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D E C I S I O N
of 28 July 2005

Case Number: T 0731/03 - 3.3.1

Application Number: 00201290.4

Publication Number: 1020464

IPC: C07D 405/12

Language of the proceedings: EN

Title of invention:
Paroxetine methanesulfonate compositions

Patentee:
SmithKline Beecham PLC

Opponent:
-

Headword:
Paroxetine/SMITHKLINE BEECHAM

Relevant legal provisions:
EPC Art. 76, 105(2), 123(2)

Keyword:
"Main and first to fifth auxiliary request: added subject-matter (yes)"
"Sixth auxiliary request: prohibition of reformatio in peius"
"Intervention: deemed not to have been filed"

Decisions cited:
G 0009/92, G 0004/93, G 0001/94, T 1007/01

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0731/03 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 28 July 2005

Patentee: SmithKline Beecham PLC
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 27 May 2003 concerning maintenance of European patent No. 1020464 in amended form.**

Composition of the Board:

Chairman: A. J. Nuss
Members: P. P. Bracke
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 1 020 464 is based on the application 00 201 290.4, which was filed as a divisional application of the prior application 99 303 151.7. It was granted on the basis of 19 claims. Granted Claim 1 read:

"A pharmaceutical composition adapted for oral administration comprising 10, 12,5, 15, 20, 25, 30 or 40 mg of paroxetine methanesulfonate per unit dose, calculated on a free base basis, and a pharmaceutically acceptable carrier which comprises a disintegrant."

II. The patent was opposed on the grounds that the claimed subject-matter was not novel and that the subject-matter of the patent extended beyond the content of the application and/or of the earlier application as filed.

III. The Opposition Division maintained the patent in amended form on the basis of three claims, which read:

"1. A pharmaceutical composition adapted for oral administration comprising per unit dose 10 mg, calculated on a free base basis, of paroxetine methanesulfonate in crystalline form having *inter alia* the following characteristic IR peaks: 1603, 1513, 1194, 1045, 946, 830, 776, 601, 554, and 539 $\pm$ 4 cm^{-1}; and/or the following characteristic XRD peaks: 8.3, 10.5, 15.6, 16.3, 17.7, 18.2, 19.8, 20.4, 21.5, 22.0, 22.4, 23.8, 24.4, 25.0, 25.3, 25.8, 26.6, 30.0, 30.2, and 31.6 $\pm$ 0.2 degrees 2 theta, and a pharmaceutically acceptable carrier comprising 2.98 mg of sodium starch glycollate,

158.88 mg of dicalcium phosphate and 1.75 mg of magnesium stearate per unit dose."

"2. A pharmaceutical composition adapted for oral administration comprising per unit dose 20 mg, calculated on a free base basis, of paroxetine methanesulfonate in crystalline form having *inter alia* the following characteristic IR peaks: 1603, 1513, 1194, 1045, 946, 830, 776, 601, 554, and 539 $\pm$ 4 cm^{-1}; and/or the following characteristic XRD peaks: 8.3, 10.5, 15.6, 16.3, 17.7, 18.2, 19.8, 20.4, 21.5, 22.0, 22.4, 23.8, 24.4, 25.0, 25.3, 25.8, 26.6, 30.0, 30.2, and 31.6 $\pm$ 0.2 degrees 2 theta, and a pharmaceutically acceptable carrier comprising 5.95 mg of sodium starch glycollate, 317,75 mg of dicalcium phosphate and 3.50 mg of magnesium stearate per unit dose or which carrier comprises 8.34 mg of sodium starch glycollate, 83,34 mg of dicalcium phosphate, 50.67 mg of microcrystalline cellulose and 1.67 mg of magnesium stearate per unit dose."

"3. A composition adapted for oral administration comprising per unit dose 30 mg, calculated on a free base basis, of paroxetine methanesulfonate in crystalline form having *inter alia* the following characteristic IR peaks: 1603, 1513, 1194, 1045, 946, 830, 776, 601, 554, and 539 $\pm$ 4 cm^{-1}; and/or the following characteristic XRD peaks: 8.3, 10.5, 15.6, 16.3, 17.7, 18.2, 19.8, 20.4, 21.5, 22.0, 22.4, 23.8, 24.4, 25.0, 25.3, 25.8, 26.6, 30.0, 30.2, and 31.6 $\pm$ 0.2 degrees 2 theta, and a pharmaceutically acceptable carrier comprising 8.93 mg of sodium starch glycollate, 476,63 mg of dicalcium phosphate and 5.25 mg of magnesium stearate per unit dose or which carrier

comprises 12.5 mg of sodium starch glycollate, 125.0 mg of dicalcium phosphate, 76.0 mg of microcrystalline cellulose and 2.5 mg of magnesium stearate per unit dose."

