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Datasheet for the decision of 15 January 2019

Case Number: T 1824/17 - 3.3.07

Application Number: 12001737.1

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Language of the proceedings: EN

Title of invention:
Pharmaceutical composition comprising solifenacin

Applicant:
Alfred E. Tiefenbacher (GmbH & Co. KG)

Headword:
Solifenacin composition / TIEFENBACHER

Relevant legal provisions:
EPC Art. 54(2), 111(1)
EPC R. 103(1)(a)

Keyword:
Novelty - main request (yes)
Appeal decision - remittal to the department of first instance (yes)
Reimbursement of appeal fee - substantial procedural violation (no)

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Case Number: T 1824/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 15 January 2019

Appellant: (Applicant)	Alfred E. Tiefenbacher (GmbH & Co. KG) Van-der-Smissen-Strasse 1 22767 Hamburg (DE)
Representative:	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 29 March 2017 refusing European patent application No. 12001737.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

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

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. 12001737.1, published as EP 2 500 013 A1.

II. The decision of the examining division was based on a single set of claims filed with letter of 4 August 2015.

Claim 1 of the main request read as follows:

"1. Pharmaceutical composition in the form of a solid oral dosage form comprising solifenacin or a pharmaceutically acceptable salt thereof as a pharmaceutically active ingredient and excipient granules, wherein the composition is obtained by a process comprising the method steps of:

i) preparing excipient granules from at least two pharmaceutical excipients by wet granulation,

ii) mixing said excipient granules with the pharmaceutically active ingredient and optionally with additional pharmaceutical excipients to obtain a mixture,

iii) subjecting the mixture obtained in method step (ii) to compression, and

iv) optionally milling the compacted mass obtained in method step (iii), optionally mixing the milled mass with pharmaceutical excipients, and subjecting the milled mass/mixture to compression."

III. The following documents were among those cited in the first instance examination proceedings:

D1: EP 1 911 444 A1
D2: US 2010/136110 A1
D3: US 2010/233260

IV. In its decision the examining division came to the conclusion that the subject-matter of claims 1-4, 6, 7 of the main request lacked novelty vis-à-vis the following disclosures of documents D1 to D3:

(a) D1: example 8, read in conjunction with example 3;
(b) D2: comparative example 3, read in conjunction with example 1;
(c) D3: examples 1, 3 as well as comparative example 1.

In particular, the examining division considered that the solifenacin-containing coated microparticles of example 3 of D1 (forming part of the quickly disintegrating tablets described in example 8 of D1) as well as the granular pharmaceutical composition of comparative example 3 of D2 and the granulated, solifenacin-containing products of examples 1, 3 and comparative example 1 of D3 were covered by the term "the pharmaceutically active ingredient" referred to in step (ii) of independent claims 1 and 7.

V. With the statement setting out the grounds of appeal, the appellant requested that

(a) the appealed decision be set aside,
(b) that a European patent be granted based on the main request underlying the impugned decision, and
(c) that the appeal fee be reimbursed.

As an auxiliary measure, the appellant requested that the case be remitted to the examining division for further prosecution of the patent application on the basis of an auxiliary request filed with letter of 7 February 2014.

VI. In a communication pursuant to Article 15(1) RPBA issued on 5 December 2018, the Board expressed its preliminary opinion that the examining division did not commit a substantial procedural violation which would justify reimbursement of the appeal fee.

The Board further observed that none of D1 to D3 appeared to anticipate the subject-matter of the claims of the main request. The Board also remarked that it intended to remit the case to the examining division for further prosecution, as the examining division had rejected the application solely upon novelty of the main request, leaving other issues including inventive step outstanding.

VII. With letter of 12 December 2018 the appellant provided additional comments in support of the alleged substantial procedural violation committed by the examining division. The appellant further indicated that it withdrew its request for oral proceedings, provided that the Board confirmed its positive opinion on novelty.

VIII. With letter of 20 December 2018 the Board notified the appellant that oral proceedings appointed for 14 January 2019 had been cancelled.

IX. The appellant's arguments can be summarised as follows:

(a) Alleged substantial procedural violation committed by the examining division:

The examining division committed an error of judgment by wrongly interpreting the feature "with the pharmaceutically active ingredient" in method step (ii) of claims 1 and 7 of the main request. Based on this claim interpretation the examining division came to the conclusion that the claimed subject-matter lacked novelty over documents D1 to D3 and refused the patent application.

The examining division neither explained in its decision why the applicant's interpretation of the process feature (ii) of claims 1 and 7 of the main request was not convincing, nor did it provide an adequate reasoning of its own claim interpretation therein. This lack of reasoning constituted a substantial procedural violation since it deprived the appellant of the possibility to challenge the examining division's claim interpretation. Consequently, the appellant was entitled to have its appeal fee reimbursed.

(b) Novelty of the claimed subject-matter vis-à-vis documents D1 to D3:

The claims of the main request were novel over D1 to D3 on the account of process step (ii) defined in claims 1 and 7.

