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DECISION
of 16 September 2003

Case Number: T 0025/01 - 3.3.1

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. 54, 56, 69(1), 83, 100(a), 114, 123(3)

Keyword:

"Main request, first and second auxiliary request: extension of the protection conferred (yes)"

"Third auxiliary request: Claim 1 - novelty and inventive step (yes); Claim 2 - sufficiency of disclosure (yes)"

"Remittal to the first instance for adapting the description (yes)"

Decisions cited:

G 0009/91; G 0001/98, T 0270/90, T 0355/97, T 0190/99

Catchword:

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Case Number: T 0025/01 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 16 September 2003

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
17 October 2000 concerning maintenance of
European patent No. 0599376 in amended form.

Composition of the Board:

Chairman: A. J. Nuss
Members: P. F. Ranguis
R. T. Menapace

Summary of Facts and Submissions

- I. The Appellant 1 (Proprietor of the patent) and the Appellant 2 (Opponent) lodged an appeal against the interlocutory decision of the Opposition Division to maintain European patent No. 599 376 (European patent application No. 93 203 163.6) in the form amended pursuant to Article 102(3) EPC.
- II. The patent as granted contained six claims. Independent Claims 1, 2 and 3 read as follows:

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

(1) crystallization 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 ^\circ C;

(2) recovering the resulting solid phase; and

(3) removing the solvent therefrom."

"2. A process for producing polymorphic Form I of 17 \hat{a} -(N-tert-butyl carbamoyl)-4-aza-5 \hat{a} -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 ^\circ C and recovering the resulting solid phase."

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

- (1) crystallization 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."

III. The opposition sought revocation of the patent in suit, in particular on the grounds that the subject-matter of Claim 1 lacked novelty and did not involve an inventive step, the subject-matter of Claim 2 did not involve an inventive step (Article 100(a) EPC) and that the subject-matter of Claim 3 did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC). In support of lack of novelty or inventive step several documents were cited including:

- (1) EP-A- 367 502
- (2) EP-A- 428 366
- (3) EP-A- 298 652
- (5) American Institute of Chemical Engineers, Symp. Ser. 284, vol. 87, 1991, pp. 58-63.

- IV. The Opposition Division held that the subject-matter of Claim 3 could be regarded as enabling (Article 83 EPC) in the light of the description, in particular example No. 3 and in the absence of counter-evidence from the Opponent. Regarding novelty of Claim 1, the Opposition Division considered that the processes for obtaining finasteride, including crystallization of crude finasteride, disclosed in example No. 5 of document (1) or example No. 1 of document (2) were not novelty destroying due to insufficient substantiation. Furthermore, regarding the inventive step of Claim 1, the Opposition Division held that in view of the disclosures of document (1) and (2), involving ethyl acetate and isopropyl acetate respectively as crystallization solvents, it would not have been obvious to arrive with a reasonable expectation of success at a controlled process for producing polymorphic form I of finasteride. Document (5) could not help in that respect since it was silent about the obtention of Forms I or II of finasteride. Regarding inventive step of Claim 2, the Opposition Division held that the claimed transformation of Form II into Form I was obvious from the teaching of document (5) combined with the common technical knowledge of the person skilled in the art.
- V. The patent was, therefore, maintained in an amended form, namely with Claims 1 to 5 (Claims 1, 3 to 6 as granted).
- VI. With the statement of grounds of appeal, Appellant 1 filed a set of six claims including Claims 1, 3 to 6 as granted and a fresh Claim 2. In a communication accompanying the summons to oral proceedings which took

place on 16 September 2003, the Board had informed the parties that the compliance of the subject-matter of the fresh Claim 2 with Article 123(3) EPC would be discussed. In a letter received on 11 August 2003, Appellant 1 withdrew his previous request and filed in lieu thereof four requests as main request and first to third auxiliary request.

The main request and the first auxiliary request had in common Claim 1 as granted (cf. point II above) and an amended Claim 2 which read as follows:

"2. A process for producing polymorphic Form I of 17 \hat{a} -(N-tert-butyl carbamoyl)-4-aza-5 \hat{a} -androst-1-en-3-one in substantially pure form, comprising stirring Form II of finasteride in dry acetonitrile at ambient temperature (about 25°C) and recovering the resulting solid phase."

The second auxiliary request contained Claim 1 as granted and an amended Claim 2 which read as follows:

"2. A process for producing polymorphic Form I of 17 \hat{a} -(N-tert-butyl carbamoyl)-4-aza-5 \hat{a} -androst-1-en-3-one in substantially pure form, comprising stirring Form II of finasteride in dry acetonitrile at about 25°C and recovering the resulting solid phase."

The third auxiliary request contained two claims: Claim 1 as granted (cf. point II above) and Claim 2 which read as follows:

"2. A process for producing polymorphic Form II of 17 \hat{a} -(N-tert-butyl carbamoyl)-4-aza-5 \hat{a} -androst-1-en-3-one, comprising the steps of:

(1) crystallization from a mixture of finasteride in an organic solvent and water, wherein the organic solvent is glacial acetic acid, and the weight percentage of water in the solvent mixture is less than about 83%, or wherein the organic solvent is ethyl acetate and the amount of water in the solvent mixture is greater than about 3.5mg/ml, or wherein the organic solvent is isopropyl acetate, and the amount of water in the solvent mixture is greater than about 1.6mg/ml, 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."

VII. In the appeal proceedings, Appellant 2 withdrew his reliance on example No. 5 of document (1) and example No. 1 of document (2) to contest the novelty of Claim 1. He submitted in lieu thereof a fresh document

(6) EP-A- 473 225.

The submissions of Appellant 2 in the written proceedings and during oral proceedings may be summarised as follows:

The subject-matter of Claim 2 of the main request and the first and second auxiliary requests extended the scope of the protection of Claim 2 as granted since the replacement of the feature "heating" by the feature

"stirring" represented a shift in the protection conferred.

Regarding novelty, example No. 2 of document (6) disclosed a process of recrystallization of finasteride in isopropyl acetate and thus anticipated the subject-matter of Claim 1 of all the requests. It was true that the temperature used for the recrystallization was not explicitly indicated in that document. However, where no explicit temperature was indicated, it was to be assumed by the person skilled in the art that the recrystallization was effected at ambient temperature. In that context document

(7) Recrystallization, C. Yoder and P. Leber, pages 1 to 4 dated 15 September 2003

was submitted at the oral proceedings before the Board as technical common general knowledge.

The experiments submitted as **Annex 3** showed that the reproduction of Example No. 2 of document (6) yielded pure Form I.

Regarding inventive step of Claim 1 of all the requests, the technical problem to be solved in view of document (5) as the closest state of the art was to provide a process for the preparation of Form I of finasteride. However, this problem was not solved for the whole range claimed within Claim 1, as shown by the experiments submitted as **Annex 5** and **10**.

Should the Board consider that the technical problem was solved within the claimed area, the claimed subject-matter of Claim 1 was obvious in view of documents (5), (1) and (6). It was known from document (5) that Form I was thermodynamically more stable than Form II, and that Form I had a lower solubility in cyclohexane and water in comparison to Form II. It followed for the person skilled in the art that Form II was interconverted to Form I when stirring a mixture of finasteride including Form I and II in the above solvents as confirmed by experiments submitted as **Annex 7** and **8**. Since isopropyl acetate and ethyl acetate were common to the person skilled in the art as recrystallization solvents as shown by documents (1) and (6), it represented an obvious measure to substitute solvents cyclohexane or water by ethyl acetate or isopropyl acetate and, as a matter of fact, to get to the subject-matter of Claim 1.

VIII. Appellant 1's submissions in the written proceedings and during oral proceedings may be summarised as follows:

The replacement of the feature "heating" by the feature "stirring" in Claim 2 of the main request and the first and second auxiliary requests restricted the scope of Claim 2 as granted. Stirring Form II was an alternative included in Claim 2 as granted. Claim 2 as granted had the same wording as Claim 34 as originally filed and that claim covered among others, the embodiment disclosed in the application as filed related to "stirring Form II overnight in dry acetonitrile at ambient temperature, and recovering the resultant solid

phase" (cf. page 11, lines 29 to 31). Decision T 190/99 was cited in that respect.

