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**Datasheet for the decision
of 29 March 2019**

Case Number: T 0452/16 - 3.3.07

Application Number: 13154290.4

Publication Number: 2764862

IPC: A61K9/20, A61K31/135, A61P25/16

Language of the proceedings: EN

Title of invention:
Immediate release tablets of rasagiline hemitartrate

Applicant:
Galenicum Health S.L.

Headword:
rasagiline hemitartrate / GALENICUM

Relevant legal provisions:
EPC Art. 113(1)
EPC R. 103(1)(a)
RPBA Art. 11

Keyword:
Substantial procedural violation - violation of the right to
be heard (yes)
Reimbursement of appeal fee - (yes)



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Case Number: T 0452/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 29 March 2019

Appellant: Galenicum Health S.L.
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Representative: Galenicum Health S.L.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 2 October 2015
refusing European patent application No.
13154290.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: E. Duval
C. Schmidt

Summary of Facts and Submissions

- I. The appeal of the applicant (appellant) lies from the decision of the examining division to refuse European patent application No. 13154290.4.
- II. The decision was issued according to the state of the file using a standard decision form and referring for its grounds to the communications dated 15 January 2015 and 22 May 2015.
- III. The relevant parts of the first instance proceedings may be summarised as follows:
- (a) In the course of the first instance proceedings, the examining division issued five communications pursuant to Article 94(3) EPC, followed by summons to oral proceedings.
 - (b) In the fourth communication dated 19 September 2014, the examining division introduced new documents D9-D11. D9-D11 were held to be prejudicial to the novelty of the then claimed subject-matter.
 - (c) After a telephone consultation (see minutes dated 8 October 2014), the applicant filed by letter dated 22 October 2014 a main request and an auxiliary request. Since, during the telephone consultation, the first examiner had expressed the preliminary opinion that the main request would overcome the novelty objections, arguments were submitted with respect to inventive step.

The main request consisted of the following sole claim:

"A packaged pharmaceutical composition, wherein said packaged pharmaceutical composition is a cardboard box with a patient information leaflet comprising at least one blister pack comprising a stable pharmaceutical composition in the form of immediate release tablets comprising (R)-N-propargyl-1-aminoindan hemitartrate, preferably for use in the treatment of Parkinson's disease, wherein the pharmaceutical composition comprises at least a filler, or a bottle containing at least 10 of said tablets".

In the auxiliary request, the following feature was added:

"wherein the pharmaceutical composition comprises tartaric acid"

- (d) In a fifth communication dated 15 January 2015, the examining division raised objections of lack of novelty over D9 and D11. The examining division furthermore introduced a new document D12, which was considered to anticipate "at least claim 1 of the main request".

The examining division justified the objections of lack of novelty as follows: the features pertaining to the packaging of the blister pack (or alternatively the bottle containing the tablets) together with a patient leaflet information within a cardboard box were "features which relate to the marketing of the medicament and do not produce any technical effect of any kind, whereby they cannot be regarded as "technical features" within the meaning of Rule 43(1) EPC".

(e) By letter dated 26 January 2015, the applicant filed an amended main request and an amended auxiliary request. Both requests respectively differed from the previous main and auxiliary requests by the following additional feature: "the (R)-N-propargyl-1-aminoindan hemitartrate is in crystalline form". Detailed argumentation was provided to support the view that the above features were of a technical nature and established novelty.

(f) Summons to attend oral proceedings before the examining division were issued on 22 May 2015. While novelty over D12 was acknowledged, the objections of lack of novelty over D9 and D11 were upheld. The annex to the summons contained *inter alia* the following statement:

"However, the examining division is still of the opinion that the features relating to the packaging and marketing of the pharmaceutical composition are not features having a technical character in the sense of Rule 43(1) EPC for claims directed to a pharmaceutical composition, and therefore cannot serve to confer novelty over Art. 54(1), (2) EPC prior art documents or Art. 54(3) EPC documents. Furthermore, it is reminded that D9 also discloses in example 4 the storage of the tablets in Alu/Alu blister. The examining division considers that the features relating to the cardboard box and patient information leaflet could be also considered as implicitly disclosed in D9".

(g) By letter dated 18 August 2015, the applicant withdrew its request for oral proceedings, maintained that the feature "cardboard box with a patient information leaflet" was a technical one for the

reasons given in the previous response, contested that this feature was implicitly disclosed in D9 and D11, and requested a decision according to the state of the file.

(h) The examining division issued the decision to refuse the application on 2 October 2015. In the grounds for the decision, the examining division referred to its communications dated 15 January 2015 and 22 May 2015. Further reasons were not given.

- IV. The appellant lodged an appeal against this decision. With its statement setting out the grounds of appeal, the appellant filed a main request and one auxiliary request. The appellant furthermore expressed the view that the examining division committed a substantial procedural violation by not taking into account the appellant's arguments with respect to novelty submitted with the letter dated 26 January 2015.
- V. The Board issued on 14 January 2019 a communication pursuant to Article 15(1) RPBA. In it, the Board preliminarily concurred with the appellant that the first instance proceedings suffered from a substantial procedural violation.
- VI. The appellant withdrew its request for oral proceedings by letter dated 15 February 2019.
- VII. The appellant's arguments, insofar as relevant for the present decision, can be summarized as follows:

The novelty objection raised by the examining division in its communication dated 15 January 2015 was primarily based on the argument that the features relating to the packaging of medicaments could not be regarded as

technical features in the sense of Rule 43(1) EPC. The appellant had provided arguments in support of novelty in its letter dated 26 January 2015. Yet, the subsequent communication annexed to the summons to oral proceedings simply repeated the novelty objection almost *verbatim*. Hence, the decision under appeal, by merely referring to the communications dated 15 January 2015 and 22 May 2015, did not satisfy the requirements of Article 113(1) EPC.

VIII. The appellant requested that the appealed decision be set aside and that either the patent application be remitted to the examining division for further prosecution, or that the patent application be allowed. Additionally, the reimbursement of the appeal fee under Rule 103(1)(a) EPC was requested.

Reasons for the Decision

1. Right to be heard (Article 113(1) EPC)

The right to be heard under Article 113(1) EPC requires that those involved be given an opportunity not only to present comments (on the facts and considerations pertinent to the decision) but also to have those comments considered, that is, reviewed with respect to their relevance for the decision on the matter (see Case Law of the Boards of Appeal, 8th edition 2016, III.B.2.4.1).

The Board considers that the examining division did not observe the appellant's right to be heard for the following reasons:

- 1.1 The claims upon which the decision under appeal was taken (i.e. the main and auxiliary requests of 26 January 2015, see III.(e) above) relate to a "packaged pharmaceutical composition, wherein said packaged pharmaceutical composition is a cardboard box with a patient information leaflet comprising at least one blister pack comprising a stable pharmaceutical composition in the form of immediate release tablets [...], or a bottle containing at least 10 of said tablets".

- 1.2 According to the examining division's reasoning on lack of novelty, as laid out in the communication dated 15 January 2015, the features pertaining to packaging of the blister pack (or alternatively the bottle containing the tablets) together with a patient leaflet information within a cardboard box are not explicitly disclosed in D9 or D11, but are "features which relate to the marketing of the medicament and do not produce any technical effect of any kind, whereby they cannot be regarded as "technical features" within the meaning of Rule 43(1) EPC", with the consequence that these features cannot distinguish the claimed subject-matter from D9 or D11.

- 1.3 The applicant's answer dated 26 January 2015 contains a detailed argumentation to support the view that the above features are of a technical nature and establish novelty, which argumentation may be summarised as follows: a cardboard box with patient leaflet information reveals a technical aspect by itself, as it contributes to solving the problem of providing a pharmaceutical composition ready for use by the end customer and produces the technical effect of protecting the compositions from light and physical damage.

- 1.4 In the communication dated 22 May 2015, these arguments were not addressed: despite the blanket statement

that "the arguments submitted by the applicant with letter of 26.01.2015 have been given due consideration", the communication merely concludes that "the examining division is still of the opinion that the features relating to the packaging and marketing of the pharmaceutical composition are not features having a technical character in the sense of Rule 43(1) EPC for claims directed to a pharmaceutical composition, and therefore cannot serve to confer novelty over Art. 54(1), (2) EPC prior art documents or Art. 54(3) EPC documents". Thus this communication merely repeats the examining division's conclusion that said features have no technical character, without a word about the specific technical aspects mentioned by the applicant.

The statement immediately following in the communication, according to which "it is reminded that D9 also discloses in example 4 the storage of the tablets in Alu/Alu blister", appears unrelated to the applicant's counter-argument or to the patient leaflet information and cardboard box features.

Lastly, the communication further indicates that "the features relating to the cardboard box and patient information leaflet could be also considered as implicitly disclosed in D9". However, it is neither explained where in D9 such features may be found, nor why the teaching of D9 may be said to constitute an implicit disclosure thereof.

- 1.5 Just indicating that the applicant's arguments filed on 26 January 2015 were found unconvincing, without addressing them in details, might be sufficient in a communication preparing oral proceedings. However, the mere reference to such a communication cannot suitably replace the grounds for a decision to refuse the

application, because the reasons why the examining division upheld its opinion are obscure.

Hence, the requirements of Article 113(1) EPC are not met. This violation of the right to be heard is regarded as a fundamental procedural violation, as the lack of reasoning concerns submissions which are clearly central to the case and affects the entire motivation of the decision, namely the lack of novelty over both D9 and D11.

2. The Board additionally notes that the decision under appeal refers to two communications raising different objections in respect of different claim versions, namely:

- the communication dated 15 January 2015 finding the subject-matter of the main and auxiliary requests filed by letter dated 22 October 2014 to lack novelty over D9, D11 and D12, and

- the communication dated 22 May 2015 (annexed to the summons) based on the main and auxiliary requests filed by letter dated 26 January 2015 and acknowledging novelty over D12 while upholding the objections based on D9 and D11.

In this, the examining division did not follow the procedure prescribed in the Guidelines in their version in force at the time (C-V, 15.2; November 2014 version): "if the different communications deal with different sets of claims, such that it is not clear which of the reasons given by the Examining Division in its communications might be essential to the decision to refuse, a fully reasoned decision should be issued instead". However, since a substantial procedural violation already

arises for the reasons given above (see 1.), the Board does not have to decide whether this reference to two communications caused another fundamental procedural deficiency.

3. Remittal to the examining division (Article 11 RPBA)

It follows from the above that the first instance proceedings are tainted by fundamental deficiencies with respect to the requirements of Article 113(1) EPC. Pursuant to Article 11 RPBA, and since no special reasons exist for doing otherwise, the case shall be remitted to the department of first instance.

Accordingly, the Board can accede to the appellant's request that the appealed decision be set aside and that the patent application be remitted to the examining division for further prosecution.

4. Reimbursement of the appeal fee (Rule 103(1)(a) EPC)

The Board considers the failure to comply with the requirement of Article 113(1) EPC to be a procedural violation that affects the entire basis of the appeal proceedings.

Accordingly, the reimbursement of the appeal fee is equitable by reason of a substantial procedural violation pursuant to Rule 103(1)(a) EPC.

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.
3. Reimbursement of the appeal fee is ordered.

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated