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**Datasheet for the decision
of 7 July 2016**

Case Number: T 2027/13 - 3.3.07

Application Number: 08852637.1

Publication Number: 2217217

IPC: A61K9/24, A61K9/22, A61P25/08,
A61K31/197

Language of the proceedings: EN

Title of invention:

CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS OF PREGABALIN

Applicant:

Lupin Ltd.

Relevant legal provisions:

EPC Art. 84, 111(1), 123(2)

Keyword:

Claims - clarity - main request (no)
Claims - clarity after amendment (yes)
Amendments - allowable (yes)
Appeal decision - remittal to the department of first instance
(yes)

Decisions cited:

T 1170/07, T 1730/09



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Case Number: T 2027/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 7 July 2016

Appellant: Lupin Ltd.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 6 May 2013
refusing European patent application No.
08852637.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
D. T. Keeling

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division announced at oral proceedings on 16 April 2013 refusing European patent application No. 08 852 637.1.

Claims 1 and 13 of the application as originally filed read as follows:

"1. A Controlled (*sic*) release pharmaceutical composition comprising therapeutically effective amount of pregabalin or salts thereof as active ingredient, a hydrophobic release controlling agent(s) and optionally other pharmaceutically acceptable excipients thereof."

"13. A controlled release pharmaceutical compositions (*sic*) comprising therapeutically effective amount of pregabalin or salts thereof and hydrophobic release controlling agent(s) thereof, in which the compositions exhibits in vitro release of Pregabalin of not less than about 55 % after 7 hours."

- II. The decision was based on five sets of claims filed with letter of 12 April 2013 as main request and auxiliary requests 1 to 4.

Claim 1 included in all request a number of amendments with respect to claim 1 as filed. In particular claim 1 of auxiliary requests 3 and 4 included *inter alia* the amendment that the hydrophobic release controlling agent was defined as "consisting essentially of ethyl cellulose".

- III. According to the decision under appeal:

- a) Claim 1 of the main request did not meet the requirements of Article 123(2) EPC as no basis could be found for the specific combination of features therein. Auxiliary requests 1 and 2 did not meet the requirements of Article 123(2) EPC for similar reasons.

- b) Claim 1 of auxiliary request 3 did not meet the requirements of Article 123(2) EPC, as there was no basis in the original application for a hydrophobic release controlling agent "consisting essentially of ethyl cellulose". The same held for auxiliary request 4.

IV. The applicant (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted 4 sets of claims as main request and auxiliary requests 1 to 3.

Claim 1 was identical in the main request and in auxiliary request 1 and corresponded to claim 1 of auxiliary requests 3 and 4 on which the decision under appeal was based. It had the following wording:

"1. A controlled release pharmaceutical composition comprising therapeutically effective amount of pregabalin or salts thereof as active ingredient, a hydrophobic release controlling agent consisting essentially of ethyl cellulose, and optionally other pharmaceutically acceptable excipients thereof, said composition exhibiting an *in vitro* release of said pregabalin or salts thereof of not less than about 55 % after 7 hours."

V. In a communication sent in preparation of oral proceedings, the Board mentioned *inter alia* that the

wording "consisting essentially of ethyl cellulose" was problematic both under clarity and under extension beyond the content of the application as filed (points 1 to 1.2 in the communication).

- VI. With a letter of 4 May 2016 the appellant filed three sets of claims as auxiliary requests 2 to 4.

Claim 1 of auxiliary request 2 read as follows:

"1. A controlled release pharmaceutical composition comprising a) therapeutically effective amount of pregabalin or salts thereof as active ingredient, b) hydrophobic release controlling agent consisting essentially of ethyl cellulose, and c) optionally other pharmaceutically acceptable excipients wherein said composition exhibits an in vitro release of the pregabalin or salts thereof of not less than about 55 % after 7 hours."

Claim 1 of auxiliary request 3 corresponded to claim 1 of auxiliary request 2 with the addition as a further ingredient of "a wicking agent selected from dicalcium phosphate, lactose". Claim 1 of auxiliary request 4 corresponded to claim 1 of the main request with the specification that the excipients were "selected from binders, diluents, glidants, and lubricants".

- VII. With a letter of 28 June 2016 the appellant filed a further set of claims.

- VIII. Oral proceedings took place on 7 July 2016. During the oral proceedings the set of claims filed with letter of 28 June 2016 was further amended and filed as auxiliary request 5. That request included a single independent claim 1, which corresponded to claim 1 of auxiliary

request 2 with the replacement of the wording "consisting essentially of" with "being".

IX. The appellant's arguments, insofar as relevant to the present decision, can be summarised as follows:

The expression "consisting essentially of ethyl cellulose" with respect to the hydrophobic release controlling agent present in claim 1 of the main request and of auxiliary requests 1 to 4 was clear and meant that the claimed composition did not contain any additional hydrophobic release controlling agent. This was in line with decision T 1170/07 of 13 March 2012, where the expression "consisting essentially of" was read to exclude the presence of further active ingredients, but to allow the presence of additional compounds; also in that case the limitation related to a single ingredient (the active ingredient). This was confirmed also in T 1730/09 of 25 October 2011, where the expression "consisting essential of" was considered to be clear and to allow the presence of other components in addition to the mandatory components, provided that the essential characteristic of the claimed composition were not materially affected by their presence. In the present case concerning a controlled release composition of pregabalin wherein the release was controlled solely by hydrophobic agents, limiting the hydrophobic agent to "consisting essentially of ethyl cellulose" necessarily meant that the composition did not contain any additional hydrophobic release controlling agent, but could contain other excipients or impurities which did not alter the controlled release properties of the composition.

The clarity issue was moot in auxiliary request 5, whose claim 1 did not contain the expression "consisting

essentially of" and was based on original claims 1 and 13 with the limitation of the hydrophobic release controlling agent to a single compound disclosed in the description.

- X. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division on the basis of the claims of the main request or auxiliary request 1, both filed with the grounds of appeal on 5 September 2013, or of auxiliary request 2, 3, or 4, filed by letter of 4 May 2016, or of auxiliary request 5, filed during the oral proceedings before the Board of Appeal.

Reasons for the Decision

Main request - clarity

1. Claim 1 of the main request concerns a controlled release pharmaceutical composition "comprising" a specific active ingredient (pregabalin or salts thereof), a hydrophobic release controlling agent "consisting essentially of" ethyl cellulose and optionally pharmaceutically acceptable excipients.
 - 1.1 The appellant has argued that the expression "consisting essentially of" was considered as clear in the case law and in the present case necessarily meant that the composition did not contain any additional hydrophobic release controlling agent, but could contain other excipients or impurities which did not alter the controlled release properties of the composition.
 - 1.2 In T 1170/07 (*supra*), where claim 1 of the main request included a dosage form which consisted essentially of an

active ingredient, the board concluded that under the specific circumstances of the case "consisting essentially of" excluded further active agents useful in the treatment of the specific disease mentioned in the claim, but allowed the presence of additional compounds forming the carrier of the agent (see point 3.1 in the reasons). By virtue of that interpretation no problem of clarity arose.

1.3 In T 1730/09 (*supra*), where claim 1 of auxiliary request 8 concerned a viscoelastic fluid consisting essentially of three ingredients, reference was made to previous decisions, wherein it was decided that the term "consisting essentially of" was clear and allowed the presence of other components in a claimed composition in addition to the components mandatory in the claim, provided that the essential characteristics of the claimed composition were not materially affected by their presence (point 1.2.3 in the reasons, first paragraph). The board agreed with these previous decisions and concluded that in the present case the wording used allowed that the composition consisted of the mandatory components listed in the claim and could contain additionally only other components which did not materially affect the essential characteristics of the composition (in the specific case the viscoelastic characteristics), e.g. minor amounts of impurities (point 1.2.3 in the reasons, second paragraph).

1.4 In all cited cases the expression "consisting essentially of" refers to the whole composition present in the claim. This is the case also in T 1170/07, where, even if the unit dosage includes a single ingredient, it is the whole dosage form which consists essentially of that ingredient (and not the ingredient which consists essentially of one component).

- 1.5 Contrary to that, in the present case the composition is defined by an open formulation (in view of the word "comprising"), which already implies the presence not only of the optional excipients, but also of any additional pharmaceutically acceptable component (including impurities) and even on further release controlling agents, and the expression "consisting essentially of" refers to a single ingredient of the composition.
- 1.6 As the usual reading of the expression does not make sense in the present case (the presence of any additional ingredient is already encompassed by the open formulation), the skilled person reading the claim is at a loss about the possible limitation introduced by the expression. In particular, he could not consider it as implying that no additional hydrophobic release controlling agent is present, which is not the case in view of the open formulation, nor could he see the limitation as necessary to allow the presence of excipients or impurities, which are already included independently of the presence of the expression.
- 1.7 As it is not clear what limitation is introduced by the expression "consisting essentially of" with respect to the hydrophobic release controlling agent in claim 1 of the main request, the claim does not meet the requirements of Article 84 EPC.

Auxiliary requests 1 to 4 - clarity

2. Claim 1 according to auxiliary requests 1 to 4 still contains the critical wording, namely the open formulation of the claimed composition by means of the word "comprising" and the definition of the hydrophobic

release controlling agent as "consisting essentially of" ethyl cellulose.

- 2.1 In view of that claim 1 according to auxiliary requests 1 to 4 does not meet the requirements of Article 84 EPC for the same reasons as outlined for claim 1 of the main request (see point 1, above).

Auxiliary request 5 - clarity and amendments

3. Claim 1 of auxiliary request 5 corresponds to claim 1 of auxiliary request 2 (which in turn corresponds to claim 1 of the main request with cosmetic amendments) with the replacement of the wording "consisting essentially of" with "being".

- 3.1 By means of this amendment the objection under Article 84 EPC valid for the previous requests is rendered moot. The Board has no reason to raise further objections under Article 84 EPC.

- 3.2 As to the requirements of Article 123(2) EPC, claim 1 of auxiliary request 5 corresponds to original claim 13 with the choice of one specific hydrophobic release controlling agent out of the listed ones (ethyl cellulose on page 6, line 2), which amounts to a single selection of a disclosed option, and the optional inclusion of excipients. The presence of excipients is part of the definition of a pharmaceutical composition both in the application (see page 5, lines 8 and 9 reading: "Pharmaceutical composition" refers to the combination of one or more drug substances and one or more excipients) and in the pharmaceutical field. On that basis, the subject-matter of claim 1 of auxiliary request 5 is directly and unambiguously derivable from the application as filed.

3.3 In view of that, the requirements of Article 123(2) EPC are met.

Remittal

4. Considering that the issues of novelty and inventive step were not addressed in the contested decision, the Board finds it appropriate to remit the case to the department of first instance for further prosecution (Article 111(1) EPC), which also corresponds to the request of the appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of the claims of auxiliary request 5, filed during the oral proceedings before the Board of Appeal.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated