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D E C I S I O N
of 7 February 2001

Case Number: T 0226/98 - 3.3.1
Application Number: 87306882.9
Publication Number: 0256747
IPC: C07D 277/48

Language of the proceedings: EN

Title of invention:
Morphologically homogenous forms of famotidine and processes
for their preparation

Patentee:
RICHTER GEDEON VEGYESZETI GYAR R.T.

Opponent:
Yamanouchi Pharmaceutical Co., Ltd.

Headword:
Famotidine/RICHTER GEDEON

Relevant legal provisions:
EPC Art. 84, 123(2)(3), 54(1)(2)
EPC R. 57a

Keyword:
"Main request: clarity (no) - obscurity of delimiting feature
"as a pharmaceutical product"
"First auxiliary request: support in the application as filed
(no)"
"Second auxiliary request: novelty (no)"

Decisions cited:
G 0009/91, G 0001/92, G 0009/92, T 0012/81, T 0181/82,
T 0401/95, T 0303/94, T 0728/98

Catchword:

1. In a claim related to a product as such (here: famotidine form "B"), the feature "as a pharmaceutical product" for defining a pharmaceutical standard of purity renders said claim unclear in the absence of a generally accepted quantitative definition for the purported standard of purity. Nor can this expression be considered to be a commonly accepted functional feature as no clear definition can be derived therefrom (see point 7.2 of the reasons).

2. As purity standards are likely to change with time for a number of reasons (e.g. new manufacturing process, new or improved analytical tools, change of criteria for obtaining a marketing authorization), it remains obscure what is considered to be the required product quality when defined by the feature "as a pharmaceutical product" (see point 7.3 of the reasons).



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Boards of Appeal

Chambres de recours

Case Number: T 0266/98 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 7 February 2001

Appellant:
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 29 December
1997 concerning maintenance of European patent
No. 0 256 747 in amended form.

Composition of the Board:

Chairman: A. J. Nuss
Members: P. F. Ranguis
 J. P. B. Seitz

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the patent) lodged an appeal against the interlocutory decision of the Opposition Division to maintain the European patent No. 0 256 747 (European patent application No. 87 306 882.9) in the form as amended (second auxiliary request filed before the Opposition Division) pursuant to Article 102(3)(a) EPC.
- II. The opposition filed by Opponent 1 against the patent as a whole was based on Article 100(a) EPC, having regard to the following documents:

(1) ES-A- 536 803

(2) GB-A- 2 055 800

(3) EP-A- 0 128 736

(7) Experimental report submitted Prof. Ishii

and to a prior sale of form "B" of famotidine supported by various affidavits.

The opposition filed by the former Opponent 2 (see point IV below) against the patent in the scope of Claim 2, Claims 4 to 8 as far as form "B" is concerned, and Claim 10 for all Contracting States except AT, and in the scope of Claim 2, Claims 3 to 6 as far as form "B" is concerned, and Claim 8 for AT was based on Article 100(a), (b) and (c) EPC. Regarding lack of novelty and inventive step of said claims, the former Opponent 2 referred to documents:

(1) ES-A-536 803

(3) EP-A-0 128 736

(4) US-A-4 496 737

(8) Experimental report submitted by Prof. Burger

and to a prior sale of form "B" of famotidine supported by various affidavits.

III. The Opposition Division found that Claim 2 of the main and first auxiliary request filed at the oral proceedings before the Opposition Division did not comply with the requirements of Article 102(3) EPC.

The Opposition Division held that the subject-matter of Claim 2 of the main as well as the first auxiliary request, as filed during oral proceedings, was novel having regard to the prior art documents cited, in particular Example No. 4 of document (3), in view of the fact that document (3) did not reveal the existence of polymorphic forms of famotidine, and in consequence neither form "A" nor form "B". However, form "B" was considered to be anticipated by public prior use.

IV. Opponent 2 (Merck & Co., Inc.) withdrew his opposition in the course of the opposition proceedings.

V. Together with the Statements of grounds of appeal, the Appellant filed a new set of Claims 1 to 8 for the Contracting States BE, CH, DE, FR, GB, IT, LI, NL and SE (claim 2 corresponding to that of the first auxiliary request) and a new set of Claims 1 to 6 for the Contracting State AT.

VI. The Respondent (Opponent 1) only requested that the appeal be dismissed without submitting in support of that request any argument and, later on, withdrew his opposition (see letter dated 9 November 1998).

VII. In accordance with the Notice from the Vice-President Directorate-General 3 dated 19 May 1998 (OJ EPO 7/1998, pages 362 to 363), the request filed by the Appellant on 24 July 2000 for acceleration of the proceedings was allowed.

VIII. In a first communication dated 26 October 2000, the Board informed the Appellant as follows:

- the incorporation in claim 2 of the feature "as a pharmaceutical product" did not seem "appropriate and necessary" (Rule 57 (a) EPC);
- the novelty of claim 2 should be discussed, *inter alia*, in respect of
 - document (3) Example No. 4 ,
 - document (4) Example No. 5,
 - document (5) Experimental report of Prof. Marko submitted by the Proprietor of the patent, and
 - documents (7) and (8).

IX. In his response received on 5 January 2001, the Appellant abandoned the previous request and filed, as **main** and so far sole request, a set of eight claims for the Contracting States other than AT and a set of five claims for the Contracting State AT. Claim 2 of the request for the Contracting States other than AT read as follows:

"2. A morphologically homogeneous polymorph, designated Form "B", of famotidine as a pharmaceutical product which has an endotherma maximum of melting at a heating rate of 1°C/min of 159°C on the DSC; its

characteristic absorption bands in its infrared spectrum are at 3506, 3103 and 777 cm^{-1} ; its melting point is 159-162°C; and it has a needle-like crystal structure."

He argued that the expression "as a pharmaceutical product" was appropriate and necessary to distinguish the claimed product from the crude famotidine obtained according to document (3) which contained impurities other than famotidine, rendering it unsuitable for use as a pharmaceutical product.

X. In a second communication dated 23 January 2001, sent by fax, the Board informed the Appellant that at the Oral proceedings it would be examined, first, whether the subject-matter of the present request met the requirements of Article 123(2) and (3) and Article 84 EPC (Article 102(3) EPC).

XI. At the oral proceedings held before the Board on 7 February 2001, the Appellant filed two auxiliary requests, Claim 2 of each of them for the Contracting States other than AT reading respectively:

first auxiliary request:

"2. A morphologically homogeneous polymorph, designated Form "B", of famotidine which has an endotherma maximum of melting at a heating rate of 1°C/min of 159°C on the DSC; its characteristic absorption bands in its infrared spectrum are at 3506, 3103 and 777 cm^{-1} ; its melting point is 159-162°C; and it has a needle-like crystal structure, obtainable by dissolving famotidine of unspecified morphological composition in water and/or a lower aliphatic alcohol under heating characterised in that a solution oversaturated at a temperature lower than 40°C is

prepared wherein the oversaturated solution is produced by liberating the free base of famotidine from its salt by addition of the salt into ammonium hydroxide and crystals of Form B are precipitated and separated therefrom."

second auxiliary request:

"2. A morphologically homogeneous polymorph, designated Form "B", of famotidine which has an endotherma maximum of melting at a heating rate of 1°C/min of 159°C on the DSC; its characteristic absorption bands in its infrared spectrum are at 3506, 3103 and 777 cm^{-1} ; its melting point is 159-162°C; and it has a needle-like crystal structure, obtainable by dissolving famotidine of unspecified morphological composition in water as an acetic salt and a solution of famotidine oversaturated at a temperature lower than 40°C is produced by liberating the free base of famotidine from its salt by addition of the salt into ammonium hydroxide and crystals of Form B are precipitated and separated therefrom."

