Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 29 November 2018

Case Number: T 0110/16 - 3.3.07

Application Number: 11171296.4

Publication Number: 2382970

IPC: A61K9/20, A61K9/26, A61K9/14, A61K9/48, A61K31/22, A61K31/40

Language of the proceedings: EN

Title of invention:
Stable Pharmaceutical Compositions Containing 7-Substituted-3,5-Dihydroxyheptanoic Acids or 7-Substituted-3,5-Dihydroxyheptenoic Acids

Patent Proprietor:
TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Opponent:
Generics [UK] Limited (trading as Mylan)

Headword:
Stable compositions / TEVA

Relevant legal provisions:
EPC Art. 76(1)

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (yes)

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0110/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 29 November 2018

Appellant: (Opponent)	Generics [UK] Limited (trading as Mylan) Building 4 Trident Place Mosquito Way Hatfield Hertfordshire AL10 9UL (GB)
Representative:	Venner Shipley LLP Byron House Cambridge Business Park Cowley Road Cambridge, Cambridgeshire CB4 0WZ (GB)
Respondent: (Patent Proprietor)	TEVA PHARMACEUTICAL INDUSTRIES, LTD. 5 Basel Street, P.O. Box 3190 49131 Petah Tiqva (IL)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 November 2015 rejecting the opposition filed against European patent No. 2382970 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	S. Albrecht
	Y. Podbielski

Summary of Facts and Submissions

I. European Patent No. 2 382 970 is based on European patent application No. 11171296.4, which is a divisional application of earlier European patent application No. 01926775.6 (EP 1 274 401), which was filed as international application PCT/US01/11514 and published as WO 01/76566 (hereinafter referred to as "earlier application"). The patent was granted on the basis of a set of 15 claims.

Independent claim 1 as granted read as follows:

"Use of a stabilizing effective amount of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof for stabilizing an active component in a composition for the treatment of dyslipidemia comprising, as an active component, at least one ring-opened 7-substituted-3,5-dihydroxyheptanoic acid or ring-opened 7-substituted-3,5-dihydroxyheptenoic acid, or a pharmaceutically acceptable acid salt thereof,; wherein said composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers;
wherein the at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof, comprises between 10 and 99 percent by weight of the composition, and wherein an aqueous dispersion of said composition exhibits a pH of 6.5 to 8 when measured on said composition when disintegrated in deionised water at a concentration of active component of 1 mg/ml."

Independent claim 3 as granted read as follows:

"A method for stabilizing an active component in a composition for the treatment of dyslipidemia comprising as an active component, at least one ring-opened 7-substituted-3,5-dihydroxyheptanoic acid or ring-opened 7- substituted-3,5-dihydroxyheptenoic acid, or a pharmaceutically acceptable acid salt thereof, by providing in said composition, a stabilizing effective amount of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof; wherein said composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers; wherein the at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof, comprises between 10 and 99 percent by weight of the composition, and wherein an aqueous dispersion of said composition exhibits a pH of 6.5 to 8 when measured on said composition when disintegrated in deionised water at a concentration of active component of 1 mg/ml."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step (Article 100(a) EPC), that it was not sufficiently disclosed (Article 100(b) EPC) and that it extended beyond the content of the application as filed and the earlier application as filed (Article 100(c) EPC).

The documents filed during the opposition proceedings included the following:

D6: WO 00/72825 A1
D13: WO 01/76566 A1 (i.e. published version of the earlier application as filed)

III. The appeal by the opponent (hereinafter the appellant) lies against the decision of the opposition division to reject the opposition.

IV. According to the decision under appeal:

(a) Claims 13 and 14 as granted fulfilled the requirements of Articles 76(1) and 123(2) EPC.

(b) The patent fulfilled the requirements of sufficiency of disclosure.

(c) The effective date of the patent was its filing date, since the claimed subject-matter was not entitled to priority.

(d) Example 2 of D6 did not anticipate the claimed subject-matter.

(e) The claimed subject-matter was inventive, since the prior art did not contain any hint pointing towards the ability of the claimed polymeric compounds to stabilise the active agents indicated in the claims against lactone formation.

V. With the statement setting out the grounds of appeal the appellant requested that the decision under appeal be set aside and that the patent be revoked.

VI. With a letter dated 27 July 2016 the patent proprietor (hereinafter the respondent) replied to the statement setting out the grounds of appeal. In this letter the respondent requested that the appeal be dismissed, and as an auxiliary measure, that the patent be maintained as amended on the basis of one of auxiliary requests 1 to 3 filed with the same letter.

VII. In a communication pursuant to Article 15(1) RPBA issued on 30 October 2018, the Board expressed *inter alia* its preliminary opinion that claims 1 and 3 of the main request did not fulfil the requirements of Article 76(1) EPC (see point 1.4 of the Board's communication).

VIII. With letter dated 30 October 2018, the respondent announced that it would not be represented at the oral proceedings.

IX. Oral proceedings took place on 29 November 2018. They were attended by the appellant only.

X. The appellant's arguments, as far as they are relevant for the present decision, may be summarised as follows:

Claims 1 and 3 as granted were directed to a use/method for stabilising a ring-opened 7-substituted-3,5-dihydroxyheptanoic acid or -heptenoic acid in general terms, i.e. against any degradation pathway, whereas the earlier application as filed solely disclosed the prevention of a specific degradation pathway, namely lactone formation. Accordingly, the claimed subject-matter represented an impermissible generalisation of the content of the earlier application as filed, contrary to the requirements of Article 76(1) EPC (see point 2.6 of

appellant's statement setting out the grounds of appeal).

XI. The respondent stated in writing that the appellant's objections under Article 76(1) EPC were without merit, and commented on several of the appellant's objections under Article 76(1) EPC. However, no arguments were presented by the respondent with regard to the appellant's specific objection based on an impermissible generalisation of the content of the earlier application as filed (see point X above).

XII. Requests

The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested in writing that the appeal be dismissed, or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 3 filed with letter dated 27 July 2016.

Reasons for the Decision

Main request (patent as granted)

1. Non-attendance of the respondent at the oral proceedings

As announced in its letter dated 30 October 2018, the respondent did not attend the oral proceedings. It also did not submit any comments on the Board's preliminary opinion set out in its communication dated 30 October 2018.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings were held without the respondent. By deciding not to attend the oral proceedings and not to file substantive arguments in reply to the Board's communication, the respondent has chosen not to take the opportunity to comment on the Board's opinion, either in writing or orally at the oral proceedings.

In the present case, the duly summoned respondent has to be treated as relying only on its written case.

2. Article 100(c) EPC in conjunction with Article 76(1) EPC

2.1 The subject-matter of independent claims 1 and 3 of the main request is directed to the use of a stabilising effective amount of at least one polymeric compound as defined therein (hereinafter referred to as "polymeric compound") for stabilising an active component in a composition for the treatment of dyslipidemia comprising, as an active component, at least one ring-opened 7-substituted-3,5-dihydroxyheptanoic acid or ring-opened 7-substituted-3,5-dihydroxyheptenoic acid, or a pharmaceutically acceptable acid salt thereof (hereinafter referred to as "active agent").

In other words, the amount of polymeric compound present in the composition provides for

- any form of stabilisation, i.e. it is not limited to the prevention of one specific degradation pathway, i.e. lactone formation (see page 5, lines 20 to 28 of D13); and

- the claimed stabilisation solely concerns the active

agent present in the composition, i.e. it is not directed at stabilising any other component of the composition or at providing a stabilised composition as a whole.

2.2 In the Board's view, the subject-matter of independent claims 1 and 3 does not fulfil the requirements of Article 76(1) EPC, because the earlier application as filed fails to provide a basis for the claimed stabilising effect of the polymeric compound on the active agent in general terms, i.e. in respect of any degradation pathway of the active agent other than lactone formation.

In particular and as already outlined in point 1.4 of the Board's communication of 30 October 2018, the passage on page 5, lines 26 to 28 of D13 as well as claim 1 of D13 define the claimed "stabilizing effective amount" of the polymeric compound as an amount which provides for a stabilised pharmaceutical composition as a whole, whereas these disclosures do not provide any support for a link between this stabilizing amount and the stabilisation of a specific component present in the claimed composition, i.e. the active agent. Such a link may be found on page 5, lines 20 to 24 of D13, albeit solely and exclusively in connection with the stabilisation of the active agent against the specific degradation pathway of lactone formation.

2.3 The respondent did not submit any comments with regard to this objection which had been raised by the appellant in its statement setting out the grounds of appeal (see point X above) and subsequently taken up by the Board in its communication dated 30 October 2018.

2.4 Accordingly, the Board concludes that the subject-matter of claims 1 and 3 of the main request consists in a generalisation which introduces subject-matter extending beyond the content of the earlier application as filed, contrary to the requirements of Article 76(1) EPC.

Auxiliary request 1

3. Auxiliary request 1 differs from the main request only by deletion of claims 13 and 14 and the renumbering of claim 15, i.e. claims 1 and 3 of this request are identical to claims 1 and 3 of the main request. Hence, the conclusions drawn above for the main request apply *mutatis mutandis* to this request.

Thus, auxiliary request 1 does not meet the requirements of Article 76(1) EPC.

Auxiliary request 2

4. Auxiliary request 2 corresponds to the main request with the exception that the term "as an active component" has been replaced by the expression "as active component" in claims 1 and 3. Hence, the conclusions reached for the main request apply *mutatis mutandis* to this request which therefore does not meet the requirements of Article 76(1) EPC.

Auxiliary request 3

5. Auxiliary request 3 is a combination of the amendments performed in auxiliary requests 1 and 2. Accordingly, the same objections apply, *mutatis mutandis*, as to auxiliary requests 1 and 2.

As a consequence, auxiliary request 3 does not meet the requirements of Article 76(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated