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Datasheet for the decision of 31 May 2022

Case Number: T 2725/19 - 3.3.07

Application Number: 10790053.2

Publication Number: 2442821

IPC: A61K38/00, A61K9/00, A61M11/00

Language of the proceedings: EN

Title of invention:
SAFE DESMOPRESSIN ADMINISTRATION

Patent Proprietor:
Serenity Pharmaceuticals LLC

Opponent:
Ferring B.V.

Headword:
Safe desmopressin administration/ SERENITY

Relevant legal provisions:
EPC Art. 123(2), 53(c), 111(1)
RPBA 2020 Art. 25, 11

Keyword:
Main request - Added subject-matter (No)
Main request - Method of treatment (No)
Remittal to the opposition division

Decisions cited:
G 0005/83, T 2003/08, T 1758/15, T 0773/10, T 1966/16, T 0547/14, T 0275/15

Catchword:

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Beschwerdekammern

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Case Number: T 2725/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 31 May 2022

Appellant: (Patent Proprietor)	Serenity Pharmaceuticals LLC 7025 Langer Drive, Suite 205 Mississauga, ON L5N 0E8 (CA)
Representative:	Simmons & Simmons City Point One Ropemaker Street London EC2Y 9SS (GB)
Respondent: (Opponent)	Ferring B.V. Polaris Avenue 144 2132 JX Hoofddorp (NL)
Representative:	Prins, Hendrik Willem Arnold & Siedsma Bezuidenhoutseweg 57 2594 AC The Hague (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 August 2019 revoking European patent No. 2442821 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 2 442 821 was granted on the basis of 1 claim.

Independent claim 1 as granted read as follows:

"1. A composition of matter comprising an intranasal desmopressin dose in the form of a plume ejected over a time interval from the nozzle of a metered dose spray device, the plume comprising a volume of moving droplets together defining a conical volume having a central axis and an apex at the nozzle of the spray device, wherein the droplet density (number of droplets per unit volume) within the conical volume increases in a direction normal to the axis, the droplets together comprising: (a) between 1 µg and 5.0 µg desmopressin; or (b) about 0.75 µg desmopressin, the plume serving to increase contact of the droplets with intranasal luminal mucosal surfaces, wherein said droplets further comprise:
(a) an oil-in-water emulsion; and
(b) a cyclopentadecanolide permeation enhancer, for use in a method of inducing an antidiuretic effect in a patient, the method comprising intranasally administering the composition to induce antidiuresis for less than about six hours."

II. An opposition was filed under Article 100(a), (b) and (c) EPC against the granted patent on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, was excluded from patentability under Article 53(c) EPC and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on 14 sets of claims, namely the claim as granted as the main request, and 13 auxiliary requests 1.

IV. According to the decision under appeal, the main request met the requirements of Article 53(c) EPC. None of the requests met the requirements of Article 123(2) EPC, since there was neither a hint in the application as filed to choose the claimed dose range or the claimed duration of antidiuretic effect over other alternatives, nor a clear pointer to the claimed combination of the dose range and the duration of antidiuretic effect.

V. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement of grounds of appeal dated 9 January 2020, the appellant submitted a main request and auxiliary requests 1-14.

Claim 1 of auxiliary request 6 read as follows:

"1. A composition of matter comprising an intranasal desmopressin dose in the form of a plume ejected over a time interval from the nozzle of a metered dose spray device, the plume comprising a volume of moving droplets together defining a conical volume having a central axis and an apex at the nozzle of the spray device, wherein the droplet density (number of droplets per unit volume) within the conical volume increases in a direction normal to the axis, the droplets together comprising about 0.75 µg desmopressin, the plume serving to increase contact of the droplets with intranasal luminal mucosal surfaces, wherein said droplets further comprise:

(a) an oil-in-water emulsion; and
(b) a cyclopentadecanolide permeation enhancer,
for use in a method of inducing an antidiuretic effect in a patient, the method comprising intranasally administering the composition to induce antidiuresis for less than about six hours.

VI. A communication from the Board, dated 9 March 2022, was sent to the parties. In it, the Board expressed its preliminary opinion that the main request did not meet the requirements of Article 123(2) EPC.

VII. Oral proceedings took place on 31 May 2022. During oral proceedings the appellant made auxiliary request 6 his new main request.

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

Main request (former auxiliary request 6) - Article 123(2) EPC

Basis for the main request could be found in original claims 1, 2, 13, 14 and 19 with the most preferred permeation enhancer from the description. The dose of 0.75 µg was clearly identified as a preferred feature by virtue of it appearing as dependent claim 13. The dose of 0.75 µg was thus derived from original claim 13, and was also disclosed in the description in paragraph [0023]. The fact that the application covered other doses was not relevant. Claiming the 0.75 µg dose did not provide the skilled person with new technical information.

An antidiuretic effect of less than six hours was also clearly identified as a preferred feature by virtue of

it appearing as dependent claim 19. It was also particularised in the description in paragraph [0024], as the "relatively brief period of antidiuresis", in contrast to "a more extended period such as between about four and seven hours". It was noted that paragraph [0024] also referred to "from two to four hours", but this was a subset of the relatively brief period of less than six hours. Thus, the skilled person understood from paragraph [0024] that the invention could induce antidiuresis for either relatively brief periods of less than about six hours, or more extended periods of between about four and seven hours. Moreover claiming a relatively brief period of antidiuresis of less than six hours made complete technical sense when one appreciated the purpose of the invention as explained in the introductory section of the application. Thus there were indeed pointers in the application as filed for the claimed duration of the antidiuresis effect.

Since there were clear pointers for the claimed dose and the claimed antidiuresis effect, their combination was derivable from the original application.

Main request - Article 53(c) EPC

Claim 1 was a product claim and could not be objected to under Article 53(c) for this reason.

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

Main request (former auxiliary request 6) - Article 123(2) EPC

The dose was a specific selection among two different possibilities given in dependent claims 12 and 13, namely between 0.5 µg and 0.75 µg.

Moreover, the duration of the antidiuretic effect of less than six was also a selection among several possibilities, given in claims 19, claim 20 (two to four hours), and claim 21 (four to seven hours). Moreover, there was no pointer to the claimed duration of less than six hours, based on the original application in paragraph [0024] that the periods of antidiuresis were to be brief. The term "brief" was not defined and the periods of claims 19, 20 and 21 were presented as equal alternatives.

The combination of the dose and the duration of the antidiuretic effect was therefore a combination among multiple possibilities for which there was no basis in the original application.

Main request - Article 53(c) EPC

The desmopressin composition forming the plume geometry provided the therapeutic effect, and this plume geometry was the result of the interaction between the desmopressin composition and the spray device. Claim 1 was a composition for use of inducing an antidiuretic effect in a patient, and was therefore a medical use claim, and medical use claims were only patentable under Article 53(c) EPC if the claimed product used in the medical treatment was a substance or composition. That was not the case here, as the claimed plume resulted from the claimed interaction between the device and the formulation, and hence the subject matter was non-patentable. Reference was made to decisions T 2003/08, T 1758/15 and T 773/10.

X. Requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution should the main request, filed as auxiliary request 6 with the statement setting out the grounds of appeal on 9 January 2020, or one of auxiliary requests 7-14 filed with the same letter, be allowable under Article 123(2) EPC.

The respondent requested that the appeal be dismissed. As an auxiliary measure they requested that the case be remitted to the opposition division for further prosecution in case one of the appellant's requests complied with the requirements of Articles 123(2) and 53(c) EPC.

Reasons for the Decision

1. Main request - Article 123(2) EPC

1.1 The feature "0.75 µg desmopressin"

The subject-matter of original dependent claims 10-13 reads as follows:
"10. A composition according to any one of the preceding claims wherein the droplets together comprise between about 0.05 µg and 1.0 µg desmopressin.
11. The composition of claim 10 wherein the droplets together comprise between about 0.2 µg and 1.0 µg desmopressin.

12. A composition according to any one of claims 1-10 wherein the droplets together comprise about 0.5 µg desmopressin.
13. A composition according to any one of claims 1-12 wherein the droplets together comprise about 0.75 µg desmopressin."

Accordingly, the dose of "0.75 µg desmopressin" is disclosed directly and unambiguously in original claim 13 and is one of the preferred alternative doses.

1.2 The feature "to induce antidiuresis for less than about six hours"

The subject-matter of original claims 15 and 19-21 reads as follows:

15. A method of inducing an antidiuretic effect in a patient, the method comprising intranasally administering to the patient a composition according to any one of claims 1-14.
19. A method according to any one of claims 15-18 wherein the administration induces antidiuresis for less than about six hours.
20. The method of claim 19 wherein the administration induces antidiuresis for between about 2 and 4 hours.
21. A method according to any one of claims 15-18 wherein the administration induces antidiuresis for between about 4 and 7 hours.

Accordingly, the antidiuresis effect of less than 6 hours is disclosed directly and unambiguously in orignal dependent claim 19, and is one of the two preferred alternatives presented in the original claims, the subject-matter of claim 20 constituting a further sub-range of claim 19.

1.3 Combination of features "0.75 µg desmopressin" and "to induce antidiuresis for less than about six hours"

Both features are individually claimed in the original claims. They both represent preferred alternative options and their combination is derivable directly and unambiguously from the original claims. Accordingly the main request does not infringe the requirements of Article 123(2) EPC.

2. Main request - Article 53(c) EPC

2.1 Claim 1 of the main request was objected to by the respondent under Article 53(c) EPC as being a method of treatment by therapy and thus excluded from patentability. According to the respondent, medical use claims are only patentable if the claimed product used in the medical treatment is a substance or composition, while in the present case the claimed plume results from the claimed interaction between the device and the formulation.

2.2 Article 53(c) EPC provides that European patents shall not be granted in respect of "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

2.3 In the present case, the claimed subject-matter relates to a "composition of matter comprising an intranasal desmopressin dose in the form of a plume... for use in a method of inducing an antidiuretic effect in a patient, the method comprising intranasally

administering the composition to induce antidiuresis for less than about six hours" . Claim 1 is therefore a purpose-limited product claim, while the exclusion from patentability under Article 53(c) EPC only applies to method claims, i.e a different category of claim. It does not apply to a product claim as specified in Article 53(c) EPC, second sentence.

The objection that the claimed subject-matter is excluded from patentability pursuant to Article 53(c) EPC cannot therefore succeed with regard to claim 1 of the main request.

2.4 The arguments brought forward by the respondent, as well as their citation of decisions T 2003/08, T 1758/15 and T 773/10 relate rather to the assessment of novelty of medical use claims under Article 54(4) and 54(5) EPC, in particular to the question of whether the claimed subject-matter relates indeed to a substance or composition instead of a device or an apparatus. This issue does not concern the exclusion from patentability of medical methods under Article 53(c) EPC. The benefits of Articles 54(4) and 54(5) EPC are indeed exclusively reserved to substances and compositions.

2.4.1 In the decision T 2003/08 of 31 October 2012, the Board concluded that the claimed "specific ligand for human immunoglobin" used in a second medical use type claim was a chemical entity (see point 19), hence a substance or composition in the sense of decision G 5/83, and accordingly that the claims had to be interpretated as claims to a second medical use wherein the indication of the purpose ("for the treatment of a patient suffering from dilated cardiomyopathy") was not merely descriptive and needed consideration when assessing the

patentability, in particular novelty and inventive step (see point 21); hence this decision dealt with whether the treatment feature had to be neglected or taken in consideration when assessing novelty and never questioned the patentability of the claim under Article 53(c) EPC.

2.4.2 The decision T 1758/15 dealt with a "biodegradable filler material for injection and for use in radiation treatment...". The Board concluded that the claimed filler material was not a substance or composition in the sense of Article 54(5) EPC and that the use defined in the claim could not be regarded as a differentiating feature with regard to the assessment of novelty (see point 5 February 2010). A possible prohibition of the product claim under Article 53(c) EPC was neither questioned nor discussed in this case.

2.4.3 In the decision T 773/10, claim 1 was directed to a particular dialysis membrane for the treatment of multiple myeloma. The question was whether the applicant could benefit from Art 54(5) EPC as the specific use of the dialysis membrane was not comprised in the state of the art. The Board concluded that the membrane was a device and not a substance or composition, and that the provisions of Article 54(5) EPC did not apply. Again, a possible exclusion of the product claim pursuant to Article 53(c) EPC was neither questioned nor discussed in this case.

2.5 Accordingly, claim 1 of the main request does not contain subject-matter which is excluded from patentability pursuant to Article 53(c) EPC.

3. Remittal to the opposition division

Both parties have requested that the case be remitted to the opposition division for further prosecution in case one of the appellant's requests complied with the requirements of Articles 123(2) and 53(c) EPC.

The Board notes indeed that the main request has not yet been examined with regard to other requirements of the EPC, such as sufficiency of disclosure, novelty and inventive step, since the decision of the opposition division only relates to Articles 123(2) EPC and 53(c) EPC. Under Article 111(1) EPC, the Board may in the present case either proceed further with the examination of the remaining grounds for opposition, or remit the case for further prosecution of said further grounds.

Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. The Board holds that such special reasons are apparent in the present case. The provision of Article 11 RPBA 2020 has to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also T 1966/16, point 2.2 of the reasons, T 547/14 points 7.1 and 7.2, and T 275/15 point 4.). This principle would not be respected if the Board were to conduct a complete examination of the opposition.

Consequently, the case is remitted to the opposition division on the basis of the main request, filed as

auxiliary request 6 with the letter of 9 January 2020, for further prosecution.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated