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**Datasheet for the decision
of 11 November 2008**

Case Number: W 0040/07 - 3.3.02

Application Number: PCT/IN 2006/000291

Publication Number: WO 2007/052289

IPC: A61K 9/20

Language of the proceedings: EN

Title of invention:
Novel dispersible tablet composition

Applicant:
Rubicon Research PVT Ltd.

Headword:
Dispersible tablet composition/RUBICON RESEARCH PVT LTD.

Relevant legal provisions:
PCT Art. 17(3)(a)
PCT R. 13, 40.1, 40.2

Relevant legal provisions (EPC 1973):
EPC Art. 154(3)

Keyword:
"Groups of inventions 2 and 3 completely covered by group of inventions 1; No justification for two additional search fees"

Decisions cited:
W 0018/06, W 0020/06, W 0022/06, W 0001/07, W 0006/07

Catchword:
-



Case Number: W 0040/07 - 3.3.02

International Application No. PCT/IN 2006/000291

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 November 2008

Applicant: Rubicon Research PVT Ltd.
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Representative: Majumdar, Subhatosh et al.
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Decision under appeal: Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicant against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 28 June 2007.

Composition of the Board:

Chairman: H. Kellner
Members: A. Lindner
T. Bokor

Summary of Facts and Submissions

I. The applicant filed an international patent application PCT/IN 2006/000291 comprising a set of 18 claims. The independent claims read as follows:

"1. A novel dispersible tablet comprising
(i) at least one pharmacologically active ingredient
and
(ii) at least one excipient, which reduces the
sedimentation rate of the pharmacologically
active ingredient.

16. A novel dispersible tablet composition comprising:
(i) at least one pharmacologically active ingredient
(ii) at least one hydrophilic polymer, and
(iii) at least one disintegrant.

17. A novel oxcarbazepine dispersible tablet
composition comprising:
(i) oxcarbazepine
(ii) hydroxyethyl cellulose, and
(iii) a combination of cross linked polyvinyl
pyrrolidone and calcium silicate.

18. A process of preparation of the pharmaceutical
composition as claimed in claim 1."

II. In its communication dated 28 June 2007, the European Patent Office, acting as an International Searching Authority (ISA), invited the applicant pursuant to Article 17(3)(a) and Rule 40.1 PCT to pay two additional search fees.

III. The following document was cited by the ISA:

(1) US 2002/022056

IV. The following groups of inventions were identified by the ISA:

Group 1: claims 1-15, 18

A dispersible tablet composition comprising an active ingredient, at least one excipient and its preparation process.

Group 2: claim 16

A dispersible tablet composition comprising an active ingredient, at least one hydrophilic polymer and at least one disintegrant.

Group 3: claim 17

A dispersible tablet composition comprising oxcarbazepine, hydroxyethyl cellulose and a combination of cross polyvinyl pyrrolidone and calcium silicate.

The ISA defined "a dispersible tablet composition comprising an active ingredient and at least one excipient" as the technical feature common to all three groups of inventions and concluded that this feature was not novel over document (1) so that it could not serve as a special technical feature. As a consequence, there was no single general inventive concept.

V. In support of the protest, the appellant argued that all three groups of inventions related to a "dispersible tablet composition comprising an active

ingredient and at least one excipient". The subject-matter of claim 16 (group of inventions 2) was a preferred embodiment of the subject-matter according to the group of inventions 1, while the even more specific subject-matter of claim 17 (group of inventions 3) was generally covered by the subject-matter of claim 1 and of claim 16.

Moreover, the appellant held that the tablets disclosed in document (1), which were characterised by a tablet core and a hydrophilic permeable film coating, were different from dispersible tablets as claimed in the present application. As a consequence, the subject-matter of the groups of inventions defined above resided within the same inventive concept.

VI. In the review pursuant to Rule 40.2(c) PCT dated 9 November 2007, the review panel of the ISA came to the conclusion that the invitation to pay additional fees was justified and that, as a consequence, the two additional search fees were not to be refunded. The review panel reasoned that document (1) disclosed dispersible tablet compositions comprising an active ingredient (oxcarbazepine) and at least one excipient that reduced the sedimentation rate of the active ingredient, such as hydroxypropyl methyl cellulose. As a consequence, the technical feature common to all three groups of inventions did not represent a special technical feature so that there was no single general inventive concept and consequently unity of invention was lacking.

VII. With the letter of 4 December 2007, the applicant paid the protest fee in accordance with Rule 40.2(e) PCT.

Reasons for the Decision

1. Given that the international application under consideration has an international filing date of 24 July 2006, the protest is subject to the provisions of the PCT in force as from 1 April 2006, including amended Rule 40 PCT.
 - 1.1 Pursuant to Article 1(6) of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000, Articles 154(3) and 155(3) EPC 1973 shall continue to apply to PCT applications pending at the time of entry into force of the EPC 2000. Accordingly, the boards of appeal shall continue to be responsible for deciding on protests made against the charging of an additional fee under Article 17, paragraph 3(a) or Article 34, paragraph 3(a) PCT. The protest procedure is governed by Rules 40 and 68 PCT. This implies that the review body specified in Rule 40.2(c) PCT, second sentence is a board of appeal of the EPO.
 - 1.2 Details of the procedure are guided by the Decision of the President of the EPO dated 24 June 2007, Article 3 (Special edition No. 3 OJ EPO, 140 to 141), and the Notice of the EPO dated 24 June 2007, points 6 to 9 (Special edition No. 3 OJ EPO, 142 to 145). This effectively maintains for PCT applications already pending at the time of entry into force of EPC 2000 the two-stage protest procedure as laid out in the Decision of the President of the EPO dated 25 August 1992

providing for review panels for the implementation of the protest procedure under the PCT (OJ EPO 1992, 547) and the Notice from the EPO dated 1 March 2005 concerning the protest procedure under the PCT (OJ EPO 2005, 226), this latter replacing the Notice from the EPO dated 26 August 1992 concerning the protest procedure under the PCT (OJ EPO 1992, 547).

1.3 The application of a two-stage protest procedure even after 1 April 2005, when Rule 40 PCT did no longer require it, has also been approved by several decisions of the boards of appeal (see in particular W 20/06 of 3 April 2007, points 2 to 9 of the reasons, W 22/06 of 15 March 2007, point 2 of the reasons, W 1/07 of 26 June 2007, point 1.6 to 1.6.4 of the reasons, W 0006/07 of 17 July 2007, points 1.2 and 1.3 of the reasons). Given that the previous procedure, and by implication, the previous general legal framework continues to apply (see points 1.1 and 1.2 above), the entry into force of the EPC 2000 does not affect the *ratio decidendi* of these decisions. Thus the present board sees no reason to question its own competence.

1.4 As far as the payment of the fees is concerned, the applicant was invited by the communication of 9 November 2007 ("Form PCT/ISA/228 (April 2005)") to pay the protest fee within one month. The payment was made by a cheque submitted on 4 December 2007. Again, the board follows the arguments and conclusions of the established jurisprudence (see in particular W 18/06 of 5 March 2007, points 2 to 18 of the reasons, W 20/06 (*supra*), points 10 to 20 of the reasons, W 1/07 (*supra*), points 1.6.5 to 1.6.15 of the reasons, W 6/07 (*supra*), points 1.3.2 and 1.4 of the reasons), as the *ratio*

decidendi underlying the finding that the protest fee, though perhaps formally paid late, nevertheless was paid effectively in time, is not affected by the entry into force of the EPC 2000. Thus, also in the present case the payment was made in time, and the protest is considered to have been made (Rule 40.2(e) PCT, second sentence).

2. Moreover, the protest complies with the requirements of Rule 40.2(c) PCT and is therefore admissible.
3. The relevant general requirements for protest proceedings are as follows:
 - 3.1 Pursuant to Rule 40.2 PCT, the protest has to be examined and, to the extent that it is found to be justified, the full or partial reimbursement to the applicant of additional fees, as far as they were paid in fact and under protest, has to be ordered.
 - 3.2 According to the established practice of the boards of appeal, the examination in protest proceedings has to be carried out in the light of the reasons given by the ISA in its invitation to pay additional fees under Rule 40.1 PCT and the applicant's submissions in support of the protest.
4. In the present case, the ISA's invitation to pay additional fees is based on the finding that the present application lacks a single general inventive concept. It therefore remains for the board to examine whether the reasons given in accordance with Rule 40.1 PCT justify the demand for two additional fees.

4.1 Claim 1 is directed to a dispersible tablet comprising at least one pharmacologically active ingredient and at least one excipient, which reduces the sedimentation rate of the pharmacologically active agent.

According to page 8, line 1, of the application as published, hydrophilic polymers are preferred excipients for reducing the sedimentation rate and hydroxyethyl cellulose is among the preferred hydrophilic polymers (see page 8, lines 21-24, of the application as published). It is additionally noted that in the present case, the subject-matter of claim 1 also includes dispersible tablet compositions (see dependent claims 2-15).

As a consequence, the subject-matter of claim 16 (group of inventions 2), which relates to a dispersible tablet composition comprising at least one pharmacologically active ingredient, at least one hydrophilic polymer and at least one disintegrant, is completely included in the subject-matter of claim 1. Although formally drafted as an independent claim, claim 16 is in fact a dependent claim, as it belongs to the same category of claims as, and comprises all the features of, claim 1.

4.2 Likewise, the subject-matter of claim 17 (group of inventions 3), which concerns a dispersible tablet composition comprising oxcarbazepine, hydroxyethyl cellulose and a combination of cross linked polyvinyl pyrrolidone and calcium silicate, is a particular embodiment of the subject-matter according to claim 16 and, therefore, is in fact dependent on claim 16 and on claim 1.

4.3 In view of the fact that the groups of inventions 2 and 3 are completely covered by the group of inventions 1, these three groups of inventions do not define separate alternative inventions. As a consequence, the request for two additional search fees is not justified.

Order

For these reasons it is decided that:

Reimbursement of the additional search fees paid for two groups of inventions and of the protest fee is ordered.

The Registrar:

The Chairman:

C. Eickhoff

H. Kellner