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Datasheet for the decision of 12 December 2022

Case Number: T 0170/20 - 3.3.10

Application Number: 15155133.0

Publication Number: 2896411

IPC: A61L27/10, A61L27/46, A61L27/58

Language of the proceedings: EN

Title of invention:
Bioactive bone graft substitute

Applicant:
Orthovita, Inc.

Headword:
Bioactive bone graft substitute/Orthovita

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (yes) - unexpected improvement shown

Decisions cited:

Catchword:

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Beschwerdekammern

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Case Number: T 0170/20 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 12 December 2022

Appellant: (Applicant)	Orthovita, Inc. 45 Great Valley Parkway Malvern, PA 19355 (US)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 10 July 2019 refusing European patent application No. 15155133.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	J.-C. Schmid
	L. Basterreix

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application No. 15 155 133.0.

II. According to the examining division, the subject-matter of claim 1 of the main and auxiliary requests 1, 2, 3 and 5 lacks an inventive step starting from WO 02/058755 (document (1)) as the closest prior art to the invention. The improved performances of Vitoss Bioactive Foam (BA) with respect to Vitoss ® Foam bone graft substitute (VT), as shown in the experimental comparisons disclosed in documents (2) and (3) filed with the letter of 25 March 2019, are not caused by the feature distinguishing the claimed subject-matter from document (1). Therefore, the technical problem underlying the invention can only be seen in the provision of a further bone graft material composition. The claimed subject-matter is obvious in the light of document (1).

Furthermore, auxiliary request 4 was rejected for non-compliance with the requirements of article 76(1) and 123(2) EPC.

III. With the statement of the grounds of appeal dated 13 November 2019, the appellant filed again the main and auxiliary requests 1 to 3 and 5 pending before the opposition division and an amended auxiliary request 4 in order to overcome the objection of added subject-matter.

IV. With a letter dated 7 December 2022, in response to a communication of the board according to Article 15(1) RPBA, the appellant withdrew the main request, the former auxiliary request 1 becoming the new main request.

Claim 1 of this new main request reads as follows:

"1. A kit comprising:
(i) a bone graft material comprising resorbable collagen and resorbable calcium phosphate, wherein the bone graft material has micro-, meso-, and macro porosity; and
(ii) a container of bioactive glass, wherein the bioactive glass has a particle size of less than 150 µm."

V. The appellant requests that the decision of the examining division be set aside and a patent be granted on the basis of the main request filed on 7 December 2022, or subsidiarily, on the basis of one of auxiliary request 2 to 5 filed with statement of the grounds of appeal dated 13 November 2019.

Reasons for the Decision

Main request – inventive step

1. *Closest prior art*

Document (1) discloses an injectable bone-like implant capable of increasing its porosity *in situ* comprising at least one bone-like compound and at least one degradable component,
wherein said at least one bone-like compound is tricalcium phosphate, dicalcium phosphate, or

monocalcium phosphate, potassium phosphate, calcium sulphate, hydroxyapatite, bioactive glass or combinations thereof,
and wherein said at least one degradable component is gelatin, polyglycolic acid and other polyhydroxypolyesters, cross-linked albumin, collagen, proteins, polysaccharides, glycoproteins, or any combination thereof (claims 24, 25 and 30). This document represents the closest prior art to the invention.

2. *Technical problem*

The appellant defined the problem to be solved as the provision of an improved bone graft system in accordance with paragraph [0005] of the application as filed.

3. *Proposed solution*

The claimed solution to this technical problem is the kit according to claim 1 of the main request characterized by
- the choice of a mixture of calcium phosphate and bioactive glass as a bone-like material
- the choice of collagen as a degradable component,
- the bioactive glass being held in a separate container
- the bioactive glass having a particle size of less than 150 µm.

According to the appellant, the porosity of the graft material is a further distinguishing feature with respect to the disclosure of document (1).
However, the aim of document (1) is to increase *in situ* the porosity of the bone graft material. That means

that the bone graft material has already a certain degree of porosity before being injected to the bone.

4. *Success*

4.1 According to the appellant, combining calcium phosphate and bioactive glass accelerates resorption of the graft and healing of the bone, and enhances the strength of the formed bone to be similar to that of the natural bone. It provides improved compression resistance, flexibility, moldability or flowability when wetted. The osteostimulative, osteoconductive and osteoinductive properties are improved (also see paragraphs [008] to [0012], [0061], [0070] and [0071] of the application as filed).

Furthermore, maintaining the bioactive glass in a separate container before injection preserves the graft material from rapid collagen degradation - see also paragraph [0139] of the application as filed.

4.2 Concerning the first aspect, the examining division disregarded the comparison between Vitoss Bioactive Foam (BA), which according to documents (2) and (3) provided faster healing with formation of stronger bone than Vitoss ® Foam bone graft substitute (VT), since the improvement was to be attributed to the addition of 45S5 bioactive glass, which is not a distinguishing feature.

4.3 The board cannot agree, since the solution is characterised by the choice of a mixture of calcium phosphate **and** bioactive glass as the bone-like material. This combination is not disclosed in the closest prior art.

In fact, according to document (1), the bone-like material is either tricalcium phosphate, dicalcium phosphate or monocalcium phosphate, potassium phosphate, calcium sulphate, hydroxyapatite, bioactive glass or combinations thereof.

Therefore, Vitoss Bioactive Foam (BA), wherein the bone-like material is the combination of calcium phosphate and bioactive glass, is according to the present invention, whereas Vitoss ® Foam bone graft substitute (VT), wherein the bone-like material is calcium phosphate, represents the closest prior art.

4.4 The board in the light of documents (2) and (3) is convinced that the technical problem of improving the bone grafting system is solved by the proposed solution. It is therefore not necessary to examine the other improvements put forward by the appellant.

5. *Obviousness*

Document (1) does not disclose or teach that the **combination** of calcium phosphate with a bioactive glass with a particle size of less than 150 µm improves the property of the bone graft. The proposed solution to the problem of improving the bone graft system is therefore not obvious in the light of the document (1).

6. Hence, the subject-matter of claim 1 of the main request involves an inventive step (Article 56 EPC).

7. Lack of inventive step was the sole objection raised by the examining division against the subject-matter of the present main request.

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 with order to grant a patent in the following version:

Claims:

No. 1 to 9 filed with the letter of 7 December 2022

Description:

pages 1-31 filed with the letter of 7 December 2022

The Registrar: The Chairman:

L. Malécot-Grob P. Gryczka

Decision electronically authenticated