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Datasheet for the decision of 1 February 2008

Case Number: T 1217/04 - 3.3.02

Application Number: 00960455.4

Publication Number: 1202716

IPC: A61K 9/20

Language of the proceedings: EN

Title of invention:
Rapidly dissolving dosage form and process for making same

Applicant:
Novartis Consumer Health S.A.

Opponent:
-

Headword:
Rapidly dissolving dosage form/NOVARTIS

Relevant legal provisions:
EPC Art.

Relevant legal provisions (EPC 1973):
EPC Art. 111(1)

Keyword:
"Remittal to the first instance - shift of invention"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1217/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 1 February 2008

Appellant: Novartis Consumer Health S.A.
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Representative: de Weerd, Petrus G.W.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 18 May 2004 refusing European application No. 00960455.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 00 960 455.4, based on international patent application PCT/EP00/07934 and published as WO 01/12161, was refused by a decision of the examining division on the basis of Article 97(1) EPC 1973 for lack of novelty under Article 54 EPC 1973 with respect to claim 12 of the main request and lack of inventive step with respect to claim 12 of the auxiliary request under Article 56 EPC 1973.

The wording of claims 1 to 11 of the main request and independent claim 12 of the auxiliary request before the examining division was:

"1. A process for the manufacture of a solid dosage form which is rapidly dissolving in aqueous medium, which process comprises

(a) preparing a powder or granulate consisting of
(1) either the active substance - or part thereof - and all other ingredients of the solid dosage form; or
(2) all other ingredients of the solid dosage form except the active substance;

(b) dispensing
(1) either an auxiliary solvent or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(c) compacting a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate so obtained on the top of the liquid which according to (b)(1) or (b)(2) is in moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(e) removing the auxiliary solvent by applying a drying system to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid dosage form, respectively.

2. A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical or veterinary dosage form for oral administration, which process comprises
(a) preparing a powder or granulate consisting of
(1) either the intended dose of the active substance - or part thereof - and all other
ingredients of the solid dosage form; or
(2) all other ingredients of the solid dosage form except the active substance;
(a') transferring said powder or granulate to a combined compacting/dosing system;
(a") placing moulds or a pre-formed container intended for storage of the solid pharmaceutical or veterinary

dosage form within the operating range of the combined compacting/dosing system;
(b) dispensing,
(1) either an auxiliary solvent or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in moulds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;
(c) compacting - within the combined compacting/dosing system - a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;
(d) putting the, compacted powder or granulate on the top of the liquid which according to (b)(1) or (b)(2) is in moulds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;
(e) removing the auxiliary solvent by applying a drying system comprising one or more techniques selected from forced warm gas, microwave radiation and reduced pressure, to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and
(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form, respectively.

3. A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of the active substance and all other ingredients of the solid dosage form;
(a') transferring said powder or granulate to a combined compacting/dosing system;
(a") placing a pre-formed container intended for storage of the solid pharmaceutical dosage form within the operating range of the combined compacting/dosing system;
(b) dispensing an auxiliary solvent in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;
(c) compacting - within the combined compacting/dosing system - an amount of the powder or granulate prepared according to (a) above, which amount of powder or granulate contains the intended dose of the active substance;
(d) putting the compacted powder or granulate on the top of the liquid which according to (b) is in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;
(e) removing the auxiliary solvent by applying a drying system comprising at least two different techniques selected from forced warm gas, microwave radiation and reduced pressure; and
(f) sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form.

4. A process according to any one of claims 1-3, where in step (b) the auxiliary solvent is selected from the group consisting of water, ethanol, acetone, isopropanol, and any mixtures thereof.

5. A process according to any one of claims 1-4, where in step (c) the density of the compacted powder or granulate prepared is between 300 and 1000 mg/ml.

6. A process according to any one of claims 1-4, where in step (c) the density of the compacted powder or granulate is between 400 and 900 mg/ml.

7. A process according to any one of claims 1-6, where in step (c) the amount of powder or granulate which is subjected to compaction contains the intended dose of the active substance.

8. A process according to any one of claims 1-7, where in step (e) the auxiliary solvent is removed by applying simultaneously or interchangeably at least two different techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure.

9. A process according to any one of claims 1-7, where in step (e) the auxiliary solvent is removed by applying simultaneously a combination of forced warm gas and microwave radiation.

10. A process according to any one of claims 1-9, wherein a solid pharmaceutical or veterinary dosage form for oral administration is manufactured.

11. A process according to claim 10, wherein a solid pharmaceutical dosage form for oral administration which is in the form of a tablet is manufactured.

12. A solid dosage form for oral administration, comprising

(1) a pharmaceutically or veterinary active substance,

(2) a filler selected from the group consisting of mannitol, lactose, starch and microcrystalline cellulose, and

(3) a disintegration agent selected from the group consisting of croscarmellose Na, sodium glycolates of starches, and cross-linked poly-N-vinyl-2-pyrrolidones;

which dosage form disintegrates when taken into the mouth within 30 seconds, and which dosage form has a density of 400-900 mg/ml."

Claims 1 to 11 of the main request are identical to claims 1 to 11 of the auxiliary request before the examining division.

II. There were no arguments or conclusions in the Reasons for the Decision with respect to Articles 84, 83 and 123 EPC 1973. Further there were no arguments or conclusions in the Reasons for the Decision with respect to claims 1 to 11 of the requests.

These claims were only mentioned in the decision under Facts and Submissions in citing the examining division's communication dated 12 September 2003: "AP's (Applicant's) attention was explicitly drawn to the fact that no objections were raised against process claims 1-11."

III. The applicant (appellant) lodged an appeal against the decision of the examining division and filed grounds of appeal. There was no request for oral proceedings.

IV. In response to a communication of the Board, the appellant submitted with its letter of 14 January 2008 that it wanted to pursue the application on the basis of claims 1 to 11 of its present main request, corresponding to the same claims of the auxiliary request before the examining division as annexed to the division's decision posted 18 May 2004 under the heading "Auxiliary request as of 05.02.2004".

In this letter the appellant further submitted that claims 12 to 22 of the present main request were to be withdrawn. As a consequence the appellant submitted with the same letter a new page 20 containing claims 5 to 11 unamended and the part of claim 12 on this page cancelled.

V. The appellant (applicant) requests in writing that the decision under appeal be set aside and that a patent be granted on the basis of claims 1-4 (= pages 17-19) of the present main request (= auxiliary request as of 05.02.2004 before the examining division) and claims 5-11 (= new page 20 of the claims as submitted with letter dated 14 January 2008).

Reasons for the Decision

1. The appeal is admissible.

2. The examining division did not finally decide on claims 1 to 11 of the auxiliary request of 5 February 2004 which are now on file as the sole request before the Board in accordance with the applicant's letter of 14 January 2008.

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 well recognised that any party may be given an opportunity for two readings of the important elements of a case.

In particular, the Board assumes that a decision of the examining division would have resulted in a correction of discrepancies of the claims in suit, for instance the claims 1-9 being referred to in claim 10 or answering the question what particular embodiment might be characterised by claim 7.

Additionally, the scope of dependent claim 2 appears to be broader than the scope of claim 1 while it is not directed to a dosage form rapidly dissolving in aqueous medium ("in aqueous medium" is missing).

As the facts on file stand, the board exercises 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, i.e. also taking into account Articles 123, 83, 84, 54 and 56 EPC, each in its applicable version.

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.

The Registrar: The Chairman:

A. Townend U. Oswald