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**Datasheet for the decision
of 15 December 2010**

Case Number: T 1723/07 - 3.3.02

Application Number: 00304912.9

Publication Number: 1059084

IPC: A61K 31/19

Language of the proceedings: EN

Title of invention:

Rapidly absorbed liquid compositions containing an amine and a NSAID

Applicant:

McNeil-PPC, Inc.

Opponent:

-

Headword:

Rapidly absorbed amine and NSAID/MCNEILL

Relevant legal provisions:

EPC Art. 54, 56, 111

Relevant legal provisions (EPC 1973):

-

Keyword:

"Remittal (yes): evidence provided that main document was published after priority date"

Decisions cited:

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Catchword:

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Case Number: T 1723/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 15 December 2010

Appellant: McNeil-PPC, Inc.
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Skillman
New Jersey 08558 (US)

Representative: Mercer, Christopher Paul
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One Southampton Row
London WC1B 5HA (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 May 2007
refusing European application No. 00304912.9
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J.-P. Seitz

Summary of Facts and Submissions

- I. European patent application No. 00 304 912.9, published as EP 1 059 084, was refused by a decision of the examining division in accordance with Article 97(1) EPC 1973, basically for lack of novelty under Article 54 EPC but also, at least with respect to some of the auxiliary requests, for lack of inventive step under Article 56 EPC.

The wording of claim 1 of the main request before the examining division was:

"A stable liquid composition comprising a pharmacologically effective amount of a pharmaceutically acceptable amine and a pharmacologically effective amount of a NSAID, wherein the composition provides an enhanced absorption rate of the amine into the blood of a human compared with a corresponding composition comprising the amine but not the NSAID."

- II. The documents cited during the proceedings before the examining division and the board of appeal included the following:

- (6) Database Chemabs [online] chemical abstracts service, Columbus, Ohio, USA; Wen, H. et al., "Preparation of suspension of ibuprofen and pseudoephedrine hydrochloride and its quality control"; Zhongguo Yiyuan Yaoxue Zazhi, vol. 19, no. 10, 1999, 584-587

(6a) English translation of the article Wen, H. et al., "Preparation and quality control of ibuprofen-pseudoephedrine hydrochloride suspension"; Zhongguo Yiyuan Yaoxue Zazhi (Chinese Journal of Hospital Pharmacy), vol. 19, no. 10, 1999, 584-587

(6b) Table of contents of the "Chinese Journal of Hospital Pharmacy", vol. 19, no. 10, October 1999, including the title Wen, H. et al., "The preparation and study on quality of suspension of ibuprofen and pseudoephedrine hydrochloride"; Zhongguo Yiyuan Yaoxue Zazhi, vol. 19, no. 10, 1999, 584-587

III. The examining division held the subject-matter of the application to be not new with respect to document (6), since this document disclosed all the claimed features explicitly and implicitly. In addition, it indicated that some of the features contained in some of the requests contravened Articles 83 and 84 EPC.

IV. The applicant (appellant) lodged an appeal against the decision of the examining division and filed grounds of appeal together with three sets of claims as main and auxiliary requests.

V. In a communication dated 5 July 2010, the board attached document (6a), the English translation of the article abstracted in document (6).

VI. With its letter of 2 November 2010, the appellant filed four new sets of claims as a main request and auxiliary requests 1 to 3, replacing all previously filed requests. In addition, evidence in the form of

document (6b) was provided, in order to demonstrate that documents (6) and (6a) were published after the priority date.

VII. The wording of claim 1 of the main request is:

"A composition for providing enhanced absorption of a pharmaceutically acceptable amine into the blood of a human, comprising a pharmacologically effective amount of a pharmaceutically acceptable amine and a pharmacologically effective amount of a non-steroidal anti-inflammatory drug (NSAID), wherein said amine and NSAID are provided in a stable liquid form, wherein the stable liquid form is a suspension, and wherein the liquid medium is water."

Claim 1 of auxiliary request 1 contains particular substances for the amine component and reads (added text in bold):

"A composition for providing enhanced absorption of a pharmaceutically acceptable amine into the blood of a human, comprising a pharmacologically effective amount of a pharmaceutically acceptable amine and a pharmacologically effective amount of a non-steroidal anti-inflammatory drug (NSAID), **wherein the pharmaceutically acceptable amine is selected from pseudoephedrine, phenylpropanolamine, dextromethorphan, chlorpheniramine, diphenhydramine, loratadine, fexofenadine, citirazine, famotidine, ranitidine, cimetidine and their pharmaceutically acceptable salts;** **and** wherein said amine and NSAID are provided in a stable liquid form, wherein the stable liquid form is a suspension, and wherein the liquid medium is water."

Claim 1 of auxiliary request 2 is restricted to pseudoephedrine for the amine component and to ibuprofen as NSAID.

Claim 1 of auxiliary request 3 contains indications regarding the state of the active substances in the suspension; it reads (amendments with respect to auxiliary request 2 in bold):

"A composition for providing enhanced absorption of a pharmaceutically acceptable amine into the blood of a human, comprising a pharmacologically effective amount of a pharmaceutically acceptable amine and a pharmacologically effective amount of a non-steroidal anti-inflammatory drug (NSAID), wherein the NSAID is ibuprofen and the pharmaceutically acceptable amine is pseudoephedrine; and wherein said amine and NSAID are provided in a stable liquid form, wherein the stable liquid form is a suspension, wherein the liquid medium is water, **and wherein the NSAID is suspended in the liquid medium and the amine is substantially dissolved in the liquid medium.**"

In a further communication dated 26 November 2010, the board indicated that, taking into consideration the evidence the appellant had provided, it intended to remit the case to the first instance for further prosecution. If the appellant was ready to withdraw its request for oral proceedings, those proceedings could be cancelled.

VIII. With facsimile of 29 November 2010 the appellant withdrew its request for oral proceedings on the understanding that the case would be remitted back to the first instance for further prosecution.

The oral proceedings were cancelled by fax the same day.

IX. In conclusion from its fax of 29 November 2010, the appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the sets of claims of the main request or alternatively of auxiliary requests 1, 2 or 3 filed with letter of 2 November 2010.

Reasons for the Decision

1. The appeal is admissible.
2. The main request and auxiliary requests 1 to 3 no longer contain any subject-matter that was objected to by the examining division under Articles 83 and 84 EPC.
3. From the evidence filed, the Chinese original of document (6a) was published in October 1999, which is in conformity with the data in document (6), indicating volume 19, no. 10 of the journal as source, the journal being issued monthly (12 issues per year, as shown by its internet archive).

Even the receiving date of the manuscript, i.e. 21 June 1998, (see document (6a), end of translation) does not support the assumption that the article was

available to the public before the priority date of the application in suit, i.e. 10 June 1999.

4. Comparison of the application as originally filed to the contents of the priority document confirmed that the priority is valid.
5. Thus, the objections of the examining division under Articles 54 and 56 EPC are no longer valid with respect to the requests on file.
6. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is recognised that any party may be given an opportunity for two readings of the important elements of a case.

In the present case, the subject-matter of the application in suit is now found to be not anticipated by documents (6) and (6a). Thus, a new situation has been created with respect to the new claims, which should now be examined on their merits.

The board has therefore decided to exercise its discretion under Article 111 EPC, and remits the case to the first instance for further prosecution in all formal and substantive aspects of the EPC.

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 for further prosecution on the basis of the main or auxiliary requests filed with letter dated 2 November 2010.

The Registrar:

The Chairman:

M. Schalow

U. Oswald