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Datasheet for the decision of 11 January 2007

Case Number: T 1176/06 - 3.3.02

Application Number: 96907007.7

Publication Number: 0749300

IPC: A61K 9/14

Language of the proceedings: EN

Title of invention:
Pharmaceutical excipient having improved compressibility

Applicant:
J. Rettenmaier & Söhne GmbH + Co. KG

Opponent:
-

Headword:
Pharmaceutical excipient/J. RETTENMAIER & SÖHNE GMBH + CO. KG

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty - yes: wording "consisting" establishes novelty over prior art"

Decisions cited:
-

Catchword:
-

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Case Number: T 1176/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 January 2007

Appellant: J. Rettenmaier & Söhne GmbH + Co. KG
Holzmühle 1
D-73494 Rosenberg (DE)

Representative: Wiliamson, Brian
OLSWANG
90 High Holborn
London WC1V 6XX (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 20 February 2006 refusing European application No. 96907007.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 96 907 007.7 was refused by a decision of the Examining Division dated 7 February 2006 under Article 97(1) EPC with regard to Article 54 EPC (lack of novelty).

II. The decision was based on claim 9 of the main request and of auxiliary requests 1 to 3.

Independent claim 9 of the main request reads as follows:

"9. A solid dosage form composition of a compressed mixture consisting essentially of from 1% to 99% of an excipient composition according to any one of claims 1 to 8, and from 99% to 1% of a therapeutically active ingredient."

III. The following document, cited during the proceedings before the Examining Division and the Board of Appeal, is relevant for the present decision:

(2) WO-A-9416693

IV. The arguments in the decision may be summarised as follows:

The Examining Division considered that, having regard to the "open wording" of the terms "consisting essentially", the subject-matter of claim 9 of the main request and of auxiliary requests 1 to 3 were anticipated by the disclosure in document (2), in

particular by the combination of claims 12, 9 and 1, and example 1 of this document.

It moreover held that the wording "A compressed solid dosage form composition of a micro-crystalline cellulose based excipient consisting of from 1% to 99% of an excipient composition according to any one of claims 1 to 8 and from 99% to 1% of a therapeutically active ingredient" in claim 9 of auxiliary request 3 was unclear, because, depending on its interpretation, the present wording left open the question whether other compounds might be present in the claimed "compressed solid dosage form".

No other objections were raised against these requests by the Examining Division.

V. The appellant (applicant) lodged an appeal against the said decision.

VI. The appellant filed a main request (corresponding to the main request before the Examining Division) and auxiliary requests 1 to 4 during the appeal proceedings.

Independent claims 9 and 24 of auxiliary request 1 read as follows:

"9. A solid dosage form composition of a compressed mixture consisting of from 1% to 99% of an excipient composition according to any one of claims 1 to 8, and from 99% to 1% of a therapeutically active ingredient.

24. A method of preparing a solid dosage form according to any of claims 9 to 13, comprising:
a. forming an aqueous slurry consisting of microcrystalline cellulose in the form of a wet cake and a surfactant;
b. drying said slurry to obtain an excipient comprising a plurality of agglomerated particles of microcrystalline cellulose in intimate association with said surfactant such that said surfactant is integrated with or partially coats said microcrystalline cellulose, said surfactant being present in an amount from 0.1 to 0.5% based on the weight of said microcrystalline cellulose;
c. mixing an active ingredient with said excipient in a ratio from 1:99 to 99:1; and
d. incorporating said mixture obtained in step (C) into a plurality of solid unit doses."

VII. In a letter dated 3 January 2007, the appellant informed the Board that it did not intend to attend the oral proceedings.

VIII. During the phone conversation with the representative of the appellant dated 9 January 2007, the representative indicated its intention to withdraw the main request and to replace it by auxiliary request 1.

By a fax dated the same day, the appellant withdrew the main request currently on file in favour of auxiliary request 1.

IX. Oral proceedings were held before the Board on 11 January 2006.

X. The appellant did not present any argument as to this main request (previous auxiliary request 1). It merely indicated that the wording of this request was in accordance with the proposal of the primary examiner during examination.

XI. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request (previous auxiliary request 1) or, alternatively, of auxiliary requests 2 to 4 filed with its letter dated 22 December 2006.

Reasons for the Decision

1. The appeal is admissible

2. Main request (previous auxiliary request 1 filed during the appeal proceedings).

Clarity of claim 9

The present wording of claim 9 satisfies the requirements of Article 84 EPC.

The claimed composition is defined in terms of clear and unambiguous features, namely its components and the relative amounts of theses ingredients.

Novelty of claim 9

Contrary to the wording of the requests presented before the Examining Division, the wording of present claim 1, namely "A solid dosage form composition of a compressed mixture consisting of …", clearly excludes the presence of ingredients not mentioned in the claim.

Thus, the subject-matter of claim 9 is restricted to a composition containing only a microcrystalline cellulose, a surfactant and a therapeutically active ingredient in the amounts as indicated in the claims.

Document (2) discloses in its claim 12 and its example 1 a composition which contains, beside the ingredients mentioned in claim 9 of the contested patent, among others, hydrous lactose, croscarmelose, hydroxypropyl cellulose, etc.

Accordingly, Document (2) does not anticipate the subject-matter of claim 9 of the main request, which is novel vis-à-vis said prior art document.

Under these circumstances, the decision of the Examining Division, which was restricted to objections relating to claim 9, no longer holds good and the case is therefore remitted to the first instance for further prosecution on the basis of the main request.

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