Reasons for the Decision

1. Alleged substantial procedural violation committed by the examining division

1.1 In the statement setting out the grounds of appeal the appellant requested reimbursement of its appeal fee on the basis of an alleged substantial procedural violation committed by the examining division. In the appellant's view, the examining division had not adequately reasoned its decision to refuse the present application, in that it had failed to provide an adequate reasoning of its claim interpretation which had led to the refusal of the present application.

1.2 The Board notes in this regard that the decision under appeal contains a detailed reasoning why the subject-matter of claims 1-4, 6, 7 of the main request did not fulfil the requirements of Article 54 EPC. Furthermore, in its decision the examining division explicitly referred to the relevant arguments of the appellant including its interpretation of the features of process step (ii) of claims 1 and 7 (see page 6, paragraph 2 to page 7, paragraph 1 of the decision), and explained in a detailed manner why the appellant's interpretation of these features were not deemed convincing.

Hence, the Board considers that the reasoning provided in this decision is sufficient enough for the appellant to understand why its submissions were not considered convincing and to enable it to base its grounds of appeal on the relevant issues. The fact that the examining division might have interpreted the features of process step (ii) of claims 1 and 7 in a wrong

manner might constitute an error of judgment, but this error alone does not amount to a substantial procedural violation. Nor does the failure of the appealed decision to indicate the reasons for interpreting these features in a different manner than the appellant constitute a substantial procedural violation, since this deficiency is not of such significance that it results in the appellant being deprived of the possibility of properly preparing the grounds for appealing the contested decision.

Accordingly, the Board concludes that the examining division did not commit a substantial procedural violation which would justify reimbursement of the appeal fee.

2. Main request - Article 54 EPC

2.1 Novelty of the claimed subject-matter vis-à-vis documents D1 and D2

2.1.1 According to the decision under appeal, example 8 in conjunction with example 3 of D1 and comparative example 3 in conjunction with example 1 of D2 anticipate the subject-matter of claims 1-4, 6 and 7 of the main request.

2.1.2 Example 8 of D1 discloses solid oral dosage forms in the form of quickly disintegrating tablets comprising solifenacin succinate and excipient granules. The dosage forms are obtained by a process comprising inter alia the following method steps:

(a) preparing the excipient granules from the two excipients mannitol and maltose by wet granulation,

(b) mixing said excipient granules with solifenacin succinate-containing particles to obtain a mixture,

(c) subjecting the mixture obtained in step (b) to compression to form the corresponding tablets.

The details of the preparation of the solifenacin succinate-containing particles referred to in step (b) above are described in example 3 of D1 to which example 8 makes explicit reference (see paragraph [0071] of example 8 of D1 in conjunction with paragraph [0060] of example 3 of D1). The particles are formed by spraying a mixed liquid comprising solifenacin succinate and polyethylene glycol 6000 onto crystalline cellulose particles, and applying further coating layers thereon.

2.1.3 Comparative example 3 of D2 equally describes solid oral dosage forms in the form of rapidly disintegrating tablets comprising solifenacin succinate and excipient granules. The dosage forms are obtained by a process comprising inter alia steps (a) to (c) as defined above.

The details of the preparation step (a) are disclosed in example 1 of D2, to which comparative example 3 makes explicit reference in paragraph [0265].

As regards the solifenacin succinate-containing particles referred to in step (b), these are manufactured in accordance with paragraph [0262] of comparative example 3 of D2. They are prepared in the same manner as the succinate-containing particles of example 3 of D1.

2.1.4 According to the decision under appeal, the processes described in example 8 of D1 (read in conjunction with

example 3 of D1) and in comparative example 3 of D2 (read in conjunction with example 1 of D2) comprise all of the mandatory process steps mentioned in independent claims 1 and 7 of the main request. In particular, the examining division considered that the solifenacin succinate-containing particles prepared in accordance with example 3 of D1 and paragraph [0262] of comparative example 3 of D2 were covered by the term "the pharmaceutically active ingredient" referred to in process step (ii) of independent claims 1 and 7 of the main request (see page 5 and page 7, third paragraph of the decision).

2.1.5 In the statement setting out the grounds of appeal the appellant contested the examining division's finding. In its view, the process mentioned in claims 1 and 7 of the main request differed from the processes described in example 8 of D1 (read in conjunction with example 3 of D1) and in comparative example 3 of D2 (read in conjunction with example 1 of D2) in terms of the pharmaceutically active ingredient employed in step (ii) of this process. In particular, granules comprising the pharmaceutically active ingredient and additional pharmaceutical excipients such as the solifenacin succinate-containing particles disclosed in example 3 of D1 and paragraph [0262] of comparative example 3 of D2 were not comprised by this term.

2.1.6 Accordingly, as a first step, the meaning of the term "the pharmaceutically active ingredient" in step (ii) of claims 1 and 7 of the main request needs to be determined.

The Board notes in this regard that step (ii) of these claims employs the definite article "the" when referring to the pharmaceutically active ingredient,

and thereby establishes a direct link with its antecedent mentioned in the second and third line of claim 1, that is "solifenacin or a pharmaceutically acceptable salt thereof as a pharmaceutically active ingredient". In view of the use of the expression "as" in this context, the definition of the term "pharmaceutically active ingredient" referred to in step (ii) of claims 1 and 7 is confined to the compound solifenacin or a pharmaceutically acceptable salt thereof (hereinafter referred to as "solifenacin (salt)") as such, whereas compositions comprising solifenacin (salt) and a further, distinct component such as a pharmaceutical excipient are not encompassed by this term.

The Board further observes that this interpretation of the term "the pharmaceutically active ingredient" is in line with the disclosure contained in the description of the present application (see in particular the examples of the application).

2.1.7 It follows that the process mentioned in claims 1 and 7 of the main request differs from the processes for preparing the tablets of example 8 of D1 (read in conjunction with example 3 of D1) and comparative example 3 of D2 (read in conjunction with example 1 of D2) in that the solifenacin (salt) as such is mixed with the excipient granules prepared in step (i) (and the additional pharmaceutical excipients, if present). Accordingly, D1 and D2 do not anticipate the subject-matter of process claim 7.

2.1.8 As regards the subject-matter of claim 1, the aforementioned difference in terms of the processes is not sufficient by itself to establish novelty thereof vis-à-vis D1 and D2, given the fact that claim 1 is a

claim directed to a product defined inter alia by a certain process. Hence, in accordance with the established case law of the boards of appeal, the process steps (i) to (iii) of claim 1 can only render the product obtained by this process distinct from the tablets described in example 8 of D1 (read in conjunction with example 3 of D1) and in comparative example 3 of D2 (read in conjunction with example 1 of D2) (hereinafter referred to as "prior art tablets"), if differences in terms of the process features result in differences in the properties of the claimed product.

2.1.9 Therefore, as a second step, it needs to be established whether the prior art tablets as such differ from the claimed oral dosage forms or not.

(a) The prior art tablets are composed of a compressed mass, wherein this mass corresponds to a mixture of

(i) excipient granules falling within the definition given in step (i) of claim 1,
(ii) and cellulosic particles coated with several layers, wherein the first, most inner layer contains solifenacin succinate.

(b) The oral dosage forms in accordance with present claim 1, on the other hand, comprise compressed matter which is composed of a mixture of

(i) excipient granules as defined in step (i) of claim 1, and
(ii) the pharmaceutically active ingredient solifenacin (salt) as such.

Thus, the compressed mass of the prior art tablets

differs from the compressed mass of the claimed dosage forms in terms of the second component of the mixture forming the mass. Whereas in the case of the claimed dosage forms, this component solely consists of the pharmaceutically active ingredient per se, the second component of the compressed mass of the prior art tablets comprises solifenacin succinate as part of a first layer coated on a cellulosic particle comprising further excipients.

In view of this difference in the compressed masses of the products, the Board finds that the subject-matter of claim 1 is novel over D1 and D2. By the same token the same conclusion applies to the dependent claims of claim 1.

2.2 Novelty of the claimed subject-matter vis-à-vis document D3

2.2.1 Examples 1 and 3 as well as comparative example 1 of D3 disclose tablets comprising two layers.

The first layer is composed of a compressed mass of a mixture of

(a) magnesium stearate and
(b) granules prepared from two excipients (macrogol 8000 and PEO) and additionally from the pharmaceutically active ingredient tamsulosin (see paragraph [0004] of D3) by wet granulation.

The second layer consists of a compressed mass of a mixture of magnesium stearate and granules, wherein the latter contain solifenacin succinate, maltose and mannitol.

Accordingly, the Board considers that the tablets described in D3 do not contain excipient granules in accordance with claim 1, as the granules of the first layer of the tablets disclosed in D3 comprise the pharmaceutically active agent tamsulosin, whereas those of the second layer contain the pharmaceutically active ingredient solifenacin succinate. Hence, already for this reason, the claimed subject-matter is novel over D3.

2.3 Overall conclusion on novelty

In view of the foregoing considerations, the Board concludes that none of D1 to D3 anticipates the subject-matter of the claims of the main request.

3. Remittal

3.1 The primary function of an appeal is to consider whether the decision issued by the first-instance department was correct. Hence, a case is normally remitted if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the boards in cases where a first-instance department takes a decision against a party having regard to only some issues decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues addressed is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

3.2 The observations above apply in full to the present case, since the examining division solely decided on novelty of the subject-matter of the set of claims filed with letter of 4 August 2015 (main request), leaving other essential issues including inventive step outstanding.

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. The request for reimbursement of the appeal fee is refused.

The Registrar: The Chairman:

B. Atienza Vivancos J. Riolo

Decision electronically authenticated