 3.3.01

Application Number: 93203163.6

Publication Number: 0599376

IPC: C07J 73/00

Language of the proceedings: EN

Title of invention:

A process for the production of finasteride

Patentee:

Merck & Co., Inc.

Opponent:

Gedeon Richter Ltd.

Headword:

Finasteride/MERCK

Relevant legal provisions:

EPC Art. 69, 84, 100, 101(2), 102(2)

EPC R. 57a), 58

Keyword:

"Adaptation of the description after a decision to maintain the patent in amended form - consistent with the amended set of claims (yes)"

Decisions cited:

T 0301/87; T 0442/91; T 0740/96; T 0025/01; T 0300/04

Catchword:

Rule 57a EPC establishes a limit to the amendments which can be made to the patent in suit, namely the amendments must be occasioned by grounds of opposition specified in Article 100 EPC, even if the respective ground has not been invoked by the opponent.

Article 84 and Rule 57a EPC are the two provisions which must guide the Proprietor of the patent when he is invited by the Opposition Division to adapt the description. In other words, the amendments must be appropriate and necessary, and nothing more (see point 3 of the reasons).



Case Number: T 0323/05 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 9 August 2007

Appellant: Gedeon Richter Ltd.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
27 January 2005 concerning maintenance of
European patent No. 0599376 in amended form.

Composition of the Board:

Chairman: A. Nuss
Members: P. Ranguis
C. Rennie-Smith

Summary of Facts and Submissions

I. The appeal lies from the decision of the Opposition Division maintaining the European patent No. 0 599 376 with an amended description, in compliance with the Order of the Board's earlier decision T 25/01 dated 16 September 2003.

II. The European patent 599 376 was granted with a set of six claims which read:

"1. A process for producing polymorphic Form I of 17β -(N-tert-butyl carbamoyl)-4-aza- 5α -androst-1-en-3-one, comprising the steps of:

(1) crystallisation from a mixture of finasteride in:

(a) a mixture of ethyl acetate and water, wherein the amount of water in the solvent mixture is at most about 3.5 mg/ml; or

(b) a mixture of iso-propyl acetate and water, wherein the amount of water in the solvent mixture is at most about 1.6mg/ml;

at an ambient temperature of about 25°C;

(2) recovering the resultant solid phase; and

(3) removing the solvent therefrom."

"2. A process for producing polymorphic Form I of 17β -(N-tert-butyl carbamoyl)-4-aza- 5α -androst-1-en-3-one in substantially pure form, comprising heating Form II of finasteride in water or an organic solvent to a temperature of at least about 25°C and recovering the resultant solid phase."

"3. A process for producing polymorphic Form II of 17β -(N-tert-butyl carbamoyl)-4-aza- 5α -androst-1-en-3-one,

comprising the steps of:

- (1) crystallisation from a mixture of finasteride in an organic solvent and water, such that the amount of organic solvent and water in the mixture is sufficient to cause the solubility of the solvated form of finasteride to be exceeded and the solvated form of finasteride to be less soluble than any other form of finasteride in the mixture;
- (2) recovering the resultant solid phase; and
- (3) removing the solvent therefrom."

"4. The process of Claim 3 wherein the organic solvent is glacial acetic acid, and the weight percentage of water in the solvent mixture is less than about 83%."

"5. The process of Claim 3 wherein the organic solvent is ethyl acetate and the amount of water in the solvent mixture is greater than about 3.5 mg/ml."

"6. The process of Claim 3 wherein the organic solvent is iso-propyl acetate, and the amount of water in the solvent mixture is greater than about 1.6 mg/ml."

III. Following an opposition requesting revocation of the patent in suit in its entirety, the Board of Appeal in its decision T 25/01 remitted the case to the first instance with the order to maintain the patent in suit on the basis of an amended set of two claims, namely Claims 1 and 2 submitted as third auxiliary request, and a description yet to be adapted.

Claim 1 was maintained in the form as granted. Claim 2 as granted no longer existed and the combined subject-

matter of Claims 3, 4, 5 and 6 as granted became new Claim 2.

IV. In compliance with the Order of the decision T 25/01, the Opposition Division in charge of the remitted case sent a communication pursuant to Article 101(2) EPC and Rule 58(1) to (3) EPC and invited the Proprietor of the patent (now Respondent) to adapt the description of the patent to the two claims which had been held patentable.

V. The Opposition Division decided to maintain the patent in suit with the pages 2 and 3 of the description submitted by the Proprietor of the patent with letter dated 30 July 2004. The description contained the following amendments:

- (a) page 2, column 2, the passage of the description referring to the subject-matter of Claim 2 as granted (now cancelled) was deleted (see lines 21 to 25).
- (b) page 2, column 2, the passage related to the subject-matter of Claims 3, 4, 5 and 6 was handwritten amended to recite exactly the wording of Claim 2 as maintained.
- (c) page 3, column 3, the three first lines belonging to the part of the description referring to Claim 3 as granted was deleted.
- (d) page 3, column 3, the integer "1" was added after the designation "Illustrative example".
- (e) page 3, column 4, the term "Illustrative" was added before the designation "Example 2".
- (f) page 3, column 4, "Example 3" was renamed "Example 2".

Otherwise, the description remained in the form as granted, including the passage on page 2, column 2, lines 4 to 19 reading as follows:

"The crystallization examples above are for procedures conducted at ambient temperature. As can be appreciated by those skilled in the art, the amount of water needed to produce Form I in any given organic solvent mixture will vary with temperature, since changes in temperature will alter the solubility of the solute. For example, when using iso-propyl acetate to produce Form I, the following amounts of water may be present at the indicated temperatures:

Temperature	Amount of water
1.4°C	0.8 mg/ml or less
6°C	0.9 mg/ml or less
12°C	1.0 mg/ml or less
18°C	1.3 mg/ml or less."

- VI. The Appellant (Opponent) objected to the maintenance of that passage and to the Illustrative Examples as amended (see point IV (d) and (e) above) and to this end lodged an appeal against the decision of the Opposition Division.

- VII. In a communication accompanying the summons to oral proceedings, the Board expressed its preliminary opinion that the adaptation of the description was regulated by Article 84 and Rule 57a EPC and had to be restricted to those parts of the description to which the amended claims are related.

- VIII. With its response filed on 4 July 2007, the Respondent submitted an amended page 3, wherein the integer "1"

after "Illustrative Example" was deleted and the passage on page 3, column 4, lines 10 to 16, corresponding to the "Illustrative Example 2" (Example 2 as granted) was deleted. This amended page 3 together with page 2 as maintained by the Opposition Division forms the main request of the Respondent.

The Respondent also submitted an auxiliary request.

- IX. The oral proceedings took place on 9 August 2007.
- X. The arguments of the Appellant submitted in the course of the written proceedings and during the oral proceedings can be summarized as follows:

When a patent is maintained with an amended set of claims, as is the case here, the adaptation of the description must be made not only vis-à-vis the sole amended claims but in consideration of the amended set of claims taken as a whole. It is in that respect necessary to suppress in the description any vague and unclear passages which would lead to a misinterpretation of the scope of the patent in the context of Article 69 EPC. It is a right of the opposing party and the public that the description be clearly adapted.

Contrary to the preliminary view expressed by the Board of appeal in its communication, the adaptation of the description is not regulated by Rule 57a EPC. According to Rule 57a EPC, the Proprietor of the patent has the (voluntary) possibility to amend the description, the claims and the drawings in order to overcome objections based on grounds of opposition specified in Article 100

EPC. The amendments have to be "appropriate and necessary". The problem in the present case, however, is not to deal with amendments made by the Proprietor of the patent in order to overcome justified grounds of opposition. The problem addressed in the present case is that the Proprietor of the patent has not amended the description so that it is in line with the claims maintained after opposition proceedings. The adaptation of the description to the claims as maintained is not regulated by Rule 57a EPC but by Rule 58(2) EPC.

The description is not correctly adapted to the claims, as they are maintained in the present version of the patent. It is incorrect to distinguish changes in the description introduced during the examination proceedings from those introduced during the opposition proceedings. If a patent is opposed in its entirety, it is justified to request that the description is correctly adapted to the claims as they are maintained by the Opposition Division or the Board of appeal. The "appropriate and necessary" amendment of the description is not only a right of the Proprietor but also of the Opponent.

Claim 1 as maintained refers to a process for producing polymorphic form I of finasteride according to which the crystallisation is effected at an ambient temperature of about 25°C. The description in column 2, lines 4 to 19 of the patent specification refers to temperatures lower than an ambient temperature of about 25°C as specified in Claim 1 of the maintained patent. Therefore, by maintaining this passage, the description of the patent specification was not adapted to the wording of the maintained claims. Accordingly, it is

irrelevant that the paragraph in Column 2, lines 4 to 19 of the description related to Claim 1 as granted. The maintenance of this passage has to be considered as a non-allowable attempt by the Proprietor to give the patent an interpretation not limited to the specific temperature defined in Claim 1. Further, it cannot be considered either as a guide for the skilled reader to perform the claimed process, or as background art. This passage should at least be preceded by a statement that it does not belong to the invention to avoid any contradiction.

The Appellant objects to this passage all the more because it also relates to Claim 2 as granted which was deleted in the set of claims as maintained.

The "Illustrative Example" given in column 3, lines 35 to 56, refers to the preparation of finasteride form I by crystallisation of a mixture of finasteride in glacial acetic/water, wherein the weight percent of water equals or exceeds 84%. A crystallisation system of glacial acetic acid/water, however, was not included in the process of Claim 1 for producing finasteride form I. The use of the word "illustrative" does not make it clear that this example does not belong to the invention.

- XI. The Respondent in substance supported the preliminary view expressed by the Board in its communication. It pointed out, in particular, that the two passages in issue were not covered by the claims as granted. No ground of opposition could be raised against them. It was, therefore, neither appropriate nor necessary to delete them. Furthermore, it was not proper to consider

the amended set of claims as a whole. There were amended claims and claims maintained as granted. With regard to the latter, an objection against the related description could only have been raised under Article 84 EPC, which is not ground of opposition. More generally, the Proprietor of the patent is free to include in the specification such information as he thinks appropriate. Regarding the term "Illustrative example", the skilled reader in the present context understands that this example is not part of the claimed subject-matter as maintained.

XII. The Appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained on the basis of either the main request or the first auxiliary request both filed on 4 July 2007.

XIII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. The main request of the Respondent seeks to adapt the description to the amended set of claims maintained by the Board of Appeal in its former decision T 25/01; it consists of page 2 of the description as maintained by

the decision of the Opposition Division dated 27 January 2005 and page 3 of the description filed on 4 July 2007.

3. Article 84 EPC, which states that the claims must be supported by the description, requires an appropriate adaptation of the description to an amended set of claims. In particular, there must not be any inconsistency between the claims and the description. However the only objections which may be raised under Article 84 EPC in opposition proceedings are those relating to amendments made in the course of such proceedings (see T 301/87, OJ EPO 1990, 335 and T 300/04 dated 21 April 2005, not published in the OJ EPO, point 5). Therefore, contrary to the Appellant's view, the purpose of the opposition-appeal proceedings is not to examine whether the description is in line with the whole set of claims to be maintained but only to examine whether the description has been properly adapted as a consequence of the amendments made to the claims as granted.

Furthermore, Rule 57a EPC establishes a limit to the amendments which can be made to the patent in suit, namely the amendments must be occasioned by grounds of opposition specified in Article 100 EPC, even if the respective ground has not been invoked by the opponent.

In the Board's judgment Article 84 and Rule 57a EPC are the two provisions which must guide the Proprietor of the patent when he is invited by the Opposition Division to adapt the description. In other words, the amendments must be appropriate and necessary, and nothing more.

Contrary to the Appellant's contention, Rule 58 EPC is not relevant to the question whether or not the description has been correctly adapted. Rule 58 EPC merely provides the procedural machinery which (as in the present case, following the Order of the Board - see point III above), empowers the Opposition Division to invite the Proprietor of the patent to adapt the description. Rule 58 EPC does not confer any power on the Opposition Division to impose any modifications. This follows from Article 102(2) EPC which states "If the Opposition Division is of the opinion that taking into consideration the amendments **made by the Proprietor of the patent ...** " (emphasis added by the Board).

4. In view of pages 2 and 3 of the description filed as main request by the Respondent, it is not disputed that the deleted passages correspond to the amendments made to the set of claims as granted (see point V, (a), (b), (c), (f) and deletion of Example 2). The Board considers that these amendments are appropriate and necessary to render the description consistent with the set of claims as maintained and comply with the requirements of Article 84 and Rule 57a EPC.
5. The only disputed points relate to the maintenance of the passage on page 2, column 2, lines 4 to 19 (see point V above) and the designation "Illustrative Example" on page 3, column 3, line 35 (see point VIII above).
6. The Appellant argued first that the disputed passage on page 2, column 2, lines 4 to 19 (see point V above) not

- only referred to the subject-matter of Claim 1 (maintained as granted) but also to the subject-matter of granted Claim 2 (now deleted).
7. However, this passage immediately follows the part of the description reciting *verbatim* the wording of Claim 1 and precedes that relating to Claim 2. Furthermore, since granted Claim 2 concerned a process involving a temperature of at least about 25°C, whereas the passage in question discusses the solubility of the solute at temperatures ranging from 1.4°C to 18°C, there is no clear relationship between this passage and Claim 2. Therefore, the argument of the Appellant is not convincing.
 8. The Appellant also argued that the maintenance of this passage had to be considered as a non-allowable attempt by the Proprietor to interpret the scope of Claim 1 without a limit to the specific temperature defined in the claim.
 9. However Claim 1 was maintained as granted by the Board (see T 25/01, point I above) and, therefore, does not give rise to any objections under Article 100 EPC. Since the passage in issue belongs to that part of the description which relates to Claim 1, its deletion would not be occasioned by grounds of opposition and therefore could not be allowed under Rule 57a EPC.

It does not matter, in that context, that the maintenance of this passage would allegedly create a misinterpretation of Claim 1. Either it is a question of ambiguity under Article 84 EPC, which is not relevant here since Claim 1 was maintained as granted

(see point 3 above), or it is a question of enforceability of the patent under Article 69 EPC and its protocol of interpretation, which is not within the competence of the EPO (see T 740/96 of 26 October 2000, point 3.3 and T 442/91 of 23 June 1994, point 3, both decisions not published in the OJ EPO).

10. The same conclusion applies to the term "illustrative" to designate the example enabling the identification of Form I of finasteride. This example clearly relates to example 1 of the patent in suit which discloses an embodiment according to Claim 1 which was maintained as granted by the Board. Therefore, amendment of this example by, for instance, replacing "illustrative" by "reference" would not be occasioned by a ground of opposition and therefore could not be allowed under Rule 57a EPC.
11. Consequently, the Appellant's objections to the description as amended are unfounded.

First auxiliary request

12. In view of the above, there is no need for the Board to decide on this request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the claims as ordered by the Board in its decision of 16 September 2003, page 2 of the description as maintained by the decision of the Opposition Division dated 27 January 2005 and page 3 of the description as in the main request filed on 4 July 2007.

The Registrar

The Chairman

N. Maslin

A. Nuss