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Datasheet for the decision of 10 December 2020

Case Number: T 0492/16 - 3.3.04

Application Number: 09812187.4

Publication Number: 2334315

IPC: A61K38/08, A61P29/00

Language of the proceedings: EN

Title of invention:
Agents and methods for treatment of pain

Applicant:
NoNO Inc.

Headword:
Peptides for pain treatment/NONO

Relevant legal provisions:
EPC Art. 84, 54, 111(1)

Keyword:
Main request - clarity of dependent claims (yes), novelty (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0492/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 10 December 2020

Appellant: (Applicant)	NoNO Inc. 479A Wellington St. W Toronto, ON M5V 1E7 (CA)
Representative:	Green, Mark Charles Urquhart-Dykes & Lord LLP Euston House 24 Eversholt Street London NW1 1AD (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 October 2015 refusing European patent application No. 09812187.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	R. Morawetz
Members:	D. Luis Alves
	L. Bühler

Summary of Facts and Submissions

I. The applicant (appellant) filed an appeal against the examining division's decision refusing European patent application No. 09 812 187.4, entitled "*Agents and methods for treatment of pain*". The application was filed as an international application under the PCT with the international application number PCT/US2009/055786, published as WO 2010/028089.

II. In the decision under appeal the examining division dealt with a main request and three auxiliary requests.

With respect to the main request, the examining division held that the subject-matter of claim 1 lacked novelty as it was anticipated by the disclosure in document EP 1 884 521 ("document D1").

III. With the statement of grounds of appeal, the appellant submitted arguments *inter alia* in support of novelty of the claimed subject-matter and filed sets of claims of a main request and two auxiliary requests. The main request was identical to the main request considered in the decision under appeal and consisted of 12 claims.

Claims 1 and 2 read as follows:

"1. A peptide having a sequence of amino acids comprising YGRKKRRQRRRKLSSIESDV (SEQ ID NO: 1), or a tat peptide not attached or conjugated to another pain-reliving agent or other therapeutic agent, the tat peptide having a sequence of amino acids comprising YGRKKRRQRRR (SEQ ID NO: 2), for use in treating or

effecting prophylaxis of pain.

2. A peptide for the use of claim 1, wherein the peptide is administered at a dose below 1 mg/kg."

In their references to higher claims, dependent claims 3 to 12 also used the wording "A peptide for the use of claim(s) ...".

IV. The board issued a communication pursuant to Rule 100(2) EPC informing the appellant *inter alia* that, with respect to the main request, the board was inclined to agree with it on the issue of novelty over the disclosure of document D1 (Article 54 EPC). However, dependent claims 2 to 12 as drafted were not considered to be clearly dependent on claim 1 (Article 84 EPC). In the board's view, the wording "*A peptide for the use of claim 1*" did not specify which peptide was meant. Whereas the claims referred to the use (in treating or effecting prophylaxis) of claim 1, the peptide was not as defined in claim 1. Similar considerations applied to claims 3 to 12. If this issue was remedied, the board intended to remit the case to the examining division for further prosecution.

V. In response, the appellant filed sets of claims of a main request and two auxiliary requests, corresponding to the requests previously on file but with the dependent claims amended so as to address the clarity issue raised in the board's communication. Claim 1 of the main request was thus identical to claim 1 of the previous main request (see section III.) while claim 2 read:

"2. The peptide as defined in claim 1 for the use of claim 1, wherein the peptide is administered at a dose below 1 mg/kg."

Dependent claims 3 to 12 had corresponding amendments.

VI. The appellant requested in writing that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

Main request - claims 1 to 12

Amendments - Article 123(2) EPC

2. The board is satisfied that the requirements of Article 123(2) EPC are met.

Clarity of the claims - Article 84 EPC

3. Article 84 EPC stipulates that the claims shall define the matter for which protection is sought, and that they shall be clear.

4. The wording "*A peptide as defined in claim 1*" specifies that the peptide used according to claim 2 is as defined in claim 1. Similar wording is found in

claims 3 to 12 of the main request.

5. The board is satisfied that the lack of clarity it had noted in respect of the claims of the previous main request (see section IV. above) has been overcome. The claims are clear.

Novelty - Article 54 EPC

6. Claim 1 is directed to a therapeutic application of peptides comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2 in the treatment or prophylaxis of pain.

7. The disclosure of document D1 may be summarised as follows. It discloses fusion peptides comprising a component (I), which is a transporter peptide, and a component (II), which is a peptide that consists entirely of D-enantiomeric amino acids and inhibits the interaction between the neuronal N-methyl-D-aspartate receptor (NMDAR) and interacting proteins, and in particular inhibits the interaction between NMDAR and postsynaptic density-95 protein (PSD-95) (see paragraphs [0013] and [0019]). A particularly preferred peptide component (II) is derived from a portion of NMDAR binding to PSD-95, the most preferred being the D-enantiomeric amino acid sequence vdseisslk, referred to as SEQ ID NO: 31 in document D1 (see page 6, lines 8 to 18). Compared with the corresponding L-enantiomeric amino acids, the D-enantiomeric amino acids in retro-inverso order show increased resistance to proteolytic breakdown and thus increased bioavailability (see page 5, lines 32 to 35 and page 6, lines 47 to 49). Pharmaceutical compositions including the fusion peptides are intended generically for

providing a neuroprotective effect and specifically for treating or preventing a number of conditions including cerebral stroke, spinal cord injuries and neuropathic pain (see paragraph [0042]).

The experimental results in the examples show the effect of various peptides on cell death inhibition in the presence of NMDA. They compare the effect of D-enantiomeric retro-inverso fusion peptides with that of the corresponding L-enantiomeric forms. The experiments test the most preferred peptide component (II), i.e. the D-enantiomeric retro-inverso peptide having the amino acid sequence of SEQ ID NO: 31, in two variants that have different components (I). In Example 2 the peptide D-TAT-D-NR2B9c, consisting of the most preferred component (II) and a tat peptide as component (I), is compared with its L-enantiomeric form, referred to as L-TAT-L-NR2B9c, having the amino acid sequence of SEQ ID NO: 32, which is identical to the peptide having the amino acid sequence of SEQ ID NO: 1 in claim 1 at issue.

8. Document D1 thus discloses a peptide which has the sequence of SEQ ID NO: 1 recited in claim 1. The question to be addressed is whether this peptide is disclosed for use in the claimed therapeutic indication, i.e. the treatment or prophylaxis of pain.

9. In the decision under appeal, the examining division held that this document disclosed the therapeutic application of a peptide having the amino acid sequence depicted in SEQ ID NO: 1 in the treatment of pain. The examining division referred to the passages in paragraph [0042], Example 2, SEQ ID NO: 32 and claim 12, noting that Example 2 "*stated that neurons*

are exposed to inventive fusion peptides, particularly TAT-NR2B9c peptides in L-form (L-TAT-L-NR2B9c) […] and their D-form […]" (see decision under appeal, point 18). On the basis of this statement in Example 2, the examining division reasoned that the peptide in the L-form was a preferred embodiment of the fusion proteins of the invention. It held that claim 12 and paragraph [0042] disclosed the use of fusion peptides in the treatment of various conditions, including the treatment of neuropathic pain. The examining division concluded that only one selection (from the list of conditions) was necessary to arrive at the subject-matter of claim 1.

10. The board disagrees with this interpretation of the disclosure of document D1. In determining the disclosure of a document, in the present case document D1, each of its parts must be construed in the context of the document as a whole. In other words, no part of the document should be construed in isolation from the remainder of the document (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, section I.C.4.1). Furthermore, according to the established case law of the boards of appeal, in the absence of any pointer to a particular combination of features, that combination does not, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (*ibid.*, section II.E.1.6.1).

11. Claim 12 and paragraph [0042] of document D1 refer to the therapeutic applications of the inventive peptides, which are consistently defined throughout the document as comprising D-enantiomeric peptide component (II) (see for example the abstract, claim 1 and

paragraphs [0001], [0012] and [0013]).

12. Document D1 mentions the peptide having the amino acid sequence of SEQ ID NO: 1 just once - in Example 2. As stated in point 7. above, in this Example the peptides of the invention are compared with the L-enantiomeric peptides, i.e. control peptides which do not form part of the invention of document D1. For this reason, the board concludes that Example 2 does not disclose the L-enantiomeric peptide as being an embodiment of the invention, let alone a preferred embodiment of the invention of document D1. Therefore, Example 2 does not give the skilled person any pointer to a combination of that peptide with any of the conditions listed in claim 12 or paragraph [0042] of document D1. For these reasons, the peptide having the amino acid sequence of SEQ ID NO: 1 in claim 1 is not directly and unambiguously disclosed in document D1 for use in the treatment of neuropathic pain.

13. The board concludes that the disclosure in document D1 does not anticipate the subject-matter of claim 1 (Article 54 EPC). Claims 2 to 12, which refer back to claim 1, are likewise novel over that disclosure.

Remittal - Article 111(1) EPC

14. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board will decide on the appeal and, in this respect, it may either exercise any power within the competence of the department which was responsible for the decision under appeal or remit the case to that department for further prosecution.

15. Lack of novelty over the disclosure in document D1 was the sole reason given in the decision under appeal for not allowing the main request. The board has reviewed this finding. The examining division has not taken an appealable decision on any other patentability requirement with respect to the set of claims of the main request. Accordingly, in line with the appellant's request, the board decides to remit the case to the examining division for further prosecution.

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 on the basis of the set of claims of the main request filed with the appellant's letter dated 7 October 2019.

The Registrar: The Chair:

I. Aperribay R. Morawetz

Decision electronically authenticated