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**Datasheet for the decision
of 17 May 2013**

Case Number: T 2011/11 - 3.3.01

Application Number: 04736845.1

Publication Number: 1633757

IPC: C07D 495/04, A61K 31/5513,
A61K 9/00

Language of the proceedings: EN

Title of invention:
Amorphous form of olanzapine

Applicant:
Generics (UK) Limited

Headword:
Amorphous olanzapine/GENERICS (UK) LTD.

Relevant legal provisions:
EPC Art. 54
EPC R. 115(1)(2)
RPBA Art. 15(3)

Keyword:
"Main and auxiliary requests - novelty - (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 2011/11 - 3.3.01

DECISION
of the Technical Board of Appeal 3.3.01
of 17 May 2013

Applicant: Generics (UK) Limited
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted 24 March 2011
refusing European patent application
No. 04736845.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: G. Seufert
Members: J.-B. Ousset
C.-P. Brandt

Summary of Facts and Submissions

- I. This appeal lies from the decision of the examining division refusing European patent application No. 04 736 845.1.
- II. The examining division found that the then pending main request, as well as auxiliary requests 1 and 2, were not novel. Auxiliary request 3 was considered to be obvious for the person skilled in the art starting from document (2) as the closest prior art.
- III. Document (2) (WO-A-03/007912) is relevant for the present decision.
- IV. New main and auxiliary requests were filed with the statement of grounds of appeal dated 3 August 2011.

Claims 1 and 11 of the main request read as follows:

"1. An amorphous form of olanzapine, wherein the olanzapine comprises less than 10% of crystalline forms of olanzapine and less than 2% of other impurities, and wherein the olanzapine is for use in therapy by oral or parenteral administration."

"11. A pharmaceutical composition, comprising an amorphous form of olanzapine as claimed in any one of claims 1 to 4."

Claims 1 and 11 of the auxiliary request differ from those of the main request in that olanzapine comprises less than 5% of crystalline form.

Moreover, the appellant argued as follows:

- The amendments carried out in claim 1 of the main request were justified by the passage on page 3, lines 13 to 15 of the description. The dependent claims added to the main and auxiliary requests were based on page 2, lines 15 to 16, and claims 8 and 9 as originally filed.
 - The subject-matter of claim 1 was novel vis-à-vis document (2), since the amounts of lactose and tartaric acid present in the compositions of document (2) exceeded the 2% impurities comprised in the claimed compound. Remaining claims 2-26 were also novel, since they related to a novel amorphous form of olanzapine.
- V. In the annex to the summons to oral proceedings, the board notified the appellant that the admissibility of claims 1 and 4 of both requests would be discussed during oral proceedings with a view to the requirements of Article 123(2) EPC. Furthermore, the board considered that claim 11 lacked novelty over the disclosure of document (2), in particular in view of claim 23 and page 5, line 32, and questioned the presence of an inventive step.
- VI. With a letter of 14 March 2013, the appellant informed the board that it would not be represented at the oral proceedings scheduled on 17 May 2013. No further comments on the issues raised in the board's communication were submitted.

VII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request, or alternatively on the basis of the first auxiliary request, both filed with letter of 3 August 2011.

VIII. Oral proceedings took place in the absence of the appellant. At the end of these, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. The appellant had been duly summoned to oral proceedings according to Rule 115(1) EPC and despite its non-appearance these proceedings were continued in its absence (Rule 115(2) EPC). Moreover, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence of a duly summoned party (Article 15(3) of the Rules of Procedure of the Boards of Appeals (RPBA)). The appellant was informed of the objections raised against the patent in suit, and of the issues that had to be discussed at the oral proceedings, with the board's communication annexed to the summons to those proceedings. It could also expect that during the oral proceedings the board would consider these objections and issues, to which it had chosen not to reply in substance. Hence, the board concludes that the appellant had an opportunity to present its observations and comments on the grounds and evidence on which the board's decision, arrived at during oral

proceedings, is based. For these reasons, the board is in a position to take a decision on the current case in spite of the absence of the duly summoned appellant.

Main request

3. Novelty

3.1 Claim 11 of the main request refers to a pharmaceutical composition comprising an amorphous form of olanzapine as claimed in claim 1, i.e. an amorphous form with less than 10% of crystalline olanzapine and less than 2% of other impurities. The nature of these impurities is not defined, that is to say that any compound which is not amorphous or crystalline olanzapine and which does not interfere with the therapeutic effect of olanzapine (according to claim 1 the olanzapine is for use in therapy by oral or parenteral administration) is to be regarded as an impurity. Due to the presence of the word "comprising" in the wording of claim 11, the pharmaceutical composition may also contain further constituents. The nature of these constituents is also not defined and they can be present in any amount as long as they do not interfere with the pharmaceutical properties of the composition. Hence, the undefined impurities contained in the olanzapine of claim 1 used to produce the pharmaceutical composition of claim 11 cannot be distinguished from the further constituents of the pharmaceutical composition. Since the impurities and the further constituents can be identical and since the further constituents are not limited to 2%, it follows that claim 11 encompasses pharmaceutical compositions containing amorphous olanzapine having less than 10% crystalline form and other, undefined

constituents in any amount as long as they do not interfere with the claimed pharmaceutical properties.

3.2 Document (2) describes formulations containing olanzapine free of crystalline form (see claim 23), thus having an amount of crystalline form lower than 10%. Furthermore, the formulations of document (2) containing olanzapine are used parenterally (see page 5, lines 19 to 22 and claim 1) to treat agitated patients (see page 3, lines 8 to 18), thus used in a therapeutic treatment. The presently claimed pharmaceutical compositions comprising olanzapine with less than 10% crystalline form and any amount of undefined constituents cannot therefore be distinguished from the formulations described in claim 23 of document (2), which contain olanzapine free of crystalline form (thus less than 10% crystalline form) and, in any amount, tartaric acid and lactose as further constituents (see claims 18 and 19 on which claim 23 depends), said constituents do not interfere with the pharmaceutical properties of that formulation.

3.3 The appellant's argument with regard to the novelty of the olanzapine of claim 1 and, as a consequence, of the pharmaceutical compositions of claim 11 comprising said compound (see point IV above) are not convincing. For the reasons set out in points 3.1 and 3.2 above, the board fails to see any difference between the presently claimed pharmaceutical composition, which comprises olanzapine with less than 2% tartaric acid and lactose as impurities and which nevertheless due to its open form includes these compounds as further constituents in any amount, and the formulations of document (2). In this context, the board also notes that according to

claim 15 of the main request the pharmaceutical composition further comprises lactose and tartaric acid (see also page 6, lines 15-16 of the description).

- 3.4 Claim 11 is thus not novel in view of the disclosure of document (2). Consequently, the whole request is not patentable (Article 54 EPC).

Auxiliary request

4. The conclusions set out above for the subject-matter of claim 11 of the main request are also valid for the subject-matter of claim 11 of the auxiliary request, since the pharmaceutical composition of document (2) contains olanzapine free of crystalline form, therefore having an amount of crystalline form lower than 5% as required in claim 11 of the auxiliary request.
- 4.1 Claim 11 of the auxiliary request is not novel and therefore the whole request is not patentable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Schalow

G. Seufert