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Datasheet for the decision of 10 April 2019

Case Number: T 2225/16 - 3.3.01

Application Number: 12753843.7

Publication Number: 2734209

IPC: A61K31/7004, A61K33/00, A61K33/04, A61K33/14

Language of the proceedings: EN

Title of invention:
INTRANASAL ADMINISTRATION OF AGENTS WITH PRO-INFLAMMATORY ACTIVITY FOR THE THERAPY OF NEUROLOGICAL DISORDERS

Applicant:
Salvinelli, Fabrizio
Salvinelli, Beatrice
Salvinelli, Emanuele
D'Eramo, Alessandra

Headword:
Intranasal therapy/SALVINELLI

Relevant legal provisions:
EPC Art. 111(1), 123(2)

Keyword:

Amendments - allowable (yes)
Appeal decision - remittal to the department of first instance (yes)

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Beschwerdekammern

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Case Number: T 2225/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 10 April 2019

Appellants: (Joint Applicants)

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Decision under appeal:

Decision of the Examining Division of the European Patent Office posted on 14 April 2016 refusing European patent application No. 12753843.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman	A. Lindner
Members:	M. Pregetter
	M. Blasi

Summary of Facts and Submissions

I. The present appeal lies from the decision of the examining division refusing European patent application No. 12 753 843.7, which had been filed as an international application published as WO 2013/011536.

II. The decision under appeal deals solely with issues under Article 123(2) EPC.

III. With the statement setting out the grounds of appeal the appellants (applicants) have submitted sets of claims of a main request and of two auxiliary requests. Oral proceedings were requested in the event that the board would consider refusing any of the requests on file.

IV. The board issued a communication pursuant to Rule 100(2) EPC giving the preliminary opinion that the subject-matter of claim 1 of the main and first auxiliary requests did not fulfil the requirement of Article 123(2) EPC and that there were clarity issues with the second auxiliary request under Article 84 EPC. A preliminary positive opinion on compliance with Article 123(2) EPC for the set of claims of the second auxiliary request was given. The board stated its intention to remit the case to the examining division if a set of claims fulfilling the requirements of Articles 123(2) and 84 EPC would be filed.

V. With their letter of reply of 17 December 2018, the appellants filed sets of claims of an amended second auxiliary request and of a third auxiliary request. In response to the information by the board of a discrepancy between the clean and marked up versions concerning the wording of the claims of the third

auxiliary request, the appellants confirmed with letter dated 23 January 2019, received in electronic form on 24 January 2019, that the clean copy was meant and a corrected marked up version was provided.

The appellants requested "*that the Board of Appeal consider the claims of the ... third auxiliary request or, in a less preferred alternative, the claims of the ... amended second auxiliary request. In the event that one of these two requests is considered allowable, the Appellant would not further prosecute the previous requests*".

No objections against a possible remittal were presented.

VI. Claim 1 of the third auxiliary request reads as follows:

"1. A product consisting of distilled water or of an aqueous solution having an osmolality not higher than 130% of the blood plasma osmolality for administration on the nasal-paranasal mucous membrane, for use in the therapy and prophylaxis of pathologies of the nervous system by means of a stimulation of the endogenous production of inflammatory mediators selected from the group consisting of NGF, neurotrophin-3, neurotrophin-4, serotonin, substance P, heparin, ECF-A, wherein said administration on the nasal-paranasal mucous membrane is carried out by dispensing an amount of product per second (PEL) comprised between 2.0 g/sec and 15 g/sec for a dispensing time (ET) comprised between 2.0 sec and 75 sec, with the proviso that the mathematical product of ET and PEL does not go beyond 150 g of dispensed product per each administration, wherein said product is selected from the group

consisting of: distilled or bidistilled water, sterile tap water, physiological solution (containing NaCl from 0.9% to 0.01% by weight, with or without the addition of glucose), Ringer solution, Ringer lactate solution, Hartmann solution, sulphur solution (in water or distilled water, with concentration from 0.1 mg to 10 mg of H_2S per litre), ionized alkaline water (having pH comprised between 8 and 11), deionised water and combinations thereof,
wherein said administration on the nasal-paranasal mucous membrane is carried out with a daily frequency comprised between 1 and 6 times a day."

Claim 1 of the amended second auxiliary request reads as follows:

"1. A product consisting of distilled water or of an aqueous solution having an osmolality not higher than 130% of the blood plasma osmolality for administration on the nasal-paranasal mucous membrane, for use in the therapy and prophylaxis of pathologies of the nervous system by means of a stimulation of the endogenous production of inflammatory mediators selected from the group consisting of NGF, neurotrophin-3, neurotrophin-4, serotonin, substance P, heparin, ECF-A, wherein said administration on the nasal-paranasal mucous membrane is carried out by dispensing an amount of product per second (PEL) comprised between 1.0 g/sec and 15 g/sec for a dispensing time (ET) comprised between 0.4 sec and 10 sec, with the proviso that the mathematical product of ET and PEL does not go beyond 150 g of dispensed product per each administration, wherein said product is selected from the group consisting of: distilled or bidistilled water, sterile tap water, physiological solution (containing NaCl from 0.9% to 0.01% by weight, with or without the addition

of glucose), Ringer solution, Ringer lactate solution, Hartmann solution, sulphur solution (in water or distilled water, with concentration from 0.1 mg to 10 mg of H_2S per litre), ionized alkaline water (having pH comprised between 8 and 11), deionised water and combinations thereof,
wherein said administration on the nasal-paranasal mucous membrane is carried out with a daily frequency comprised between 1 and 10 times a day."

VII. The following arguments by the appellants are relevant:

The claims of the third auxiliary request corresponded to those of the main request filed with the statement setting out the grounds of appeal, wherein in claim 1 the last passage had been deleted. The remaining passages were based on claim 1 as filed with adaptions concerning the specification of the medical use and the preferred set of values mentioned in the "Technical feature 6" of the description as filed in combination with claim 5 as filed. The remaining claims, being left unamended, were only renumbered.

The claims of the amended second auxiliary request corresponded to those of the second auxiliary request filed with the statement setting out the grounds of appeal with an amendment in the dependency of claim 3. Claim 3 now depended on any one of claims 1-2. Claim 1 of the amended second auxiliary request was based on claims 1, 2 and 5 as filed.

VIII. The appellants' requests (see point V. above) are understood by the board as a request for grant of a patent based on one of the sets of claims of the following requests in the following order: the third auxiliary request filed as clean version with letter

dated 17 December 2018 and as marked up version with letter dated 23 January 2019, the amended second auxiliary request filed with letter dated 17 December 2018, the main request filed with the statement of grounds of appeal, or the first or second auxiliary request filed with the statement of grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

2. The board decided to admit the amended second auxiliary request and the third auxiliary request filed by the appellants together with their letter dated 17 December 2018 into the proceedings pursuant to Article 13(1) RPBA.

3. The subject-matter defined in the claims of the third auxiliary request and of the amended second auxiliary request fulfils the requirement of Article 123(2) EPC for the following reasons:

3.1 Third auxiliary request

Claim 1 is based on a combination of claims 1 and 5 as filed with the most effective parameters in relation to tolerability as described under point 6. of table 4 on page 31 of the description as filed. The slight rewording regarding the formulation of the second medical use does not add subject-matter. Dependent claims 2 to 8 correspond respectively to dependent claims 4 and 6 to 11 as filed.

3.2 Amended second auxiliary request

Claim 1 is based on a combination of claims 1, 2, 3 and 5 as filed. The slight rewording regarding the formulation of the second medical use does not add subject-matter. Dependent claims 2 to 8 correspond respectively to dependent claims 4 and 6 to 11 as filed.

4. As the grounds for the refusal were overcome by the amendments made in the sets of claims of the third and the amended second auxiliary requests, the decision under appeal was to be set aside.

5. The decision under appeal concerned only the allowability of amendments under Article 123(2) EPC. The examining division has not come to a conclusion on any further issues. In these circumstances the board, exercising its power under Article 111(1), second sentence, EPC, considers it appropriate to remit the case to the examining division for further prosecution. The appellants had also not objected to the board's intention set out in the communication pursuant to Rule 100(2) EPC.

6. As the board does not refuse any of the appellants' requests submitted to it, the present decision can be made without holding oral proceedings.

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 based on the set of claims of the third auxiliary request filed as clean version on 17 December 2018 or on the amended second auxiliary request filed on 17 December 2018.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated