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Datasheet for the decision of 18 November 2010

Case Number: T 0861/07 - 3.3.04

Application Number: 97935396.8

Publication Number: 0922058

IPC: C07K 14/78

Language of the proceedings: EN

Title of invention:
Self-aligning peptides derived from elastin and other fibrous proteins

Applicants:
Protein Specialties Ltd., et al.

Opponent:
-

Headword:
Self-aligning peptides/PROTEIN SPECIALTIES

Relevant legal provisions:
EPC Art. 54, 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request: added subject-matter (no) - novelty (yes)"
"Remittal (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0861/07 **-** 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 18 November 2010

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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 December 2006 refusing European patent application No. 97935396.8 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chair: G. Alt
Members: R. Gramaglia
R. Moufang

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division issued on 27 December 2006, whereby European patent application No. 97935396.8, filed as International application No. PCT/CA97/00560 and published as WO-A-98/05685 (hereinafter referred to as the "WO application as filed"), was refused pursuant to Article 97(1) EPC 1973.

II. The reason given by the examining division for refusing the application was that the claims of the main request and of the first to third auxiliary requests then on file did not fulfil the requirements of Article 123(2) EPC, while the claims of the fourth auxiliary request then on file lacked novelty over document D1.

III. The appellants (applicants) filed an appeal against the decision of the examining division. The statement of grounds of appeal included new claims in the form of a new main request.

IV. The following documents are cited in the present decision:

D1 WO-A-94/14958;

D6 WO-A-95/24478;

D8 US-A-5,250,516;

D11 Urry D.W. et al., Biochemistry, Vol. 15, No. 18, pages 4083-4089;

D20 Gosline J.M., Symposia of the Society for Experimental Biology No. 34, Cambridge University Press, pages 331-357 (1980);

D26 Gray W.R. et al., Nature, Vol. 246, pages 461-466 (1973);

D27 Foster J.A. et al., J. Biol. Chem., Vol. 248, No. 8, pages 2876-2879 (1973).

V. In a communication accompanying the summons to oral proceedings, the board expressed its preliminary opinion, drawing the appellants' attention to documents D26 and D27, which came to the board's attention upon reviewing the references in document D20 (cited by the appellants).

VI. A reply dated 20 November 2009 was received from the appellants, which contained amended claims in the form of auxiliary requests I, II and III. The appellants expressed in this letter their intention to waive their right to oral proceedings, provided the board could acknowledge the novelty of any of the claim requests mentioned above, and remit the case to the examining division for assessment of the inventive step of this claim request.

VII. In a further communication dated 22 December 2009, the board expressed its view that the claims of, inter alia, auxiliary request II filed on 20 November 2009 fulfilled the requirements of both Articles 54 EPC and 123(2) EPC. Subsequently, the board cancelled the scheduled oral proceedings.

VIII. In reply to the board's further communication dated 14 September 2010, the appellants filed on 14 October 2010 a new main request, the claims of which were identical to those filed on 20 November 2009 as auxiliary request II.

IX. Independent claims 1 and 8 of this new main request read as follows:

"1. A prosthesis comprising two or more polypeptides selected from the group consisting of:

(A) a polypeptide consisting essentially of a portion of the amino acid sequence set forth in Figure 1B comprising at least three beta-sheet/beta-turn structures and wherein each of the beta-sheet structures comprises from 3 to 7 amino acid residues;

(B) a polypeptide consisting essentially of a portion of the amino acid sequence of an animal elastin comprising at least three beta-sheet/beta-turn structures and wherein each of the beta-sheet structures comprises from 3 to 7 amino acid residues;

(C) a polypeptide consisting essentially of a portion of the amino acid sequence of lamprin comprising at least three beta-sheet/beta-turn structures and wherein each of the beta-sheet structures comprises from 3 to 7 amino acid residues; and

(D) a polypeptide consisting essentially of a portion of the amino acid sequence of spider silk protein comprising at least three beta-sheet/beta-turn structures and wherein each of the beta-sheet structures comprises from 3 to 7 amino acid residues;

wherein the two or more polypeptides may be the same or different; and wherein the two or more

polypeptides each has a length of at least 10 amino acid residues."

"8. A polypeptide consisting of an amino acid sequence selected from the group consisting of amino acid residues 374-499, 19-160, 188-367 and 607-717 of Figure 1B."

Claims 2 to 7 related to specific embodiments of the prosthesis according to claim 1.

X. The submissions by the appellants (applicants), insofar as they are relevant to the present decision, can be summarized as follows:

Article 123(2) EPC

- Claim 1 was directed to a prosthesis comprising two or more polypeptides. This claim corresponded to claim 22 of the WO application as filed, wherein the term "material" has been replaced with "prosthesis". Basis for the term prosthesis was to be found on page 4, lines 28-30 and on page 18, lines 20-25 of the WO application as filed. Basis for the limitation in claim 1 specifying that each of the beta-sheet structures of the polypeptides specified in (A) to (D) comprised from 3 to 7 amino acid residues could be found on page 10, lines 28-31, of the WO application as filed. The further limitation over claim 22 of the WO application as filed that each of the two or more polypeptides had a length of at least 10 amino acid residues was supported by page 12, lines 4-5, of the WO application as filed.

– Claims 2 to 4 were identical to claims 23 to 25 of the WO application as filed, except for the replacement of the term "material" with "prosthesis".

– Claim 5 was based on both claim 6 and page 14, lines 27-32, of the WO application as filed, except for the replacement of the term "polypeptide" with "prosthesis".

– Claim 6 was based on claim 6 of the WO application as filed, except for the replacement of the term "polypeptide" with "prosthesis".

– Claim 7 was based on claim 4 of WO application as filed, except for the replacement of the term "polypeptide" with "prosthesis".

– Claim 8 was based on claim 6 of WO application as filed.

Novelty (Article 54 EPC)

– Document D1 nowhere disclosed a prosthesis comprising two or more polypeptides (being identical or different) selected from a portion of the proteins specified in (A) to (D) in claim 1.

– Both documents D26 and D27 dealt with early efforts to sequence elastin and disclosed tryptic peptides of elastin, without describing any use of

the disclosed peptides, let alone a prosthesis as claimed comprising such peptides.

– As for claim 8, it was directed to certain very specific sequences, which were not disclosed in documents D26 and D27.

– Accordingly, documents D1, D26 and D27 did not anticipate the claims of the new main request.

XI. The appellants (applicants) requested that the decision under appeal be set aside and that the case, based on the claims of the new main request submitted on 14 October 2010, be remitted to the examining division for assessment of the inventive step.

Reasons for the Decision

Article 123(2) EPC

1. Claim 1 corresponds to claim 22 of the WO application as filed, wherein the term "material" has been replaced with "prosthesis". Basis for the term prosthesis can be found on page 5, lines 9-27; page 17, lines 21-23; page 26, lines 6-7 and page 29, lines 7-8 of the WO application as filed. These passages show that the polypeptides of the invention become a material serving to manufacture a prosthesis. Basis for the limitation in claim 1 specifying that each of the beta-sheet structures of the polypeptides specified in (A) to (D) comprises from 3 to 7 amino acid residues can be found on page 10, lines 28-31, of the WO application as filed. The further limitation over claim 22 of the

WO application as filed that each of the two or more polypeptides have a length of at least 10 amino acid residues is supported by page 12, lines 4-5, of the WO application as filed.

Claims 2 to 4 correspond to claims 23 to 25 of the WO application as filed, with the change of the term "material" into "prosthesis" (see preceding paragraph).

Claim 5 is based on claim 6 of the WO application as filed with the change of the term "material" into "prosthesis" (see preceding paragraph).

Claim 6 differs from claim 5 of the new main request by the more restrictive term "consists of" rather than the expression "comprises" as in claim 5. This wording "consists of" in claim 6 is based on Example 1 of WO application as filed, dealing with the selection of several "Minimal Functional Units" ("MFUs"), namely, polypeptides exhibiting at least three beta-sheet/beta-turn (secondary) structures (see page 10, lines 18-26). Example 1 (see page 22, lines 5-6) discloses "MFU-1", corresponding to the amino acid sequence 374-499 of human elastin underlined in Fig. 1B. Other "MFUs" (exhibiting all at least three beta-sheet/beta-turn (secondary) structures) referred to in Example 1 (see page 23, lines 1-4 and page 14, lines 29-32) correspond to amino acid sequences 19-160, 188-367 and 607-717 of human elastin shown in Fig. 1B.

Claim 7 is based on claim 4 of the WO application as filed, with the term "polypeptide" (WO application) changed into "prosthesis" (see the comment about present claims 2 to 4, 5 and 6).

Independent claim 8 is based on claim 6 and on page 14, lines 28-32 of the WO application as filed.

2. In conclusion, the claims of the new main request comply with the requirements of Article 123(2) EPC.

Novelty
Claim 1
Document D1

3. The examining division concluded (see paragraph 5.2 of the decision under appeal) that document D1 disclosed a polypeptide falling under claim 1 of the fourth auxiliary request then on file. This document discloses a fusion protein of tropoelastin with N-terminal glutathione-S-transferase (see paragraph bridging pages 7-8), synthetic tropoelastin (see Figure 3) and tropoelastin fragments of 20 amino acids in length or longer (see first and second full paragraphs on page 6).

4. However, present claim 1 is directed to a prosthesis. The commonly accepted definition of a prosthesis is an artificial tissue or device that replaces a missing body part.

The passage in document D1 starting from page 15, line 15 through page 16, line 6 relates to the modes of administration of the compositions described in this document. On page 16, line 5, of document D1, it is stated that these compositions may be in the form of "surgical implants". The wording "surgical implant" is broader than the term "prosthesis" and thus the disclosure of a "surgical implant" does not amount to

the disclosure of a "prosthesis". Even upon narrow interpretation of the expression "surgical implants" in the light of page 8 of document D1 (see lines 30-36) as a slow-release vehicle or as a coating for protecting active agents during their transit through the stomach, these special embodiments of "surgical implants" cannot be regarded as the disclosure of artificial substitutes for a missing part of the body.

Nor does the statement in page 25, lines 18-20 of document D1 that "the tropoelastins and variants of this invention may be used in the repair and treatment of elastic and non-elastic tissues" represent a direct and unambiguous disclosure of a prosthesis, as referred to in claim 1.

Document D6

5. The examining division was of the opinion (see page 7 of the "Minutes") that document D6 disclosed copolymers falling under claim 1 of the 4th auxiliary request then on file. This document (see page 3, lines 10-14 and Table 1 on page 10) relates to copolymers based on repetitive units, namely VPGVG from elastin and GAGAGS from fibroin (i.e., silk protein) and their use as "implantable devices". These devices according to document D6 serve "as an aid to healing or as a temporary aid in surgical repair" (page 1, lines 14 to 18) in contrast to "permanent implants" which are made of "inert materials, such as metals, ceramics and plastics" (page 1, lines 12 to 14).

The board is not convinced that this disclosure of "implantable devices" in document D6 can be considered

as a clear and unambiguous disclosure of a "prosthesis" (see point 4 above, first paragraph).

6. Moreover, there is no evidence before the board that the copolymers described in document D6 exhibit the alternating beta-sheet/beta-turn structures (wherein each of the beta-sheet structures should comprise from 3 to 7 amino acid residues) required by present claim 1, which structures are illustrated in Figures 1E and 4C of the present application. Rather, the repeated beta-turns of the $(VPGVG)_8$, $(VPGVG)_{12}$ and $(VPGVG)_{16}$ portions of the copolymers described in document D6 (see Table 1 on page 10) results in a polypeptide with a coil structure, i.e., a β-spiral (helix) (see document D8, column 4, lines 39-41 and the term "β-spiral" in the legend to Fig. 8 on page 4088 of document D11). Moreover, even assuming that the $(GAGAGS)_2$, $(GAGAGS)_4$, $(GAGAGS)_6$ and $(GAGAGS)_8$ portions of these copolymers (see Table 1 on page 10) exhibit a beta-sheet structure, these sequences in any case exceed the 7 amino acid length required by present claim 1 (c.f. the wording "wherein each of the beta-sheet structures comprises from 3 to 7 amino acid residues").

In conclusion, the disclosure in document D6 is not novelty-destroying for the subject-matter of claim 1.

Documents D26 and D27

7. As foreshadowed in the communication accompanying the summons to the oral proceedings (see section V above), documents D26 and D27 disclose animal elastin tryptic peptides which inherently exhibit the beta sheet-beta turn structure according to claim 1 (see e.g., peptide

"T2" of 60 residues listed in Table 2 of document D26; see also document D27, page 2876, under "Materials and Methods", providing the technical information for the skilled person to prepare this tryptic peptide from elastin isolated from aortas of swine).

8. However, claim 1 of the new main request is limited to prostheses, whereas documents D26 and D27 do not disclose any prostheses.

Claim 8

9. Independent claim 8 covers specific amino acid sequences of Figure 1B which are not disclosed in any of documents D1, D6, D26 or D27.

10. Therefore, the subject-matter of independent claims 1 and 8 is novel over documents D1, D6, D26 and D27. This conclusion extends to dependent claims 2 to 7, relating to specific embodiments of the prosthesis according to claim 1.

Remittal

11. As decided in points 2 and 10 above, the claims according to the new main request meet the objections on which the appealed decision relies. Since all other substantive issues required by the EPC before a patent application may proceed to grant have not been examined yet, the board considers it appropriate to exercise its discretion under Article 111(1) EPC and to remit the case to the department of first instance 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 department of first instance for further prosecution on the basis of the claims of the new main request submitted on 14 October 2010.

The Registrar: The Chair:

P. Cremona G. Alt