IV. Both the Proprietor and the Opponent filed an appeal against the decision.

V. A Notice of Intervention was submitted on behalf of CHIESI S.A. by fax on 24 July 2003 based on infringement proceedings under the patent in suit having been started against them on 30 April 2003. The Notice of Intervention indicated that if the appeal fee were due it should be debited to the representatives account, and there was an accompanying voucher relating to payment of the appeal fee of Euro 1020,00. This sum was in fact debited by the EPO accounts department. Nothing was said in the Notice of Intervention about payment of the opposition fee.

VI. With the statement setting out the Grounds of Appeal dated 6 October 2003 the Appellant-Proprietor filed sets of claims according to six auxiliary requests.

Claim 1 of the first auxiliary request read:

"A pharmaceutical composition adapted for oral administration which is a tablet or capsule comprising 10, 12,5, 15, 20, 25, 30 or 40 mg of paroxetine methanesulfonate per unit dose, calculated on a free base basis, and a pharmaceutically acceptable carrier which comprises a disintegrant."

Claim 1 of the second auxiliary request read:

"A pharmaceutical composition adapted for oral administration which is a tablet or capsule comprising 10, 12,5, 15, 20, 25, 30 or 40 mg of paroxetine methanesulfonate per unit dose, calculated on a free base basis, and a pharmaceutically acceptable carrier which comprises a disintegrant which is sodium starch glycollate."

Claim 1 of the third auxiliary request read:

"A pharmaceutical composition adapted for oral administration which is a tablet or capsule comprising 10, 12,5, 15, 20, 25, 30 or 40 mg of paroxetine methanesulfonate per unit dose, calculated on a free base basis, and a pharmaceutically acceptable carrier comprising sodium starch glycollate, dicalcium phosphate and magnesium stearate."

The sole claim of the fourth auxiliary request was identical to Claim 1 of the first auxiliary request.

Claim 1 of the fifth auxiliary request read:

"A pharmaceutical composition adapted for oral administration which is a tablet comprising per unit dose, 10 mg of paroxetine methanesulfonate, calculated on a free base basis, and a pharmaceutically acceptable carrier comprising 2.98 mg of sodium starch glycollate, 158,88 mg of dicalcium phosphate and 1.75 mg of magnesium stearate."

The three claims according to the sixth auxiliary request corresponded with the three claims with which the patent was maintained by the Opposition Division.

VII. In a communication dated 17 November 2003 the Board indicated its preliminary non-binding opinion on the intervention, namely that since pursuant to Article 105(2) EPC, the Notice of Intervention shall not be deemed to be filed until the opposition fee has been paid, and the period for filing the Notice of Intervention expired on 30 July 2003, by which time the opposition fee had not been paid, the Notice of Intervention might be deemed not to have been filed in this case, and the payment of the appeal fee then having no legal basis, the sum would be repaid.

By facsimile dated 16 December 2003, it was submitted on behalf of CHIESI S.A. that since decision G 1/94 made clear that an intervention under Article 105 EPC could also be filed during pending appeal proceedings, but did not clarify what fee(s) were then due it would be quite normal to pay the appeal fee, as done in this case, and not the opposition fee. Alternatively the intention to intervene had been clearly expressed, and more had been paid than the necessary for the opposition fee, so that merely the designation of the fee should be treated as inappropriate but all the requirements of Article 105 EPC should be treated as fulfilled.

By letter received 30 December 2004, the intervention application was withdrawn.

VIII. The Appellant-Opponent had withdrawn its opposition with letter dated 11 January 2005.

IX. To the summons to oral proceedings, sent out on 24 May 2005, a communication was annexed wherein the question was raised whether the pending sets of claims meet the requirements of Article 123(2) EPC and Article 76(1) EPC.

X. The Appellant-Proprietor withdrew its request for oral proceedings with telefax dated 22 July 2005 and invited the Board to make a decision on the basis of its Grounds of Appeal dated 6 October 2003.

The Appellant-Proprietor requested that the decision under appeal be set aside and, as a main request, that the patent be maintained with Claims 1 to 5 as granted, or as auxiliary requests, that the patent be maintained on the basis of any of the sets of claims filed as first to sixth auxiliary requests with the Grounds of Appeal dated 6 October 2003.

Moreover, CHIESI S.A. asked to refund the "intervention official fees".

Reasons for the Decision

1. The appeal is admissible.

2. *Article 76 EPC and Article 123(2) EPC*

A divisional application has to meet both the requirement of Article 76(1) and that of Article 123(2)

EPC: it may neither extend beyond the parent application nor be amended after filing in such a way that it contains subject-matter which extends beyond the content of the divisional application as filed.

In accordance with the established jurisprudence of the Boards of Appeal, the relevant question to be decided in assessing whether an amendment adds subject-matter extending beyond the content of the application as filed or the parent application as filed, is whether the proposed amendments were **directly and unambiguously** derivable from the application as filed or from the parent application as filed.

2.1 Main request

In the first paragraph on page 14 of the parent application as filed it is taught, that the compositions are usually presented as a unit dose composition containing 1 to 200 mg of paroxetine methanesulfonate, more usually from 5 to 100 mg, for example 10 to 50 mg such as 10, 12.5, 15, 20, 25, 30 or 40 mg, most preferably 20 mg by a human patient. Moreover, on page 14, line 14 to page 15, line 1 of the parent application as filed, suitable carriers for use in the invention are said to include a diluent, a binder, a disintegrant, a colouring agent, a flavouring agent and/or preservative.

From those passages, however, the compositions defined in present Claim 1 are not directly and unambiguously derivable, since, in order to come to the claimed compositions a selection had to be made from the

amounts of paroxetine methanesulfonate and from the carrier used therein.

Since compositions containing the claimed combination of 10, 12.5, 15, 20, 25, 30 or 40 mg of paroxetine methanesulfonate and disintegrant as carrier are neither unambiguously disclosed in the description nor in the examples or the claims of the parent application as filed, Claim 1 is amended in such a way that subject-matter extending beyond the content of the parent application as filed is added, contrary to the requirement of Article 76 EPC.

Already for this reason alone, the set of claims according to the main request is not allowable.

2.2 First, second, third and fourth auxiliary requests

Since Claim 1 in each of those requests also contains the combination of 10, 12.5, 15, 20, 25, 30 or 40 mg of paroxetine methanesulfonate and disintegrant as carrier, those requests must fail for the same reasons as given above for the main request.

2.3 Fifth auxiliary request

Claim 1 defines any composition containing per unit dose 10 mg paroxetine methanesulfonate and a carrier comprising 2.98 mg of sodium starch glycollate, 158,88 mg of dicalcium phosphate and 1.75 mg of magnesium stearate.

Although it is true that such composition is disclosed in example 55 of the parent application as filed and

the divisional application as filed, Claim 1 is not restricted to a composition containing only those components. To the contrary, Claim 1 defines any composition containing those components **besides any possible other components not defined therein**, whereas example 55 describes a composition **consisting of** those components, without containing any other ingredient.

Since Claim 1 is thus an unacceptable generalisation of example 55 of the parent and divisional application as filed and nowhere else in those applications such compositions are described in a more general way, Claim 1 cannot be considered to meet the requirement of Article 123(2) EPC and Article 76 EPC.

3. Sixth auxiliary request

The sixth auxiliary request is to maintain the patent in the amended form allowed by the Opposition Division. Given that the Appellant-Opponent has withdrawn its opposition and the intervention has also been withdrawn, the Proprietor is the sole remaining Appellant. His sixth auxiliary request is thus equivalent to the Board dismissing his appeal. By dismissing the appeal the decision of the Opposition Division to maintain the patent in amended form (see point III. above) takes legal effect. The principle of reformatio in peius precludes the Board from reconsidering the allowability of the claims found allowable by the Opposition Division (see G 9/92 and G 4/93, both OJ EPO, 1994, 875).

4. Reimbursement of the appeal fee to CHIESI S.A.

4.1 As submitted, decision G 1/94 (OJ EPO 1994, 787) of the Enlarged Board of Appeal held an intervention to be admissible during pending appeal proceedings, but did not state what fee(s) were to be paid in such a situation. In the case law two views exist, firstly that according to the plain wording of Article 105(2) EPC only the opposition fee is to be paid, or alternatively that both the opposition fee and the appeal fee are due. Decision T 1007/01 (OJ EPO 2005, 240) has referred a question of law relating to this to the Enlarged Board of Appeal, where the case is pending under number G 3/04 and on which a decision is expected to issue shortly. The decision by the Enlarged Board in that case might or might not make it possible for this Board to accept that the intervention here met the requirements of Article 105 EPC on one of the bases proposed in the letter received 30 December 2004 (see point VI above), or possibly on some other basis. For future cases on the fees due from an intervener this expected decision of the Enlarged Board of Appeal will need to be taken into account.

4.2 In the present case, however, given that the "intervention application" was withdrawn, the most favourable outcome possible for CHIESI S.A. is for the appeal fee to be repaid, which is the result achieved in this case if the Board looks only at the actual wording of Article 105(2) EPC and the actual wording used in the Notice of Intervention. Article 105(2) EPC explicitly requires that the opposition fee be paid. In this case only the appeal fee was paid with the intervention, so that applying Article 105(2) EPC

literally, the intervention must be deemed not to have been filed, and the appeal fee paid is to be reimbursed, as there can be no legal basis for paying it if the intervention is deemed not to have been filed.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The appeal fee paid on behalf of Chiesi S.A. is to be reimbursed.

The Registrar: The Chairman:

N. Maslin A. Nuss