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Datasheet for the decision of 4 December 2008

Case Number: W 0010/08 - 3.3.02

Application Number: PCT/IN 2006/000309

Publication Number: WO 2007/052299

IPC: A61K 9/20

Language of the proceedings: EN

Title of invention:
Controlled Release Formulation

Applicant:
Rubicon Research PVT Ltd.

Opponent:
-

Headword:
Controlled release formulation/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 0018/07, W 0020/07, W 0040/07

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: W 0010/08 - 3.3.02

International Application No. PCT/IN 2006/000309

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 4 December 2008

Applicant: Rubicon Research PVT Ltd.
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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 2 July 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 2006/000309 comprising a set of 34 claims. The independent claims read as follows:

"1. An oral controlled release dosage form comprising:
a. therapeutically effective amount of active substance having high water solubility,
b. at least one non-polymeric release retardant, and
c. at least one pH independent non-swelling release retardant,
wherein the said dosage form provides controlled release of the active agent with reduced initial burst release.

33. A novel controlled -release oral dosage form comprising,
a. therapeutically effective amount of active ingredient having high solubility,
b. glyceryl behenate, and
c. mixture of polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w)
wherein the said dosage form provides controlled release of the active agent with reduced initial burst release.

34. A novel sustained-release oral dosage form comprising,
a. therapeutically effective amount of vitamin C
b. glyceryl behenate, and
c. mixture of polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w)

Wherein the said dosage form provides controlled release of the active agent with reduced initial burst release."

II. In its communication dated 2 July 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 2001/038852 A1

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

Group 1: claims 1-32

An oral controlled release dosage form comprising an active substance of high water solubility, at least one non-polymeric release retardant and at least on pH independent non-swelling release retardant.

Group 2: claim 33

An oral controlled release dosage form comprising an active substance of high water solubility, glyceryl behenate and a mixture of polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w).

Group 3: claim 34

An oral controlled release dosage form comprising vitamin C, glyceryl behenate and a mixture of

polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w).

The ISA defined "an oral controlled release dosage form comprising an active substance of high water solubility, at least one non-polymeric release retardant and at least on pH independent non-swelling release retardant" 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. The appellant paid two additional search fees under protest and in support of the protest, he argued that all three groups of inventions were related to oral controlled release dosage forms. The subject-matter of claim 33 constituted a limitation of the broad definition of the invention as claimed in claim 1, while the subject-matter of claim 34 provided a further specific limitation of claim 33. As a consequence, the claims of all three groups resided in the same inventive concept.

Moreover, the appellant contested that the technical feature common to all three groups of inventions was anticipated by document (1).

VI. In the review pursuant to Rule 40.2(c) PCT dated 21 January 2008, 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 the

use of an oral controlled release composition comprising an active substance (such as propranolol HCl), at least one non-polymeric release retardant (such as stearyl alcohol) and at least one pH independent non-swelling release retardant (mixture of polyvinyl acetate and polyvinylpyrrolidone). Thus, the common technical feature between the groups of invention was already known. As a consequence, the three groups of inventions were not linked by a single general inventive concept and consequently unity of invention was lacking.

Reasons for the Decision

1. The application in suit was filed on 24 August 2006. Therefore, the protest is subject to the provisions of the PCT as in force from 1 April 2006. The Boards of Appeal are responsible for deciding on protests relating to PCT applications pending at the time of entry into force of the EPC 2000 (13 December 2007). Details of the procedure are guided by the Decision of the President of the EPO dated 24 June 2007, Article 3 (OJ EPO 2007, Special edition No. 3, 140-141). Reference is also made to decisions W 18/07, W 20/07 and W 40/07 (see points 1.1-1.3 of the reasons in decision W 40/07).

2. As far as the payment of the fees is concerned, the applicant duly paid the prescribed additional search fees (see point II above). The protest fee was paid later, following a communication of the ISA of 21 January 2008 ("Form PCT/ISA/228 (April 2005)"). The communication erroneously indicated 750 Euro to be paid

instead of 1.065 Euro, the 750 Euro, however, were paid in time. Later, the ISA issued further invitations to the applicant, in order to correct the error. By forwarding another amount of 290 Euro and, in August 2008, the rest of 25 Euro, the applicant finally paid the entire amount of the protest fee valid until 31 March 2008. In view of this fact and given the fact that the Office acting as ISA was responsible for the erroneous indication of the fee amount, and under the provisions of the principle of good faith, there is no reason to charge the increased amount of the protest fee valid from 1 April 2008 (1.120 Euro).

In spite of the fact that the remaining amount of the protest fee as set out in the latest invitation for full payment was paid after the time limit set in this invitation, pursuant to Article 8(1) RRF, last sentence, the payment is considered to have been made in time, since the difference to be paid was well below 10% of the total amount of the protest fee.

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).

3. Moreover, the protest complies with the requirements of Rule 40.2(c) PCT and is therefore admissible.

4. The relevant general requirements for protest proceedings are as follows:

4.1. 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.

4.2. 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.

5. 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.

5.1. Claim 1 is directed to an oral controlled release dosage form comprising a therapeutically effective amount of active substance having high water solubility, at least one non-polymeric release retardant and at least one pH independent non-swelling release retardant, wherein the said dosage form provides controlled release of the active agent with reduced initial burst release.

According to page 10, line 17, of the application as published, glyceryl behenate is a specific embodiment of a non-polymeric release retardant, while the passage on page 11, lines 10-15 reveals that Kollidon SR (mixture of polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w)) is the most preferred pH independent non-swelling release retardant.

As a consequence, the subject-matter of claim 33 (group of inventions 2), which relates to a controlled release oral dosage form comprising a therapeutically effective amount of active ingredient having high solubility, glyceryl behenate, and a mixture of polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w) wherein the said dosage form provides controlled release of the active agent with reduced initial burst release, is completely included in the subject-matter of claim 1. Although formally drafted as an independent claim, claim 33 is in fact a dependent claim, as it belongs to the same category of claims as, and comprises all the features of, claim 1.

5.2. Likewise, the subject-matter of claim 34 (group of inventions 3), which concerns a sustained-release oral dosage form comprising a therapeutically effective amount of vitamin C, glyceryl behenate, and a mixture of polyvinyl acetate (8 parts w/w) and polyvinylpyrrolidone (2 parts w/w) is a particular embodiment of the subject-matter according to claim 33 and, therefore, is in fact dependent on claim 33 and on claim 1. In this context, it is noted that vitamin C is the most preferred active agent (see page 7, lines 21-22 of the application as published). Furthermore, it is emphasized that the terms "controlled release dosage form" (claims 1 and 33) and "sustained release dosage form" are synonymous (see e.g. present claim 31, which defines a **sustained** release oral dosage form and which is dependent on claim 30 relating to a **controlled** release oral dosage form) [emphasis added by the board].

5.3. 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