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Datasheet for the decision of 5 December 2006

Case Number: T 0870/03 - 3.3.02

Application Number: 95904476.9

Publication Number: 0734260

IPC: A61K 31/445

Language of the proceedings: EN

Title of invention:
Paroxetine tablets and process to prepare them

Patentee:
SMITHKLINE BEECHAM PLC

Opponent:
BASF PharmaChemikalien GmbH & Co. KG
Synthon BV
NORTON HEALTHCARE LTD
Biogian Generics Limited

Headword:
Paroxetine tablets/SMITHKLINE BEECHAM PLC

Relevant legal provisions:
EPC Art. 54

Keyword:
"Main request - Novelty - yes: no tried and unambiguous disclosure"

Decisions cited:
-

Catchword:
-

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Case Number: T 0870/03 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 5 December 2006

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 15 July 2003 revoking European patent No. 0734260 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Willems

Summary of Facts and Submissions

I. European patent No. 0 734 260 based on application No. 95 904 476 was granted on the basis of a set of 10 claims.

Independent claim 1 as granted read as follows:

"1. A process for preparing tablets containing paroxetine, reliably and on a commercial scale, which comprises formulating the tablets in the absence of water, without the use of wet granulation process."

II. Notices of opposition were filed by opponents 1 to 4 against the granted patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and Article 100(c) EPC because the claimed subject-matter contained added matter contrary to the requirements of Article 123(2) EPC.

The following document was cited *inter alia* during the proceedings before the Opposition Division and the Board of Appeal:

(2) WO-A-9209281
(3) Aulton, Ed., "Pharmaceutics: The Science of Dosage from Design" pp 11, 127-128, 245, 304-321, 618, 627, and 647-661, Churchill Livingstone, Edinburgh (1988)

III. The decision of the Opposition Division pronounced on 15 May 2003 revoked the patent under Article 102(1)EPC.

The Opposition Division held that the subject-matter of the set of claims of the main request and the sets of claims of auxiliary requests 1 and 2 filed with letter of 14 April 2003 was anticipated by example 1 of document (2) and that the subject-matter of auxiliary request 3 filed during the oral proceedings was not inventive vis-à-vis the disclosure of document (2) in combination with the disclosure in document (3).

As to novelty, the Opposition Division was of the opinion that, although example 1 did not mention that the paroxetine containing tablet was prepared in the absence of water, it was clear to the skilled person that this was the case, because no water was listed among the ingredients of the tablet and because the presence of hydroxypropylmethyl cellulose in the tablet composition implied that the process was performed in the absence of water since hydroxypropylmethyl cellulose was a typical ingredient for dry processes.

Claim 1 of the main request reads:

"1. A process for preparing pharmaceutical tablets containing paroxetine, reliably and on a commercial scale, which comprises formulating the tablets in the absence of water by dry direct compression of paroxetine or dry granulation of paroxetine followed by compression into tablets, without the use of wet granulation process."

IV. The appellant (patentee) lodged an appeal against the said decision.

V. By letters dated 13 July 2004, 25 May 2005 and by fax dated 30 November 2006 opponents 2, 1 and 4 withdrew their opposition.

VI. By a letter dated 4 December 2006, the respondent (opponent 3) informed the Board that it would not attend the oral proceedings.

VII. Oral proceedings were held before the Board on 5 December 2006.

VIII. In the appellant's view, the Opposition Division was wrong in deciding that "mixed together in a conventional manner and compressed into a tablet in a conventional manner" directly and unambiguously meant that the ingredients were mixed in a dry state.

In its opinion, it could only be concluded that the ingredients may have been mixed together in a dry state or a wet state, there was no direct and unambiguous disclosure of dry mixing since the language "mixed together in a conventional manner" comprehended the use of both dry mixing and wet mixing.

It moreover held that the words "mixed together in a conventional manner" in example 1 of document must be construed as of the date of publication of document (2), namely 11 June 1992 and that the conventional method(s) of mixing prevailing at 11 June 1992 was the wet mixing. Moreover, the appellant pointed out that example 1 of D2 says "mixed together in a conventional manner" (emphasis added), not "the conventional manner", which immediately implies that there are than one conventional manner.

According to the appellant, in the early 1990s, conventional methods of pharmaceutical tablet preparation included, wet granulation (or wet massing), dry granulation (slugging or roll compaction) and direct compression and the most conventional method of preparing pharmaceutical tablets was wet granulation.

In that respect, it referred to numerous prior art documents where wet granulation was used for the preparation of paroxetine containing tablets.

It also expressed the view that the Opposition Division was wrong in assuming that because water was not listed as an ingredient in example 1 of document (2), water could not have been used. In its view, in doing so, the Opposition Division ignored the fact that in example 1 of document (2) the ingredients listed were those in the final tablet, which does not contain water apart from the normal level of moisture that would be present in a nominally dry product.

Finally, it argued that the Opposition Division was guilty of ignoring evidence in the nature of the ingredients which strongly suggests that a wet process was used.

It held that example 1 of Document (2) specified that the grade of hydroxypropylmethyl cellulose used was not any hydroxypropylmethyl cellulose (HPMC) but 2910 and it provided evidence (documents, product literature, expert's statement) showing that HPMC 2910 was used in a wet granulation process and not a dry direct compression process.

It concluded that, given these indications that a wet granulation formulation would be understood by a person skilled in the art, it could not be legitimately concluded that Document (2) clearly and unambiguously discloses dry mixing of the listed dry ingredients.

IX. The respondent (opponent 3) did not file any submission during the appeal procedure.

X. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the claims of the main request or, alternatively, on the basis of the first or second auxiliary requests, rejected by the Opposition Division, or, more alternatively, on the basis of the third auxiliary request, filed with letter dated 24 November 2003.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

Novelty

Document (2) discloses, in example 1 on page 5, the preparation of a formulation of paroxetine hemihydrate hydrochloride in the following terms:
"Example 1

The following were mixed together in a conventional manner
and compressed into a tablet in a conventional manner.

22.88 mg Paroxetine hydrochloride hemihydrate
244.12 mg Dibasic calcium phosphate dihydrate
15.00 mg Hydroxypropylmethyl cellulose 2910
15.00 mg Sodium starch glycollate
3.00 mg Magnesium Stearate

300.00 mg Total tablet weight."

The Board notes that, as pointed out by the appellant, example 1 does not refer to a mixing process in particular and that it does either not indicate that the list of ingredients are the ones which were mixed or the ones which are present in the final tablet, so that the absence of water in the mixing process is not unambiguously established.

The Board observes also that the evidence and arguments provided by the appellant in order to establish, on the one hand, that the conventional process at the priority date was the wet process as acknoleged in the patent itself (page 2, lines 26 to 28) and, on the other hand, that the ingredient HPMC 2910 was a typical ingredient used in the wet granulation process, remained unchallenged and unanswered.

Accordingly, under these circumstances, the Board has no reason to doubt that the appellant's submissions (see point VIII) are correct.

The subject-matter of claim 1 and of its dependent claims is therefore novel over document (2) as required by Article 54 EPC, because it cannot be concluded that example 1 of document (2) constitutes a direct and unambiguous disclosure of a dry process.

3. *Remittal to the first instance*

3.1 Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that a party should be given two opportunities to read the important elements of a case. The essential function of an appeal in *inter partes* proceedings is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is taken into consideration by the boards in cases where a first-instance department issues a decision solely on one particular issue which is decisive for the case against a party and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues.

3.2 The above observations and comments apply fully to the present case. The Opposition Division decided that claim 1 was not patentable on the grounds of lack of

novelty (Article 54 EPC), but ignored the essential issues of inventive step (Articles 52(1), 56 EPC) and sufficiency of disclosure (Article 83 EPC).

These issues, however, form, *inter alia*, the basis for the requests of the opponents that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

3.3 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution on the basis of the set of claims according to 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