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Datasheet for the decision of 4 April 2019

Case Number: T 0754/14 - 3.3.01

Application Number: 07755989.6

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Language of the proceedings: EN

Title of invention:
OSMOTIC DRUG DELIVERY SYSTEM COMPRISING RELEASE ENHANCING AGENT

Patent Proprietor:
Supernus Pharmaceuticals, Inc.

Opponent:
Sandoz AG

Headword:
Treprostinil/SUPERNUS

Relevant legal provisions:
EPC Art. 123(2)
RPBA Art. 13

Keyword:
Amendments - main request, auxiliary request V: extension beyond the content of the application as filed (yes)
Late-filed auxiliary requests I to IV - justification for late filing (no)

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Case Number: T 0754/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 4 April 2019

Appellant: (Patent Proprietor)	Supernus Pharmaceuticals, Inc. 1550 East Gude Drive Rockville, MD 20850 (US)
Representative:	Walcher, Armin Louis, Pöhlau, Lohrentz Patentanwälte Postfach 30 55 90014 Nürnberg (DE)
Respondent: (Opponent)	Sandoz AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 6 February 2014 revoking European patent No. 2010189 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	R. Hauss
Members:	M. Pregetter
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 2 010 189 is based on European patent application No. 07755989.6, filed as an international application published as WO 2007/127216.

II. Claim 1 of the patent as granted reads as follows:

"1. An oral sustained release osmotic pharmaceutical delivery system comprising a highly water-soluble drug with a short half-life ranging from several minutes to three hours, and at least one release enhancing agent, wherein said drug is a prostacyclin."

III. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).

IV. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division revoking the patent. In the decision under appeal the opposition division had found that the set of claims as granted (main request) contravened Article 123(2) EPC. Auxiliary requests I to VI were found not to meet the requirements of Article 83 EPC.

V. With its statement setting out the grounds of appeal, the appellant re-submitted auxiliary requests I to VI.

The reply of the opponent (respondent) to the statement setting out the grounds of appeal, dated 23 October 2014, was sent to the appellant on

5 February 2016.

With a letter dated 29 November 2016, the appellant filed auxiliary requests I to V, replacing auxiliary requests I to VI filed with the grounds of appeal.

Claim 1 of auxiliary request V reads as follows:

"1. An oral sustained release osmotic pharmaceutical delivery system comprising a highly water-soluble drug, and at least one release enhancing agent, wherein said drug is treprostinil diethanolamine, and wherein said releasing agent is sodium lauryl sulfate.

VI. In a communication pursuant to Article 15 RPBA, dated 31 October 2018, the board provided, *inter alia*, its preliminary opinion that the introduction of new dependent claims, not present in the set of claims as granted, was not in accordance with Rule 80 EPC.

VII. Oral proceedings were held on 4 April 2019. During the oral proceedings, the appellant submitted new auxiliary requests I to IV, replacing auxiliary requests I to IV of 29 November 2016.

VIII. The arguments of the appellant may be summarised as follows:

Main request - amendments

Claim 1 of the application as filed defined an osmotic delivery system for highly water-soluble drugs. There was no limitation to a drug having a water solubility of at least about 30 mg/ml. Page 4, second paragraph, described the invention by stating that it dealt with the delivery of drugs that exhibited incomplete and

erratic release from osmotic dosage forms. It was then explicitly stated that "such drugs may be exemplified by prostacyclins". This passage provided a clear basis for the replacement of the functional definition of "drugs exhibiting an erratic or an incomplete release profile when formulated in a standard osmotic delivery device" by a structural definition, i.e. the term "prostacyclin". The subject-matter of claim 1 of the main request was thus based on the application as filed.

Admission of claim requests

The filing of auxiliary requests I to V with its letter dated 29 November 2016 could not be seen as the submission of late-filed auxiliary requests. The subject-matter of these requests corresponded to what had been requested in the statement setting out the grounds of appeal, see page 2, first paragraph. Claim 1 of auxiliary request V related specifically to treprostinil diethanolamine. The half-life range had been deleted to avoid redundant information.

As far as auxiliary requests I to IV filed during the oral proceedings were concerned, the only change was the deletion of one or two dependent claims. The deletion of the dependent claims had no impact on the discussion of issues relating to the independent claims. Consequently, such deletions did not give rise to to issues that justified a postponement of oral proceedings or necessitated a further search. The late filing of these requests was due to a misunderstanding in the communication with the US client.

Auxiliary request V - amendments

The basis for the subject-matter of claim 1 of auxiliary request V could be found in example 5 of the application as filed. The headings of the example and of Table 4 were the basis for the combination of treprostinil diethanolamine with sodium lauryl sulfate as release enhancing agent. The tablets of example 5 contained further excipients; however, a functional relationship existed exclusively between treprostinil diethanolamine and sodium lauryl sulfate. A person skilled in the art knew that the further excipients could be varied and various amounts of sodium lauryl sulfate employed. Furthermore, it could be seen from Table 3 that it was the absence or presence of a release enhancing agent which was responsible for the differences in release patterns. Osmotic release devices as such were well known. The inventive concept relied solely on the combination of drug and release enhancing agent, i.e. treprostinil diethanolamine and sodium lauryl sulfate, for which a basis was given in example 5.

IX. The arguments of the respondent may be summarised as follows:

Main request - amendments

Claim 1 of the main request had no basis in the application as filed. From page 5, which gave a summary of the invention, it was clear that there were two mandatory main features: a water solubility of more than 30 mg/ml of the drug, and the occurrence of an erratic or an incomplete release profile when the drug was formulated in a standard osmotic delivery device. The introduction of the generic class of prostacyclines could not make these features redundant. Prostacyclines include compounds with a wide range of substituents

leading to varying properties. The passage in paragraph 2 of page 4, relied on by the appellant, did not describe the invention, but related to the explanation of the problem underlying the invention.

Admission of claim requests

None of the auxiliary requests had been filed in due time. The sets of claims submitted with the letter dated 29 November 2016 had been filed, in fact, about two and a half years after the term for filing the grounds of appeal had lapsed. Furthermore, due to the introduction of treprostinil diethanolamine and the deletion of the half-life range, claim 1 of auxiliary request V differed considerably from what had been requested earlier.

Concerning auxiliary requests I to IV filed during the oral proceedings of 4 April 2019, it had to be noted that the appellant had had several months to react after receiving the communication pursuant to Article 15 RPBA. This communication contained a clear indication of the board's preliminary opinion on Rule 80 EPC. The filing of requests overcoming this objection only during the oral proceedings was not justified.

Auxiliary request V - amendments

The subject-matter of claim 1 of auxiliary request V was an inadmissible intermediate generalisation of a single example. The active agent, treprostinil diethanolamine, was only disclosed in the examples of the application as filed. While example 5 relied on sodium lauryl sulfate as single release enhancing agents, the other examples contained a further release

enhancing agent, namely meglumine. It was clear from the description, e.g. page 4, second paragraph, line 6, that the drug interacted with further components and elements of the oral sustained release osmotic delivery system. As further components and elements, the description discussed, *inter alia*, the osmotic agents (page 10, paragraph 2) and the size of the opening in the semi-permeable wall (page 11, last sentence). The intermediate generalisation in claim 1 was therefore not allowable.

X. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the case be remitted to the opposition division for consideration of the ground for opposition under Article 100(a) EPC of lack of inventive step on the basis of the patent as granted (main request) or, alternatively, of one of the sets of claims of auxiliary requests I to IV dated 4 April 2019, or of auxiliary request V filed with its letter dated 29 November 2016. Alternatively, the appellant requested that the opposition be rejected and the patent be maintained as granted, or, alternatively, that the patent be maintained in amended form in accordance with one of the sets of claims of auxiliary requests I to IV dated 4 April 2019, or of auxiliary request V filed with its letter dated 29 November 2016.

XI. The respondent (opponent) requested that the appeal be dismissed. It further requested that auxiliary requests I to IV dated 4 April 2019, auxiliary request V filed with the letter dated 29 November 2016, and documents D17 to D27 not be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - amendments (Article 123(2) EPC)*

Claim 1 as granted defines an oral sustained release osmotic pharmaceutical delivery system combining technical features to be found in claims 1, 4, 6 and 7 of the application as filed. When relying on the claims as filed, there is no basis for the deletion of the term "exhibiting an erratic or an incomplete release profile when formulated in a standard osmotic delivery system", present in claim 1 as filed but absent from claim 1 as granted. Consequently, the claims as filed cannot provide any basis for the subject-matter of claim 1 of the main request.

The appellant relied on the second full paragraph of page 4 of the description as filed in support of the subject-matter of claim 1 of the main request.

The passage in question states that the present invention "overcomes" inadequacies of the prior art in the delivery of drugs that are highly soluble in water but have challenges in release from osmotic dosage forms. "While there are several approaches to deal with the delivery of poorly soluble drugs in osmotic delivery systems, none of these approaches deals with the problem of an incomplete and erratic release of medicinal agents which are highly water soluble but of limited solubility and release in the presence of other components of a dosage form. Such drugs may be exemplified by prostacyclins".

From this passage it can be understood that there are drugs that undesirably exhibit incomplete and erratic release. It can furthermore be inferred that the problem also arises with highly water-soluble drugs. The problem is furthermore linked to "the presence of other components of a dosage form". Such a link must necessarily be a result of the nature of the other components (such as the components of a "standard osmotic delivery system") and the physico-chemical properties of the drug. Prostacyclins cover compounds which may be substituted in different ways, resulting in different physico-chemical properties. While all of these differently substituted compounds fall within the generic group of prostacyclins due to a common core structure, it cannot be automatically assumed that they will show that same interaction with "other components of a dosage form". Consequently, the deletion of the passage "exhibiting an erratic or an incomplete release profile when formulated in a standard osmotic delivery system" results in the claim also covering prostacyclin derivatives that, when tested in the standard osmotic delivery system, exhibit a normal and/or complete release profile. An oral sustained release osmotic pharmaceutical delivery system comprising such prostacyclins has, however, no basis in the application as filed. No other text passage has been invoked by the appellant.

Consequently, the deletion of the terms "exhibiting an erratic or an incomplete release profile when formulated in a standard osmotic delivery system" extends the subject-matter of claim 1 of the main request beyond the content of the application as filed.

Claim 1 of the main request thus contravenes the

requirement of Article 123(2) EPC.

3. *Admission of claim requests (Article 13 RPBA)*

3.1 *Auxiliary requests I to IV*

Auxiliary requests I to IV as filed with the submission dated 29 November 2016 all contained at least one new dependent claim which did not correspond to any claim in the patent as granted.

According to established case law, the addition of a dependent claim is not appropriate or necessary to overcome a ground for opposition as set out in Rule 80 EPC (see "Case Law of the Boards of Appeal", 8th edition 2016, section IV.D.4.1.4a)).

As a matter of fact, the respondent had objected to the introduction of these new dependent claims under Rule 80 EPC in its letter dated 24 February 2017, i.e. more than two years prior to the oral proceedings.

Furthermore, in the communication pursuant to Article 15 RPBA, the board had given a preliminary opinion on the matter for auxiliary requests I to III. This communication was issued five months prior to the oral proceedings.

The appellant was thus made aware of the objections under Rule 80 EPC well in advance of the oral proceedings, at least for auxiliary requests I to III. However, it chose not to react until the actual day of the oral proceedings.

The filing of amended claim sets at this late stage of the proceedings is not excluded per se. Their

admission, however, is at the discretion of the boards (Article 114(2) EPC and Article 13(1) RPBA). Criteria to be taken into consideration by the boards when exercising their discretion are, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (R 16/09, point 2.2.4). These criteria are not exhaustive, and the boards also have considered aspects such as the reasons for the new submission or the extent of the amendments (R 6/17, point 3.6). As observed by the Enlarged Board of Appeal (R 16/09, points 2.2.11 and 2.2.12), it pertains to the discretion of the boards of appeal to decide which criteria are to have precedence according to the circumstances of the case. In the exercise of discretion on the admissibility of amended claims, the criterion of lateness may even outweigh the criterion of the subject-matter to be considered.

However understandable the problems in internal communication between a representative and client may be, in the present case covering a considerable period of time, they cannot justify the late filing of these requests.

The filing of claim requests overcoming the objection pursuant to Rule 80 EPC only during the oral proceedings, and thus at the latest possible point in time, cannot be regarded as complying with the duty of the parties to act diligently. The appellant could reasonably have been expected to replace the claim requests that were indicated to be deficient under Rule 80 EPC well in advance of the oral proceedings unless it intended to address the objection by way of argument. The statement made by the appellant that the deletion of the dependent claims did not change the

subject-matter of the independent claims is misplaced, since it amounts to saying that the board and the respondent should have anticipated the amendments and thus should have made up for the appellant's failure to clarify its requests prior to the oral proceedings. In these circumstances, the criterion of lateness outweighs the criterion of the subject-matter to be considered. In any case, the late submission is clearly not in the interest of procedural efficiency or fairness.

Consequently, the board, exercising its discretion under Article 13(1) RPBA, did not admit auxiliary requests I to IV into the proceedings.

3.2 *Auxiliary request V*

In its reply to the statement setting out the grounds of appeal, the respondent requested that the case not be remitted to the opposition division for the assessment of inventive step. Furthermore, in the context of its inventive-step approach, the respondent addressed issues concerning drug solubility and questioned whether the data provided in figures 6 and 7 of the patent in suit could be taken into account, especially for drugs other than treprostinil diethanolamine (letter dated 23 October 2014, points 1.3 and 4.1). Auxiliary request V, being limited to treprostinil diethanolamine and a specific release enhancing agent, takes this line of argument into account.

The filing of auxiliary request V can thus be seen as a reaction to the submission of the respondent. Furthermore, it was filed well in advance of the oral proceedings and did not delay the decision.

Consequently, the board, exercising its discretion under Article 13(1) RPBA, admitted auxiliary request V into the proceedings.

4. *Auxiliary request V - amendments (Article 123(2) EPC)*

The appellant identified example 5 as the basis for the subject-matter of claim 1 of auxiliary request V.

The question to be answered is thus whether this single example may be generalised by claiming a particular active agent (treprostinil diethanolamine) in combination with a particular release enhancing agent (sodium lauryl sulfate) contained in an oral sustained release osmotic pharmaceutical delivery system, in the absence of any further mandatory technical features.

In order to be acceptable, an intermediate generalisation has to be the result of unambiguous information that a skilled person would draw from a review of (i) the specific embodiment to be generalised and (ii) the content of the application as filed. Furthermore, features thus extracted must not be inextricably linked with further features of that embodiment.

Example 5 does, in fact, disclose an oral sustained release osmotic pharmaceutical delivery system comprising treprostinil diethanolamine and sodium lauryl sulfate.

It is, however, not directly and unambiguously derivable from the application as filed that the specific drug and the specific release enhancing agent used in example 5 are not inextricably linked with the

further features in the form of the further components of this example.

Looking at the content of the application as filed, the skilled person would consider several passages. One of these passages can be found on page 4, second paragraph, stating that the invention aims at tackling the "problem of an incomplete and erratic release of medicinal agents which are highly water soluble but of limited solubility and release in the presence of other components of a dosage form". These "other components" include the osmotic agents (page 10, second paragraph).

Thus, according to the description of the application as filed, the release of a drug from an osmotic pharmaceutical delivery system depends, *inter alia*, on the other components, such as the osmotic agents, of a dosage form. Consequently, it cannot be excluded that there exists a functional relationship and thus an inextricable link, between the specific osmotic agent, the specific drug and the specific release enhancing agent of example 5.

The appellant argued, with reference to Table 3 of the application as filed, that for comparing osmotic delivery systems according to the invention with osmotic delivery systems not falling within the invention, merely the release enhancing agent can be identified as decisive. The board cannot draw any conclusion from that table, since it relates to delivery systems containing the same drug (treprostinil diethanolamine) and the same osmotic agent (Maltrin M150). No changes due to different osmotic agents can be deduced from such experimental data. The presence, or absence, of a functional relationship between the specific drug and the specific osmotic agent can thus

not be assessed based on the data of Table 3.

In sum, the description suggests that there are interactions between the drug and various components of the osmotic delivery system. A functional relationship between the drug and other components, such as the osmotic agent, cannot thus be ruled out. Consequently, there is no direct and unambiguous basis for the extraction of a specific drug in combination with a specific release enhancing agent from a single example.

Treprositinil diethanolamine is only disclosed in the examples of the application as filed. No further mention of this specific drug is made.

Consequently, there is no basis in the application as filed for the subject-matter of claim 1 of auxiliary request V which therefore contravenes the requirement of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

T. Buschek R. Hauss

Decision electronically authenticated