Document (6) was late-filed and was to be disregarded in accordance with the provisions of Article 114(2) EPC. On the substance, document (6) was not novelty-destroying since Example No. 2 was completely silent about the temperature at which the recrystallization took place whereas the patent in suit specified that the crystallization took place at an ambient temperature of about 25°C.

Regarding inventive step, document (5) indicated that solubilities could be determined for Form I and Form II of finasteride in cyclohexane and water. This unambiguously taught that no interconversion of Form I and Form II was taking place in those solvents. It followed that the person skilled in the art would have been unable to predict with a reasonable expectation of success, whether it would be possible to produce polymorphic Form I of finasteride by a crystallization process involving ethyl acetate or isopropyl acetate as defined in Claim 1.

IX. Appellant 1 requested that the appeal be dismissed and that the patent be maintained on the basis of Claim 1 as granted and

- Claims 3 to 6 as granted and Claim 2 as submitted as main request on 11 August 2003, or
- Claims 2 and 3 according to the first auxiliary request, or

- Claims 2 and 3 according to the second auxiliary request, or
- Claim 2 according to the third auxiliary request.

(All auxiliary requests as submitted at the oral proceedings.)

Appellant 2 requested that the decision under appeal be set aside and the patent be revoked.

- X. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeals are admissible.

Main request, first and second auxiliary request

2. *Article 114 EPC - Extent of scrutiny*

The Appellant has amended Claim 2 as granted in the course of the proceedings before the Board (cf. point VI above). In case of amendments, they must be fully examined by the Board as to their compatibility with the requirements of the EPC, in particular with the provisions of Article 123 EPC (cf. G 9/91, OJ EPO 1993, 408, point 19 of the reasons).

3. *Article 123(3) EPC*

3.1 The wordings of Claims 2 of the main request, first and second auxiliary requests have in common the replacement of the term "heating" present in Claim 2 as granted (cf. points II above) by "stirring" (cf. point VI above). The feature "heating" means an external action to transfer energy to a system so that the temperature of the system increases. Deleting this feature "heating" thus amounts to covering a process where such an external action is not implemented. Furthermore, "stirring" is not commensurate with "heating" since it is commonly known that mechanical agitation (stirring) of a mixture neither automatically nor necessarily causes the said mixture to be heated. Such an amendment extends, therefore, the protection conferred by Claim 2 as granted.

3.2 The finding above cannot be rebutted by reference to the description of the application as filed (Claim 34 in combination with page 9, lines 30 to 33 and page 11, lines 22 to 26) which would allegedly cover both unrelated variants "heating" and "stirring". The Board observes that such an interpretation would amount to a reference to Article 69(1) EPC. However, this article does not deal with the issue related to amendments which is controlled by the provisions of Article 123 EPC. The provisions of Article 69(1) EPC are primarily intended to be applied by the Courts responsible for deciding on infringement cases (cf. G 1/98, OJ EPO 2000, 111, point 4 of the reasons or Singer, the European Patent Convention, English Version, 1995, page 253). These provisions are, therefore, not designed to be a substitute for the requirements of Article 123(3) EPC.

3.3 Nor can the Board rely on the previous decision T 190/99 to deviate from the above finding. Indeed, that decision related to a situation where definitions in a claim were wrong or could be wrongly understood (cf. point 2.2.1 of the reasons). However, in the present case, nothing was submitted by Appellant 1 in that respect.

3.4 In view of the above, the subject-matter of Claim 2 of the main request, first and second auxiliary requests extends the scope of protection conferred by Claim 2 as granted in contravention with the requirements of Article 123(3) EPC by covering a process where the mixture is not heated. Since the Board can only decide on a request as a whole, those requests must be rejected.

Third auxiliary request

4. *Article 123(2) and (3) - Amendments*

4.1 The subject-matter of Claim 2 is identical to the subject-matter of Claims 4, 5 and 6 as granted, all dependent on Claim 3 as granted. The wording of present Claim 2 results from a purely formal rearrangement of Claims 4, 5 and 6 as granted due to the deletion of Claim 3 as granted. Therefore, the amendments do not give rise to an objection under Article 123(2) EPC. Furthermore, those amendments restrict the scope of independent Claim 3 as granted and thus satisfy the requirements of Article 123(3) EPC. Those findings were not contested by Appellant 2.

5. *Article 114 EPC - late-filed evidence*

5.1 Document (6) was submitted by Appellant 2 with the statement of grounds of appeal against the novelty and inventive step of Claim 1. Its admissibility was contested by Appellant 1 on the ground of being a belated submission. However, the citation of this document may be viewed, in the Board's judgment, as a response to the Opposition Division's decision and is, therefore, admitted into the appeal proceedings.

5.2 Document (7) was submitted by Appellant 2 at the oral proceedings before the Board as common general knowledge. Appellant 1 contested its admissibility as a late-filed document. The Board observes that the sole date indicated in that document is 15 September 2003 whereas the patent application No. 93 203 163.6 was filed a long time ago, namely on 12 November 1993. Since it is not established that the relevant information contained therein was known before the date of filing of the application of the patent in suit and it is not the purpose of an oral proceedings to find that out, this document is disregarded on the ground that it is a belated submission.

6. *Article 54(1)(2) EPC - Novelty*

6.1 The question to be decided is whether Example No. 2 of document (6) unambiguously discloses the subject-matter of Claim 1.

6.2 Example No. 2 of document (6) discloses a process for preparing 3-oxo-4-aza-5 α -androst-1-ene-17 β -N-(1,1-dimethylethyl)-carboxamide or finasteride by condensing

potassium t-butoxide with 2-iodo-3-oxo-4-aza-5 α -androstane-17 β -N-(1,1-Dimethylethyl)-carboxamide. After treatment with acetic acid and a first crystallization in a sodium chloride solution, "recrystallization from isopropyl acetate gave the title compound".

6.3 To support his challenge against novelty of Claim 1 in view of this example, Appellant 2 submitted experiments disclosed in **Annex 3** deemed to reproduce example No. 2 of document (6). In this experiment, the crude finasteride, obtained by the reaction of 2-iodo-3-oxo-4-aza-5 α -androstane-17 β -N-(1,1-dimethylethyl)-carboxamide with potassium t-butoxide, was dissolved in hot isopropyl acetate and cooled to 25°C. The crystalline suspension was filtered to yield crystals of polymorphic Form I.

6.4 The Board concurs with Appellant 2 that the process disclosed in that experiment falls within the subject-matter of Claim 1. However, an unbiased assessment of novelty requires that the claimed invention be compared with the subject-matter which emerges **unambiguously** from a prior disclosure. In that context, it is not contested by Appellant 2 that example No. 2 of document (6) is silent about the temperature at which the recrystallization takes place, whereas Claim 1 specifies that the crystallization takes place at an ambient temperature of about 25°C. Furthermore, nothing relevant in the form of common general knowledge was submitted to show that such a crystallization occurred necessarily at this quite defined temperature (about 25°C). Therefore, the experiment of **Annex 3** goes beyond the disclosure of Example No. 2 of document (6). It might well be that the description of Example No. 2 is

incomplete. However, if the description of the example is incomplete, in the sense that no information about the recrystallization temperature is given, that does not allow a party to complete it according to the disclosure of the contested invention. Therefore, the experiment disclosed in **Annex 3** is to be disregarded for assessing novelty of the claimed process.

6.5 In conclusion, since the subject-matter of a claimed invention is novel if it includes even one technical feature which distinguishes it from the prior art, the subject-matter of Claim 1 is new in view of example No.2 of document (6) which does not disclose unambiguously the feature "crystallization from a mixture of finasteride ... at an ambient temperature of about 25°C" present in Claim 1.

7. *Article 56 EPC - Inventive step*

7.1 The patent-in-suit in the form of Claim 1 as granted relates to a process for producing polymorphic Form I of finasteride.

7.2 Document (5) is the sole document of the cited prior art which reveals the existence of polymorphic Form I of finasteride. Since the closest prior art can only be a document aiming at the same objective as the claimed invention, the Board considers, in agreement with both parties, that document (5) represents the closest prior of the art and, thus, the starting point in the assessment of inventive step.

7.3 In view of this state of the art, the problem underlying the patent-in-suit in the form of Claim 1 as

granted may be viewed in the provision of a process for preparing polymorphic Form I of finasteride.

7.4 As the solution to this problem, Claim 1 proposes to achieve a process as set out in the characterizing part of Claim 1 (cf. point II above).

7.5 Relying on experimental evidence submitted in the appeal proceedings as **Annex 5** and **10**, Appellant 2 argued that the stated problem was not solved within the whole claimed area.

7.5.1 The first experiment disclosed in **Annex 5** concerns a process for preparing finasteride derived from example No.5 of document (1) wherein the crude finasteride is obtained by the reaction of t-butylamine with 1-(((5 α , 17 β)-3-oxo-4-azaandrost-1-ene-17yl)-carbonyl)-1H imidazole. The mixture of crude finasteride and ethyl acetate is cooled to room temperature in 2 hours and after that is stirred at 0°C for 1 hour and the precipitated crystals are filtered. No Form I is obtained. However, it results from this experiment that the crystallization occurs at 0°C contrary to one of the essential features of the claimed invention, i.e. "crystallization from a mixture of finasteride ... at an ambient temperature of about 25°C". It follows that this experiment must be disregarded as not reproducing the process conditions within the scope of Claim 1.

7.5.2 The second experiment disclosed in **Annex 5** concerns a process for preparing finasteride derived from example No.2 of document (3) wherein the crude finasteride is obtained by dehydrogenation of 17 β -N-(t-butylcarbonyl)-4-aza-5 α -androstane-3-one. Isopropyl

acetate is added to the crude finasteride and the mixture stands in a cooler where the solid material is filtered and dried. No Form I is obtained. It results from this experiment that the crystallization occurs in a cooler, contrary to one of the essential features of the claimed invention, i.e. "crystallization from a mixture of finasteride ... at an ambient temperature of about 25°C". It follows that this experiment must also be disregarded.

7.5.3 In addition, the Board observes that the argumentation of Appellant 2 is somewhat contradictory. In the appeal proceedings Appellant 2 withdrew reliance on example No. 5 of document (1), to contest the novelty of Claim 1 (cf. point VII above). He can then hardly contend that the reproduction of this example falls within the scope of Claim 1. The same remarks apply to example No. 2 of document (3) which was never opposed to the novelty of Claim 1.

7.5.4 The experiment disclosed in **Annex 10** concerns a process for preparing finasteride derived from example No. 2 of document (6) wherein the crude finasteride, obtained by the reaction of
2-iodo-3-oxo-4-aza-5 α -androstane-17 β -N-(1,1-dimethylethyl)-carboxamide with potassium t-butoxide, is suspended and stirred in dry isopropyl acetate at 25°C for 12 hours. Form I of finasteride was not obtained.

7.5.5 Appellant 1 contested that the experiment disclosed in Annex 10 reproduced the subject-matter of Claim 1 since the starting crude material was not finasteride but a solvate of finasteride, i.e. a form where more water was present than in the non-solvated form, as shown in

Figure 17a attached to the experiment report. To the contrary, Appellant 2 argued that the title of Example No. 2 was
3-oxo-4-aza-5 α -androst-1-ene-17 β -N-(1,1-dimethylethyl)-carboxamide, which was the chemical name of finasteride and not a solvate of finasteride.

Furthermore, both parties agreed that the content of water of the crude finasteride was an important issue. From the explanations given at the oral proceedings, it appeared that the crude finasteride could exist in two forms, namely a non-solvated form and a solvated form (solvate), depending on the content of water of the crude finasteride. When the content of water was lower than a certain limit, the crude finasteride existed under the non-solvated form, whereas beyond the said limit, the crude finasteride was present as a solvate. Form I could only be obtained by recrystallisation from the non-solvated form (cf. page 8, lines 13 to 17 of the application as filed).

7.5.6 On the evidence submitted by the parties, the Board has, therefore, to decide whether or not the experiment of **Annex 10** demonstrates that the technical effect of preparing Form I of finasteride is successfully solved within the whole area of Claim 1.

7.5.7 First, the Board observes that the issue is not to decide on the experiment disclosed in Example No. 2 of document (6). The examination for the purpose of Article 56 EPC is, therefore, restricted to the question of whether the crude finasteride obtained in the experiment disclosed in **Annex 10** is in solvated form or not.

7.5.8 In that context, it is noted that the DSC spectrum of crude finasteride (Figure 17a) shows a large peak between 90°C and 110°C in addition to a peak at about 253°C, i.e. finasteride. Appellant 1 contended that the first peak revealed the presence of water. Appellant 2, in contrast, held it was impurity. This situation is rendered even more obscure given it is admitted by both parties that water has a peak at 100°C. In the Board's judgment, the evidence brought by Appellant 2 is, therefore, not sufficient to raise a reasonable doubt in order to discharge him from the burden of proof which rested upon him. According to the jurisprudence of the Boards of Appeal each of the parties to the proceedings carries the burden of proof for the facts it alleges. If a party, whose arguments rest on alleged facts, is unable to discharge its onus of proof, it loses thereby. (cf. T 270/90, OJ EPO 1993, 725, point 2.1 of the reasons or T 355/97, point 2.5.1 of the reasons).

7.5.9 In the absence of sufficient evidence, the Respondent has, therefore, not substantiated his allegation that the subject-matter of Claim 1 did not solve the technical problem defined above (cf. point 7.3) within the whole claimed area.

7.6 It remains to be decided whether or not the claimed solution is obvious in view of the cited prior art.

The relevant question is whether the person skilled in the art guided by the technical problem to be solved would have been led to prepare Form I of finasteride in the way proposed by the subject-matter of Claim 1.

7.6.1 Appellant 2 argued that document (5) taught that Form I was thermodynamically more stable than Form II and that Form I had a lower solubility in cyclohexane and water in comparison to Form II. It followed that Form II was transferred into Form I when stirring a mixture of finasteride including Form I and Form II in the above solvents. Appellant 2 relied, in that respect, on experiments reported in **Annex 7** and **Annex 8**. It would have been obvious for the person skilled in the art when exchanging cyclohexane by other organic solvents, like ethyl acetate or isopropyl acetate as disclosed in documents (1) and (6) respectively, to produce Form I from a mixture of finasteride.

7.6.2 However, the above mentioned transformation of Form II into Form I when stirring a mixture of finasteride including Form I and Form II in cyclohexane and water, does not emerge from the teaching of document (5). In the Board's judgment, that finding could only result from an investigation that the person skilled in the art would have made once he had known that in ethyl acetate or isopropyl acetate such a transformation occurred, i.e. once the invention was made. This approach, however, is dependent upon the knowledge of the teaching of the patent in suit, and does not arise from the state of the art. An argument based on such considerations is an ex post facto argument and thus not acceptable.

7.6.3 On the contrary, the teaching of document (5) is limited to the indication of solubilities of Form I and Form II in cyclohexane and water. There is no hint of any transformation of those forms in the above solvents

or any other solvents. Even in view of documents (1) and (6), the person skilled in the art would have had no incentive to produce Form I in the claimed way since those documents are silent about Form I or Form II.

7.7 As, starting from document (5) and in the light of the other documents cited, the person skilled in the art would not have been led in an obvious manner to the claimed solution in order to solve the technical problem defined above (cf. point 7.3 above), the subject-matter of Claim 1 meets the inventive step requirement.

8. *Article 100(b) EPC - Article 83 EPC*

The objection based on Article 100 (b) EPC only concerned Claim 3 as granted (cf. point III above).

Appellant 2 raised no objection against Claim 2 based on independent Claim 3 as granted (cf. point 4.1 above). The Board finds on its own, in particular in view of example No. 3, that the patent in suit discloses the claimed invention, in the form of the said claim, in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

9. *Remittal to the first instance - Article 111(1) EPC*

Although the Board has come to the conclusion that the third auxiliary request was to be allowed, it was noted that the description has still to be put into conformity with the claims of the present third auxiliary request. Therefore, 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 exercises its discretion under Article 111(1) EPC to remit the case to the first instance in order for the description to be adapted to the allowable claimed subject-matter according to the third auxiliary 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 third auxiliary request:

Claim 1 as granted and Claim 2 as submitted at the oral proceedings,

and a description yet to be adapted.

The Registrar:

The Chairman

N. Maslin

A. Nuss