XII. The Appellant's submissions both in the written proceedings and at the oral proceedings can be summarised as follows:

- Since no appeal had been filed by the only remaining Opponent 1, neither the Board of Appeal, nor the non-appealing opponent might challenge the maintenance of the patent as amended in accordance with the interlocutory decision.

- The only relevant issue in the Appeal was therefore the alleged anticipation "by prior public use" of form "B" as a pharmaceutical product. Former issues, such as the alleged anticipation by Example No. 4 of document (3) were dismissed by the reasons given in the Decision.

- Regarding the main request, the amendment related to inclusion of the expression "as a pharmaceutical product", in Claim 2 of the patent as granted, met the requirements of Rule 57a EPC because it was occasioned by an attack against the novelty of said Claim 2 as granted. It was supported by various parts of the description as filed, in particular the passages on page 1, lines 3 to 4 and lines 13 to 14; page 2, line 22 to page 3, line 7 and page 14, lines 20 to 23. Moreover, this added feature was clear for it was a commonly admitted functional feature and it was clearly related to the required purity of a product for use as a pharmaceutical product.

- Regarding the first auxiliary request, the amendment relating to the introduction of a process feature into Claim 2 of the patent as granted was supported by the application as filed on page 4, lines 11 to 13 and lines 23 to 27; page 5, lines 15 to 17 and 22 to 26; page 6, lines 12 to 14 and page 18 (Example No. II/4). Said Claim 2 was also clear.

- Regarding the second auxiliary request, the amendment relating to the introduction of a process feature into Claim 2 of the patent as granted was supported by the same parts of the application as those indicated for the first auxiliary request. Said Claim 2 was also clear.

Claim 2 of the second auxiliary request was novel in view of the prior art cited. In particular, Example No. 4 of document (3) disclosed a process in three steps for manufacturing famotidine. The product obtained at the end of the first step was an intermediate product, a so called "crude product" according to both Prof. Marko and Prof. Ishii, which contained impurities other than famotidine and was not suitable for use as a pharmaceutical product. Therefore, there was no reason to stop the process disclosed in document (3) at this first step. Moreover, the experiments presented by Prof. Marko showed that the product obtained after the third step was form "A" of famotidine. Furthermore, the result of performing the first step was not inevitably form "B" as shown by

document (6) Experimental report submitted
by Dr. Harsanyi (Expert of
the Appellant)

who obtained 80% of form "A" and 20% of form "B".

Moreover, the melting point of the crude product was 157.6°C which was different from the melting point of the claimed product (159-162°C) and the infrared spectra presented in the report of Prof. Ishii showed that the crude product still contained impurities. In conclusion, there was an essential distinction between the crude product obtained according to the first step of Example No. 4 of document (3) and the claimed product which presented a purity sufficient to be considered as a pharmaceutical product.

XIII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained:

- (1) on the basis of the main request filed by a letter dated 5 January 2001, or
- (2) on the basis of the first auxiliary request filed during the oral proceedings, or
- (3) on the basis of the second auxiliary request filed during the oral proceedings.

XIV. At the end of the oral proceedings the decision of the Board was given orally.

Reasons for the Decision

1. The appeal is admissible.
2. Although the sets of claims of the main, first and second auxiliary request for the Contracting States other than AT each comprise several claims, in view of the outcome of the present appeal, it is not necessary in the present case to consider any other claim than Claim 2 of each request. Nor is it necessary to consider any corresponding set of claims for the Contracting State AT.
3. Claim 2 of each request differs from Claim 2 as granted. In case of amendments of the claims of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (see G 9/91, OJ EPO 1993, 408, point 19 of the Reasons).

Main request

4. *Rule 57a EPC*

The incorporation of the expression "as a pharmaceutical product" in Claim 2 as granted (see point IX above) is designed to overcome a ground of opposition, namely absence of novelty, raised by the Opponents. Therefore, that amendment can be admitted under Rule 57a EPC.

5. *Article 123(2) EPC*

In view of the submissions of the Appellant concerning the amendment "as a pharmaceutical product", the Board is satisfied that the subject matter of Claim 2 does not extend beyond the application as filed (see description as filed on page 1, lines 3 to 4 and lines 13 to 14; page 2, line 22 to page 3, line 7 and page 14, lines 20 to 23).

6. *Article 123(3) EPC*

The Board concurs with the Appellant that the subject matter of Claim 2 i.e. the morphological variant form "B" of famotidine "as a pharmaceutical product" is directed to that compound as such. Consequently, the feature "as a pharmaceutical product" incorporated in Claim 2 does not extend the protection conferred. The requirement of Article 123(3) EPC is met.

7. *Article 84 EPC*

7.1 Article 84 EPC in combination with Rule 29(1) EPC stipulates the requirements that the claims shall be clear and define the matter for which protection is

sought in terms of technical features of the invention. Those requirements serve two purposes (see T 728/98 dated 12 May 2000, intended for publication in OJ EPO, in particular point 3.1 of the reasons):

- ensuring that the public is not left in any doubt as to which subject-matter is covered by a particular claim and which is not;
- delimiting the subject-matter claimed from the prior art in order not to give rise to uncertainty regarding the technical contribution to the art it provides.

7.2 In the present case, Claim 2 according to the main request is directed to a particular crystalline form of famotidine "as a pharmaceutical product". The Appellant argued that the expression "as a pharmaceutical product" related to a pharmaceutical standard of purity. However, for the specific case of famotidine, the Appellant has submitted nothing relevant in support of any generally accepted quantitative definition for the purported standard of purity. Thus, the feature "as a pharmaceutical product" cannot be accorded any quantitative definition let alone one having general validity. Nor can this expression be considered as a commonly accepted functional feature as submitted by the Appellant. Even if one accepted for the sake of argument that the expression "as a pharmaceutical product" is a functional feature, it would still be the case that a functional feature must be clear in the sense that the person skilled in the art with his common general knowledge in reading the claim must be able to derive a clear definition of what is intended to be claimed. This is not the situation here.

7.3 Moreover, purity standards are likely to change with time for a number of reasons (e.g. new manufacturing process, new or improved analytical tools, change of criteria for obtaining a marketing authorization). It remains obscure what is considered to be the required product quality. For this reason, the feature "as a pharmaceutical product" is not clear either.

7.4 As Claim 2 of this request is not in conformity with Article 84 EPC and a decision can only be taken on a request as a whole, none of the further claims of that request need be examined. Consequently, the appeal insofar as it relates to the Appellant's main request must be dismissed,.

First auxiliary request

8. *Article 123(2) EPC*

8.1 Article 123(2) EPC requires that a European patent application (or a European patent) may not be amended in such a way that it contains subject-matter extending beyond the content of the application as filed. The term "content of the application" relates to the parts of a European patent application which determine the disclosure of the invention, in particular the description and claims.

8.2 The Board is not satisfied that the amendment made to Claim 2 relating to the production of the oversaturated solution "by liberating the free base of famotidine from its salt by addition of the salt into ammonium hydroxide" (see point XI above) is supported by the application as filed. From the parts of the description relied upon by the Appellant i.e. page 4, lines 23 to 27; page 6, lines 12 to 14 and page 18, Example No. II/4, it can only be inferred from the disclosure that the free base of famotidine can be liberated from

salts of famotidine with **carboxylic acids** by addition of this salt into ammonium hydroxide. A generalisation to **any salts** of famotidine extends, therefore, the subject-matter of Claim 2 beyond the content of the application as filed.

- 8.3 As Claim 2 of this request is not in conformity with Article 123(2) EPC, the Appellant's first auxiliary request must also be dismissed.

Second auxiliary request

9. *Scope of the Appeal*

- 9.1 Claims 1, 3 to 8 of this request for the Contracting States other than AT and Claims 1 to 5 of this request for the Contracting State AT correspond respectively to Claims 1 to 7 for the Contracting states other than AT and Claims 1 to 5 for the Contracting State AT of the request as maintained by the Opposition Division. According to the principle of prohibiting *reformatio in peius*, the Board is not empowered to decide on this matter (G 9/92, OJ EPO 1994, 875, point 1 of the Order), since no appeal was filed by the only Respondent (Opponent 1).

- 9.2 However, contrary to the view expressed by the Appellant, it is the Board's power and duty pursuant to Article 111(1) and 102(3) EPC to decide for itself upon each matter and each issue with regard to requests not allowed by the Opposition Division or any other requests filed in appeal and the Board is not bound by any finding of the decision under appeal (see T 401/95 dated 28 January 1999, not published in OJ EPO, in particular point 2 of the reasons and T 303/94 dated 16

September 1999, not published in OJ EPO, in particular point 2 of the reasons). In particular, the Board is empowered to examine the novelty of Claim 2 in view of document (3), even though the Opposition Division has reached a positive conclusion in that respect.

10. *Article 123(2) and (3) EPC*

The Board is satisfied that Claim 2 of the request for the Contracting State other than AT has not been amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. In particular, the amendment related to the production of a solution of famotidine oversaturated at a temperature lower than 40°C by dissolving famotidine **as an acetic salt** and liberating the free base of famotidine from its salt by addition of the salt into ammonium hydroxide is supported by the application as filed on page 4, lines 23 to 27; page 6, lines 12 to 14 and page 18, Example No. II/4. This amendment does not extend the protection conferred either.

11. *Article 84 EPC*

The Board is satisfied that Claim 2 of the request for the Contracting state other than AT meets the requirements of Article 84 EPC. According to the well established jurisprudence of the Boards of Appeal, a claimed product may be defined by a process for manufacture. Furthermore, the definition of the process is clear.

12. *Article 54(1) and (2) EPC*

12.1 Claim 2 at issue relates to a product defined partly in terms of physical parameters, and partly in terms of its process of manufacture (product-by-process claim).

Thus, despite the fact that this product is characterized in part by the process for its preparation, the claim nevertheless belongs to the category of claim directed to a physical entity, i.e. a product. The sole question to be decided is whether or not the product as defined in Claim 2 is anticipated by the disclosure of document (3), in particular that in its Example No. 4.

12.2 Document (3) relates to the preparation of famotidine, a medicament useful as histamine H-2 receptor blocker or gastric acid secretion inhibitor (see page 2, lines 10-19). Reference Example No. 4 discloses the following method to prepare famotidine:

- (a) condensation of sulfamide and methyl 3-[[[2-[(diaminomethylene)amino]-4-thiazolyl]-methyl]thio]propionimidate.

After reaction "the crystals formed are collected by filtration, washed with 200 l of cooled methanol, and air-dried at room temperature to provide 87.5 kg of the desired product showing a melting point of 157.6°C";

- (b) some of the obtained product is recrystallized from dimethylformamide-water, and
- (c) is dissolved in an equivalent molar amount of aqueous acetic acid. To the solution is added an equivalent molar amount of dilute sodium hydroxide solution in water to separate crystals showing a melting point of 163-164°C.

- 12.3 It is the well established jurisprudence of the Boards of Appeal that a chemical substance described in a cited document by indication of the starting compound and the process specified therewith belongs to the state of the art (see T 12/81, OJ EPO 1982, 296, point 13 of the reasons and T 181/82, OJ EPO 1984, 401, point 7 of the reasons).
- 12.4 The Appellant first argued that the person skilled in the art would not have paid attention to the product obtained at step (a) which he chose to call "intermediate product" and would have carried on the process until the product obtained at step (c) which he chose to call "end-product". However, such an argument fails to recognize that the purpose of Article 54(1) EPC is to prevent the state of the art being patented. Article 54(2) EPC defines the state of the art as comprising everything made available to the public before the date of filing in any way. As confirmed by the decision G 1/92 (OJ EPO 1993, 277, in particular point 2.1 of the reasons), any element of subjectivity must be excluded in applying the concept of novelty as defined in Article 54(1) and (2) EPC.
- 12.5 In that context, the Board notes that the product obtained at the end of the step (a) was isolated under the form of crystals and characterised as "the desired product", i.e. famotidine. This product was, therefore, available to the public within the meaning of Article 54(2) EPC.
- 12.6 As evidence, step (a) of Example 4 was reproduced independently by three experts, the reports of which were submitted in the course of the opposition proceedings:

- Prof. Marko, an expert of the Proprietor of the patent in suit, reproduced said example (see document (5) to point VIII above) and obtained a famotidine containing 98.3% form "B", no measurable amount of form "A", with a melting point of 161°C (see page 8 of the experimental report). Prof. Marko comments as follows:

"The raw famotidine obtained by following the preparative procedure described in *Example 4* was found to be mostly form "B" though of course the products needs substantial further purification" (see page 10, "conclusions").

- Prof. Ishii, an expert of the Opponent 1, reproduced said example (see document (7) - point II above) and obtained a famotidine containing 97.32% form "B", no measurable amount of form "A" (pure form "B" crystals), with a melting point of 158-160°C (see page 6 of the report and page 3 of the addendum).
- Prof. Burger, an expert of the Opponent 2, reproduced said example (see document (8) - point II above) and obtained a famotidine form "B", no measurable amount of form "A" (pure form "B" crystals). This product was three times analysed on its purity to give respectively 96.8%, 97.6%, 96.1% of famotidine form "B" (see pages 29, 33 and 34 of the report).

12.7 The fairness and accuracy of the experimental results of the three reports were not contested by the Appellant. He disputed, nevertheless, that form "B" of famotidine was the "inevitable result" of the method disclosed in *Example 4*, step a) because, so he argued, the experimental details given were incomplete and Dr. Harsanyi's report (document (6) - point XII above)

showed that form "A" could just as well be obtained. However, contrary to the evidence represented by the reports of Pr. Marko, Pr. Ishii and Pr. Burger, the Board's conclusion is that the experiment reported by Dr. Harsanyi cannot be considered as a reproduction of Example 4, step (a) given that Dr. Harsanyi did not reproduce the conditions leading to a crystal product as disclosed but used instead some pure famotidine "B" as starting product. This difference was not contested by the Appellant. The Board thus comes to the conclusion that (i), the Appellant has not brought any relevant evidence that in following the method disclosed in Example 4, step (a), the claimed product, i.e. famotidine form "B", was not inevitably obtained and (ii) the reports of Pr. Marko, Pr. Ishii and Pr. Burger do show independently with a noteworthy convergence of results, that a product with a content of pure famotidine form "B" (without form "A") of 96.1 to 98.3% was obtained. Consequently, crystals containing 96.1 to 98.3% of morphologically pure form of famotidine are inevitably obtained when the method indicated in step a) of Example No. 4 of document (3) is followed. The variation in the yields is sufficiently narrow to be regarded as usual (Pr. Burger analysed the obtained product three times and found that the content of famotidine "B" varied from 96.1% to 97.6%).

- 12.8 The Appellant also argued that the claimed product was novel in view of the product obtained in Example 4, step (a) due to the differences in the physical parameters values. The values given in Claim 2 defined a product the purity of which rendered it suitable as a pharmaceutical product as opposed to the crude product obtained in Example 4, step (a).

Those values relate to three different categories of physical measures, namely melting point, absorption bands of the infrared spectrum and DSC.

- The melting point of the claimed famotidine is 159-162°C, while the melting point of the product given at Example 4, step a) is 157.6°C. However, Pr. Marko found 161°C (see page 8 of the report) and Pr. Ishii found a melting-point range from 158-160°C (see page 6 of the report). In the Board's judgment, this situation is comparable to error margins when the accuracy of a measurement is to be assessed. Furthermore, notwithstanding the question to know whether the purity of a product is an essential feature of it, the Board cannot see here an unequivocal relationship between the alleged purity of the claimed product and the melting point. Referring to the various experiments reported by Prof. Marko in document (5), it appears that products containing 99.7%, 99.6%, 98.3% and 98.2% form "B" correspond respectively to melting points of 163-164°C, 162°C, 161°C and 162°C (see pages 5, 8 and 10 of the report). The range of 159-162°C mentioned in Claim 2 cannot be attributed to a defined purity differing from the purity of the product of Example 4, step (a). Moreover, these uncontested experimental results show that melting points outside the range mentioned in the claim in no way disqualify the corresponding products as famotidine "B". This shows that any indication of the melting point is an unreliable parameter for characterising the product. Consequently, differences in melting points do not indicate in the present case that the products are different.

- Nor can the characteristic absorption bands of the infrared spectrum at 3506, 3103 and 777 cm^{-1} define a new product, for those bands are present in the infrared spectrum of the product obtained according to Example 4, step a). Pr. Marko provided a transparency of the infrared spectrum between 3000 and 3540 cm^{-1} of pure form "B" (see fig. b of the report) to be placed upon the spectra of the samples and the Board notes that there is absolute concordance between this spectrum and the spectrum of the product obtained according to Example No. 4, step (a) of document (3) as provided by Pr. Marko (see Figure 20b of the report). Furthermore, the spectra of the product obtained according to Example No. 4, step a) provided by Pr. Burger (see page 27 of the report) and Pr. Ishii (see Chart B) confirm that the characteristic absorption bands 3506, 3103 and 777 cm^{-1} , i.e. the only ones indicated in the claim, are present.

- Regarding the endotherma maximum of melting at a heating rate of 1°C/min of 159°C on the DSC, one cannot directly compare this value with any of the values obtained by the reports of Prs. Marko and Ishii because the reported heating rates were respectively of 5°C/min and 10°C/min. However, it appears that the charts enclosed with those reports each contain a single peak which is said to be famotidine form "B". In the Board's judgment, the difference in the temperature of the endotherma maximum is only due to the difference in the conditions of measurements and cannot therefore qualify as support for another product. The three reports confirm that only a crystal form designated as "B" is obtained. It is only the way of making the measure which can explain the

variations. From his own results, Prof. Marko had noted that the two endothermic maxima of respectively pure forms "A" and "B" measured by him differed each of 7-8°C (see pages 3 and 4, bridging paragraph) from the values mentioned in the patent in suit. He had concluded from this that the variations of values obtained by DSC was caused partly by the different instruments and partly by the different heating rates.

- 12.9 Finally, the Board observes that the product obtained according to Example No. 4, step a) possesses a morphologically homogeneous crystal form as shown by DSC (see previous point 12.8, last paragraph) and reveals a needle-like structure as reported by Pr. Ishii (see page 3 of the addendum to document (7) and photography A).
- 12.10 Consequently, the product disclosed in document (3) is the same as that claimed. This conclusion cannot be altered by the indication of its process of preparation even if this process is new.
- 12.11 As Claim 2 of this request is not in conformity with Article 54(1) and (2) EPC, the Appellant's second auxiliary request must also be dismissed,

13. *Jurisdiction of the Board of Appeal*

- 13.1 Since no appeal has been filed by Opponent 1, who meanwhile has withdrawn his opposition (see point VI above), no one may, on the principle of prohibition of "reformatio in peius", challenge the patent maintained as amended by the first instance.

13.2 On the contrary, the Board was fully entitled to examine if the main and auxiliary requests filed by the Appellant during the appeal proceedings met the requirements of the EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:



N. Maslin

The Chairman:



A. Nuss

