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Datasheet for the decision of 9 April 2021

Case Number: T 2944/18 - 3.3.04

Application Number: 11775737.7

Publication Number: 2629785

IPC: A61K38/04, C07K14/47

Language of the proceedings: ΕN

Title of invention:

Short peptides for enhancing muscle function

Applicant:

Ruprecht-Karls-Universität

Headword:

Short peptides/RUPRECHT-KARLS-UNIVERSITÄT

Relevant legal provisions:

EPC Art. 54(1), 54(3), 111(1) RPBA 2020 Art. 11

Keyword:

Novelty - main request (no) Remittal - special reasons for remittal

Decisions cited:

Catchword:

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Beschwerdekammern Boards of Appeal Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar GERMANY Tel. +49 (0)89 2399-0 Fax +49 (0)89 2399-4465

Case Number: T 2944/18 - 3.3.04

DECISION
of Technical Board of Appeal 3.3.04
of 9 April 2021

Appellant: Ruprecht-Karls-Universität

(Applicant) Grabengasse 1

69117 Heidelberg (DE)

Representative: Zwicker, Jörk

ZSP Patentanwälte PartG mbB

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 4 July 2018 refusing European patent application No. 11775737.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairwoman G. Alt
Members: B. Claes
E. Mille

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Summary of Facts and Submissions

- I. The applicant (appellant) appealed against the decision of the examining division to refuse European patent application No. 11 775 737.7, published as international patent application WO 2012/052177, entitled "Short peptides for enhancing muscle function".
- II. The examining division refused the application because they held that the subject-matter of claim 1 of a main request and of auxiliary requests 1 to 3 lacked novelty over the disclosure of document D3 (WO2010/118878), a document pursuant to Article 54(3) EPC.

Claim 1 of the main request read:

"1. A positive inotropic peptide comprising or consisting of a hydrophilic domain and/or one or more membrane penetration enhancing domains, and a domain derived of a S100Al protein with the amino acid sequence of SEQ ID NO 38 [sic], wherein said S100Al protein derived domain consists of 4 to 9 consecutive amino acids of the inotropic motif:

$$\Phi^{1}-\Phi^{2}-\Phi^{3}-\Phi^{4}-X^{5}-\Psi^{6}-L^{7}-[T/A]^{8}-\Psi^{9}-\Psi^{10}$$

and comprises at least the core motif $\Phi^4-X^5-\Psi^6-L^7$, wherein Φ and Ψ are in each instance independently selected from the group consisting of alanine, methionine, isoleucine, leucine, and valine, and X is any amino acid, wherein said peptide:

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- (a) has a length of between 10 to 40 amino acids, and
- (b) exhibits a positive inotropic action, and wherein said peptide
- (i) does not contain more than 9 continuous amino acids of SEQ ID NO: 39; or
- (ii) differs from the amino acids of SEQ ID NO: 39 by at least 80% outside of said S100A1 protein derived domain."
- III. With the statement of grounds of appeal, the appellant submitted a set of claims of a new main request and of nineteen new auxiliary requests. The new main request was identical to the main request dealt with by the examining division but for a correction of the wording "S100A" to "S100A1" in independent claim 2. In the context of claim 1 of the main request, the appellant argued inter alia in favour of novelty over the disclosure of document D3.

Claim 1 and claim 2 of auxiliary request 1 were amended compared with claims 1 and 2 of the main request by inserting at the end of the wording of these claims the feature "wherein the positive inotropic peptide is for medical use".

- IV. In a communication pursuant to Rule 100(2) EPC which accompanied the summons to oral proceedings, the board expressed the preliminary opinion that the subjectmatter of claims 1 and 2 of the main request lacked novelty over peptides disclosed in document D3, and questioned the admittance of the auxiliary requests into the proceedings (Article 12(4) RPBA 2007).
- V. In their reply to the communication, the appellant submitted further arguments in defence of novelty and arguments to justify the filing of the nineteen

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auxiliary requests with their statement of grounds of appeal.

- VI. After hearing the appellant at the oral proceedings, the Chair announced the board's decision.
- VII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the set of claims of the main request, or alternatively, on the basis of the set of claims of one of the new auxiliary requests 1 to 19, all requests filed with the statement setting out the grounds of appeal, or further alternatively, that the case be remitted to the examining division at least with a ruling that the reasons for refusing the application are not justified.

Reasons for the Decision

1. The appeal is admissible.

Main request - claim 1 - novelty (Article 54(3) EPC)

- 2. A positive inotropic peptide is claimed, comprising or consisting of a) a domain derived from the S100A1 protein (SEQ ID NO:38) and consisting of a peptide of defined length (4 to 9 amino acids) and comprising at least a particular core motif (positions 4, 5, 6 and 7), b) a hydrophilic domain and/or c) (a) membrane penetration domain(s) (see section II).
- 3. Document D3, a document pursuant to Article 54(3) EPC, discloses peptides comprising a muscle function enhancing amino acid sequence derived from the S100A1 protein which can be used *inter alia* in treating

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cardiac muscle disorders (see e.g. page 1, lines 5 to 9).

- 4. Claim 1 of document D3 is for a peptide comprising a positive inotropic amino acid sequence consisting of or comprising the amino acid sequence motif Φ_4 -X- Ψ -L-[T/A]- Ψ , being a 6-mer comprising the very core motif (here denoted Φ_4 -X- Ψ -L) of the 10-mer inotropic motif in the claim under consideration. Dependent claims 6 and 7 define the amino acids designated Φ and Ψ - like the claim under consideration - as being selected from the group of alanine, methionine, isoleucine, leucine and valine. Dependent claims 8 and 9 disclose particular 10-mer peptides comprising the 6-mer amino acid sequence motif defined in claim 1. Dependent claim 12 provides that the peptide as claimed also includes a hydrophilic motif and/or a membrane penetration enhancing motif domain, which according to claim 16 consists of 6 amino acids.
- As concerns the various 10-mer peptides of claims 8 and 9 and also disclosed on pages 29 to 34 of document D3, the appellant submitted, in a first line of argument, that these disclosed 10-mers were derived from S100A1 as a whole and therefore failed to comply with the predefined structural features of the domain derived from S100A1 in the claim under consideration. In particular, they comprised all 10 consecutive amino acid sequences of the 10-mer motif referred to in the claim, and not just the 4 to 9 which it stipulates. The appellant held in particular that it was "not valid to consider the VAAL motif in isolation of the rest of the sequence of [e.g.] SEQ ID NOS: 100 and 102".
- 6. However, the claim allows the domain which is derived from the S100Al protein and which consists of a

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predefined structure to be *comprised* in the claimed positive inotropic peptide as a whole. The peptides disclosed in claim 9 (e.g. SEQ ID Nos 4, 6, 7 and 50) and on pages 29 to 34 (e.g. SEQ ID Nos 100 and 102) of document D3 can therefore equally be considered to be *constituted* of the core motif (Φ^4 -X⁵- Ψ^6 -L⁷) of the 10-mer inotropic motif defined in the claim, fused to two 3-mers, which this claim does not exclude from also being present in the claimed peptide (due to the wording "comprising"). The board notes that the claim in fact does not define, and thus restrict, the sequence of the amino acids present in addition to the "core motif", and nor do the claims of document D3 refer to any of the domains and motifs referred to in these claims as "being derived from \$100A1" either.

- 7. Moreover, the peptide SEQ ID No 100 (I-I-L-V-A-A-L-T-I-A), for example, matches the definition of the S100A1 protein derived domain of claim 1 for the following reasons as well: it consists of an S100A1 derived peptide which consists of positions 4 to 10 in claim 1 (i.e. 7 consecutive amino acids, with position 8 being T, position 9 being isoleucine and position 10 being alanine) plus ("comprising") the trimer of I-I-L (undefined amino acid according to claim 1).
- 8. The appellant, in a second line of argument, submitted that, because document D3, unlike the application under consideration, failed to disclose that peptides comprising less than 10 amino acids of the muscle function enhancing motif of the claim possessed a positive inotropic action, the claimed peptides had to be held novel.
- 9. However, as the board has elaborated in point 6 above, this claimed positive inotropic peptide is not defined

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as to be excluded from comprising, in addition to the 9 or fewer amino acids of the muscle function enhancing motif recited in the claim, further amino acid sequences surrounding this motif. The appellant's functionality argument, which is in fact based on a peptide seen in isolation from the structural context, thus fails.

10. In view of the above considerations, the subject-matter of claim 1 lacks novelty over the disclosure in document D3 (Article 54(3) EPC).

Auxiliary request 1

- 11. Amended claim 1 and claim 2 of auxiliary request 1 (see section III) are "for medical use" of the positive inotropic peptide which is the subject-matter of claims 1 and 2 of the main request. The amendment thus shifts the category of the claims from product claims to first medical use claims.
- 12. The appellant argued that document D3 failed to disclose a therapeutic effect of peptides comprising less than 10 amino acids derived from the inotropic motif of an S100Al protein as claimed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and that therefore document D3 could not anticipate the therapeutic effect of the peptide as claimed for use in medicine.
- 13. The board concurs with the appellant that the reasons given in the decision under appeal for lack of novelty of subject-matter of structural product claims do not apply to claims for a first medical use of such products. The amendment thus overcomes the objections of the examining division which led to the refusal of

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the application. The decision under appeal therefore has to be set aside and the appeal is thus allowable.

Remittal (Article 111(1) EPC, Article 11 RPBA 2020)

- 14. According to Article 111(1) EPC, the board has the discretion either to exercise any power within the competence of the department which was responsible for the decision under appeal or to remit the case to that department for further prosecution.
- 15. In the present case, the decision under appeal deals exclusively with the requirement of novelty of the subject-matter of product claims, and accordingly is silent on the specific aspects of the novelty assessment of first medical use claims such as aspects relating to sufficiency of disclosure of the pertinent state of the art as now argued by the appellant. In the present circumstances, therefore, the board would thus, for the first time in the proceedings, have to examine sufficiency of disclosure of document D3, as a decision to review in this respect was lacking.
- 16. The board considers these circumstances to represent "special reasons" within the meaning of Article 11 RPBA 2020 justifying, in the exercise of its discretion as provided by Article 111(1) EPC, the remittal of the case to the examining division for further prosecution, namely in order to assess inventive step.

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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 auxiliary request 1 filed with the statement of grounds of appeal.

The Registrar:

The Chair:



I. Aperribay

G. Alt

Decision electronically authenticated