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Datasheet for the decision of 12 November 2019

Case Number: T 0349/15 - 3.3.02

Application Number: 07764495.3

Publication Number: 2044043

IPC: C07D295/08, A61K31/495, A61P25/24, A61P25/28, A61P25/18, A61P25/22, A61P25/32, A61P25/34, A61P25/36

Language of the proceedings: EN

Title of invention:

1-[2-(2,4-DIMETHYLPHENYLSULFANYL)-PHENYL]PIPERAZINE AS A COMPOUND WITH COMBINED SEROTONIN REUPTAKE, 5-HT3 AND 5-HT1A ACTIVITY FOR THE TREATMENT OF COGNITIVE IMPAIRMENT

Patent Proprietor:

H. Lundbeck A/S

Opponent:

Sandoz AG

Headword:

Relevant legal provisions:

Keyword:

Decisions cited:
G 0003/14

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Chambres de recours

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Case Number: T 0349/15 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 12 November 2019

Appellant: (Opponent)	Sandoz AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Best, Michael Lederer & Keller Patentanwälte Partnerschaft mbB Unsöldstrasse 2 80538 München (DE)
Respondent: (Patent Proprietor)	H. Lundbeck A/S Ottiliavej 9 2500 Valby-Copenhagen (DK)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 December 2014 rejecting the opposition filed against European patent No. 2044043 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	A. Lenzen
	M. Blasi

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the decision of the opposition division (decision under appeal) to reject its opposition against European patent No. 2 044 043 (patent in suit).

II. In its notice of opposition, the appellant requested the revocation of the patent in suit in its entirety based on Article 100(a) (lack of novelty and lack of inventive step) and Article 100(b) EPC.

III. Oral proceedings before the board were held on 12 November 2019. During these, the patent proprietor (respondent) filed a set of claims 1 to 16 as its new main request. It withdrew all other auxiliary requests filed previously.

IV. The appellant requested that the decision under appeal be set aside and the patent in suit not be maintained in the form considered allowable by the opposition division. The appellant had no objections to a maintenance of the patent in amended form on the basis of the new main request.

V. The respondent requested that the impugned decision be set aside and the patent in suit be maintained in amended form on the basis of claims 1 to 16 of the main request, filed as "AR1" during the oral proceedings before the board.

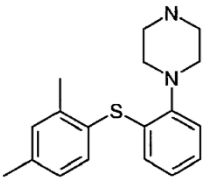
VI. The independent claims of the new main request read as follows:

Claim 1

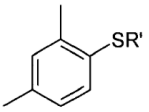
"*1-[2-(2,4-dimethylphenylsulfanyl)-phenyl]piperazine hydrobromide salt, which compound is in a crystalline form having XRPD reflections at approximately 6.89, 9.73, 13.78 and 14.64 (°2θ).*"

Claim 3

"*A process for the preparation of crystalline 1-[2-(2,4-dimethylphenylsulfanyl)-phenyl]piperazine or a pharmaceutically acceptable salt thereof*

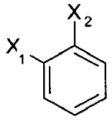


the process comprising reacting compound II



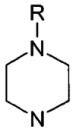
[II]

wherein R' represent hydrogen or a mono-valent metal ion, with a compound of formula III



[III]

wherein X_1 and X_2 independently represent halogen, and a compound of formula IV



[IV]

wherein R represent [sic] *hydrogen or a protecting group, in the presence of a solvent, a base and a palladium catalyst consisting of a palladium source and*

a phosphine ligand at a temperature between 60°C and 130°C."

Claim 16

"*A process for the manufacturing of crystalline 1-[2-(2,4-dimethyl-phenylsulfanyl)-phenyl]-piperazine hydrobromic acid addition salt in which process 2-5 equivalents of NaO(t-Bu), 2-5 equivalents piperazine, 0.2-0.6 mole-% Pddba$_2$, and 0.6-1 mole-% rac-BINAP are dispersed in toluene to obtain mixture A', to which mixture approximately 1 equivalent 2-bromo-iodobezene is added to obtain mixture B', to which mixture 1 equivalent 2,4-dimethylthiophenol is added and the resulting mixture is heated to reflux for 4-6 hours to obtain 1-[2-(2,4-dimethyl-phenylsulfanyl)-phenyl]-piperazine, which is further reacted with aqueous hydrobromic acid.*"

For simplicity, the compound 1-[2-(2,4-dimethylphenylsulfanyl)phenyl]piperazine will be referred to as vortioxetine in the following.

Reasons for the Decision

Main request

1. During the oral proceedings before the board, the respondent filed a new set of claims 1 to 16 as its new main request. The appellant stated that it had no objections to a maintenance of the patent in amended form based on this new main request.

2. Claim 1 is based on a combination of claims 1, 5 and 6 as filed. In claim 1, the disclaimer of claim 1 as filed ("*provided said compound is not the free base in*

a non-crystalline form") has been omitted. This omission does not go beyond the content of the application as filed because said disclaimer has become superfluous. More specifically, since the compound of claim 1 is now defined as the hydrobromide salt, the free base (be it crystalline or non-crystalline) does not any more fall within the subject-matter of claim 1.

Claim 2 is based on claim 17 as filed.

Process claims 3 to 15 are based on claims 18 to 21, 23, 26, 28, 30, 32 to 34, 39 and 40 as filed. Compared to the claims as filed, claims 3 to 15 are further limited in that they relate to "*the preparation of* ***crystalline*** *1-[2-(2,4-dimethylphenylsulfany)-phenyl]piperazine* ***or a pharmaceutically acceptable salt thereof***" (emphases added). As the processes disclosed in the application as filed are intended to synthesise the target compound vortioxetine and its pharmaceutically acceptable salts and crystalline forms, these limitations follow implicitly from the application as filed.

Process claim 16 is based on claim 43 as filed and further requires the product of the process to be **crystalline**. With regard to this additional feature, the reasoning in the preceding paragraph applies.

Thus, the subject-matter of the main request meets the requirements of Article 123(2) EPC.

3. Claim 1 is a combination of claims 1, 4 and 5 as granted. Claim 2 is a combination of claims 1, 4, 5 and 11 as granted. Process claims 3 to 16 are a combination of process claims 12 to 25 as granted with claim 1 as granted.

Because the claims of the main request are the result of combinations of granted claims the protection they confer does not extend beyond the protection of the patent as granted (Article 123(3) EPC). For the same reason, the claims of the main request are not open to objections under Article 84 EPC (see decision G 3/14, OJ EPO 2015, A102, catchword).

Thus, the claims of the main request also meet the requirements of Articles 123(3) and 84 EPC.

4. As set out above, the appellant had no objections as regards the further requirements of the EPC and the board is satisfied that these requirements are fulfilled.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of claims 1 to 16 of the main request filed as "AR1" during the oral proceedings before the board, and a description to be adapted thereto.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated