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Datasheet for the decision of 6 August 2024

Case Number: T 0346/22 - 3.3.10

Application Number: 11836764.8

Publication Number: 2632504

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Language of the proceedings: EN

Title of invention:
COMPOSITES OF HYDROXYAPATITE AND CALCIUM CARBONATE AND RELATED METHODS OF PREPARATION AND USE

Patent Proprietor:
Cap Biomaterials, LLC

Opponent:
Omya International AG

Headword:

Relevant legal provisions:
EPC Art. 56, 83, 123(2)

Keyword:

Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0346/22 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 6 August 2024

Appellant: (Opponent)	Omya International AG Baslerstrasse 42 4665 Oftringen (CH)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Respondent: (Patent Proprietor)	Cap Biomaterials, LLC 2485 Corporate Circle, Unit 1 East Troy, WI 53120 (US)
Representative:	Cabinet Becker et Associés 25, rue Louis le Grand 75002 Paris (FR)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 December 2021 concerning maintenance of the European Patent No. 2632504 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	A. Zellner
	F. Blumer

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the opposition division to maintain the European patent No. 2 632 504 in amended form on the basis of the main request then pending, said request being also the main request in these appeal proceedings (Article 101(3)(a) EPC).

II. Notice of opposition has been filed on the basis of Article 100(a) EPC for lack of novelty and lack of inventive step (Articles 54 and 56 EPC), Article 100(b) EPC for lack of sufficiency of disclosure, and Article 100(c) EPC for added subject-matter.

III. In the opposition proceedings the patent proprietor defended the patent in amended form. In the impugned decision the opposition division held that the main request met the requirements of Article 123(2) EPC, and that the subject-matter of claims 1 and 9 of this request was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). The opposition division further concluded that the composition according to claim 1 and the method according to claim 9 were novel in view of the disclosure of documents D2 and D8 (claim 1), and of documents D2, D7 and D8 (claim 9) (Article 54 EPC). According to the opposition division, the main request also met the requirements of Article 56 EPC, because the provision of the claimed subject-matter was based on an inventive step. Documents D2 (for claim 1) and D7 (for claim 9) were considered to be closest prior art. Document D13 was not admitted into the proceedings.

IV. In support of its appeal, the appellant (opponent) argued that the opposition division erred in their decision when holding the patent as maintained to fulfil the requirements of Article 123(2) EPC, the claimed invention to be sufficiently disclosed (Article 83 EPC), and the claimed subject-matter to be based on an inventive step (Article 56 EPC).

V. With its reply to the appellant's statement setting out the grounds of appeal the respondent (patent proprietor) requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of auxiliary requests 1 to 15, or 3a, 5a, 10a and 11a, filed with its reply.

VI. The board informed the parties in a communication under Article 15(1) RPBA about its preliminary opinion that the respondent's main request appeared to meet the requirements of Articles 123(2) and 83 EPC. The board further informed the parties about the points to be discussed during the oral proceedings, in particular in relation to inventive step.

VII. With letter dated 28 June 2024 the respondent submitted auxiliary requests 16 to 31 and provided further arguments in support of its requests.

VIII. Oral proceedings were held on 6 August 2024. At the end of the proceedings the decision was announced.

IX. Claims 1, 9 and 13 of the main request read as follows:

"1. A composition comprising a two-phase composite comprising a matrix phase comprising sintered hydroxyapatite and a discontinuous phase within said matrix phase, said hydroxyapatite comprising a Ca/P

ratio of 1.67, said discontinuous phase comprising a plurality of elongated calcium carbonate inclusions having a length dimension of 5 microns to 20 microns."

"9. A method of preparing a two-phase carbonated hydroxyapatite composition, said method comprising:

providing a hydroxyapatite material comprising an extraneous carbonatable calcium component, said carbonatable calcium component providing said hydroxyapatite material a Ca/P ratio greater than 1.67;

sintering said hydroxyapatite material;

and treating said sintered hydroxyapatite material with a carbon dioxide source to convert at least a portion of said carbonatable calcium component to a discontinuous calcium carbonate phase within a hydroxyapatite phase."

"13. A method of using elongated carbonate inclusions to affect the strength of a hydroxyapatite material, said method comprising:

providing a sintered hydroxyapatite material comprising a carbonatable calcium component, said carbonatable calcium component providing said hydroxyapatite material a Ca/P ratio greater than 1.67;

and contacting said sintered hydroxyapatite material and a carbon dioxide source, said contact at least partially sufficient to provide elongated carbonate inclusions randomly-oriented within said sintered hydroxyapatite material, said inclusions affecting the strength of said carbonated hydroxyapatite material;

wherein said affected strength may be gauged by crush-test compression and particle size data."

X. The following documents are referred to:

D2: Synthesis of Composite Biomaterials in the Hydroxyapatite-Calcite System, V.V. Smirnov et al., Doklady Chemistry, 2010, Vol. 432, Part 1, pages 151-154

D6: WO 01/83367 A2

D7: GB 2 349 877 A

D8: Development of graded hydroxyapatite/$CaCO_3$ composite structures for bone ingrowth, J Mater Sci: Mater Med (2007) 18:1817-1824

D9: WO 2012/057836 A2 (International application underlying the contested patent)

D13: Declaration by L. Shrimp, of CAP Biomaterials, filed 10 September 2021

D16: "Sintering", IUPAC Compendium of Chemical Terminology, 2014

XI. The appellant argued essentially as follows:

Claim 1 of the respondent's main request is not based on the application as filed and thus contains added subject-matter. Neither claim 1, nor claim 9 of this request, discloses the invention in a way sufficiently clear and complete for it to be carried out by a person skilled in the art. Finally, the subject-matter of independent claims 1, 9 and 13 was not based on an inventive step considering documents D2 and D7 as closest prior art. The main request does therefore not meet the requirements of Articles 123(2), 83 and 56 EPC.

XII. The respondent argued essentially as follows:

The main request fulfils all of the requirements of the EPC. In particular, claim 1 was based on claim 1 and the description of the application as filed. The patent also provided the person skilled in the art with sufficient information to provide a composition according to claim 1, as well as a method according to claim 9 of the main request. The disclosure of document D2 is closest prior art for the subject-matter of claims 1, and that of D7 for claims 9 and 13. The claimed subject-matter is inventive because the prior art does not suggest a composition and the methods as claimed.

XIII. The appellant (opponent) requests that the decision under appeal be set aside and that the European patent No. 2 632 504 be revoked.

XIV. The respondent (patent proprietor) requests that the appeal be dismissed or that the decision under appeal be set aside and the patent be maintained on the basis of any one of the following auxiliary requests:

- auxiliary requests 1 to 15, 3a, 5a, 10a and 11a as filed with the response to the grounds of appeal on 22 August 2022;
- auxiliary requests 16 to 31 as filed with letter dated 28 June 2024.

Reasons for the Decision

1. The appeal is admissible.

Main request (patent as maintained by the opposition division)

Amendments (Article 123(2) EPC)

2. According to the opposition division, claim 1 of the main request meets the requirements of Article 123(2) EPC. The opposition division came to the conclusion that the claim was based on the disclosure of claim 2 and paragraphs [0014], [0016], [0018] and [0028] of the application as filed (in this decision, reference is made to the published International Application underlying the contested patent, document D9, which was also relied upon by the parties).

3. The appellant argued that claim 1 as maintained did not find a basis in the application as filed.

In particular, the appellant argued by reference to claim 9 and paragraphs [0012], [0016] and [0035], that document D9 did not provide a basis for the feature that the carbonate inclusions are "*calcium*" carbonate inclusions. According to the appellant, this feature was disclosed in document D9 only in combination with a hydroxyapatite having a Ca/P ratio of more than 1.67. Amended claim 1, however, comprised the feature "*... hydroxyapatite comprising a Ca/P ratio of 1.67 ...*", rather than more than 1.67.

Furthermore, the appellant argued that the feature "*... said discontinuous phase comprising a plurality of elongated calcium carbonate inclusions having a length dimension of 5 microns to 20 microns*" was also only disclosed in D9 in combination with a hydroxyapatite material having a Ca/P ratio of more than 1.67. Neither claim 9, nor paragraph [0013] of D9 provided a basis for the addition of the feature.

4. The respondent disagreed and submitted that the Ca/P ratio was 1.67 in the hydroxyapatite matrix phase, whereas additional Ca was present in the discontinuous phase comprising the elongated calcium carbonate inclusions. According to the respondent, this increased the ratio in the composite - but not in the hydroxyapatite matrix phase - in line with the disclosure of D9. In support of its argumentation, the respondent referred to paragraphs [0010], [0012], [0014] and [0016], as well as [0018] and [0028] and to the examples of document D9.

5. The board comes to the following conclusions:

5.1 Claim 1 of the main request has been amended in the following way with respect to claim 1 of document D9 (amendments are highlighted by the board):

"A composition comprising a two-phase composite comprising a matrix phase comprising sintered hydroxyapatite ~~a sintered calcium phosphate component~~ and a discontinuous phase within said matrix phase, said hydroxyapatite comprising a Ca/P ratio of 1.67, said discontinuous phase comprising a plurality of elongated calcium carbonate inclusions having a length dimension of 5 microns to 20 microns."

5.2 The claimed composition thus comprises a two-phase composite which comprises a matrix phase and a discontinuous phase.

The matrix phase comprises sintered hydroxyapatite. Hydroxyapatite, $Ca_5(PO_4)_3(OH)$, has a Ca/P ratio of 1.67. This was undisputed.

The discontinuous phase is within the matrix phase. It

comprises a plurality of elongated calcium carbonate inclusions. These elongated calcium carbonate inclusions have a length dimension of 5 microns to 20 microns.

5.3 The claimed composition may thus well have a Ca/P ratio of more than 1.67, as argued by the appellant, since the Ca/P ratio of the matrix phase as such is 1.67, and since calcium is also present in the discontinuous phase of the composition, in the form of its carbonate as elongated carbonate inclusions having a length dimension of 5 to 20 microns. The ratio of 1.67 according to claim 1 clearly refers to the Ca/P ratio of the sintered hydroxyapatite, which is comprised in the matrix phase.

5.4 According to claim 1 as filed, the matrix phase comprises a sintered calcium phosphate component, which - according to claim 2 - is sintered hydroxyapatite with a Ca/P ratio selected of one of equal to about and greater than about 1.67. Claims 2 and 1 of document D9 thus provide a basis for a matrix phase comprising sintered hydroxyapatite with a Ca/P ratio of 1.67.

5.5 Paragraph [0010] of document D9 discloses a two-phase composite comprising a matrix phase comprising a sintered calcium phosphate component, which can be selected from sintered hydroxyapatite materials with a Ca/P ratio equal to about or greater than 1.67, and a discontinuous phase within the matrix phase. The discontinued phase comprises a plurality of elongated carbonate inclusions. In case the composite - not the hydroxyapatite - comprises a Ca/P ratio greater than 1.67, the discontinuous phase comprises a plurality of elongated inclusions comprising the excess calcium (see paragraph [0012] and claim 9). According to paragraph

[0013] of document D9, the inclusions can have a length of about 5 microns to about 20 microns. This disclosure is not limited to a composite wherein the hydroxyapatite phase has a Ca/P ratio of more than 1.67. The description of document D9 also discloses a composition comprising a discontinuous calcium carbonate phase within the sintered hydroxyapatite phase (see paragraphs [0014] and [0016]).

5.6 In conclusion, document D9 discloses a composition comprising a two-phase composite, which comprises a matrix phase and a discontinuous phase, and wherein the matrix phase comprises sintered hydroxyapatite with a Ca/P ratio of 1.67 (see claims 1 and 2). Document D9 also discloses that additional calcium - leading to a Ca/P ratio of the composite of more than 1.67 - is present in the discontinuous phase of the composite in the form of elongated carbonate inclusions. Excess calcium does not have to be in the matrix phase comprising the hydroxyapatite. The length of the inclusions of about 5 to about 20 microns is not limited to embodiments wherein the hydroxyapatite has a Ca/P ratio more than 1.67 (paragraph [0013]). The Ca/P ratio of 1.67 in the hydroxyapatite phase is thus disclosed in combination with additional calcium in the discontinuous phase, in particular in the form of elongated carbonate inclusions having a length dimension of 5 microns to 20 microns. As a consequence, the appellant's argumentation (see point 3. of this decision) is not convincing.

6. Claim 1 of the main request meets, for these reasons, the requirements of Article 123(2) EPC.

Sufficiency of disclosure (Article 83 EPC)

7. The appellant argued that the application as filed did not provide any evidence for a composition comprising elongated calcium carbonate inclusions with the claimed length dimension of 5 microns to 20 microns. The appellant concluded that the skilled person was not able to provide the composition according to claim 1 of the main request.

8. The appellant also argued that claim 9 did not contain a temperature for the carbonization step, although the description disclosed that carbonization had to be carried out at a temperature below 825°C.

9. The respondent referred to the examples of the contested patent and submitted that the skilled person, when repeating these examples, would obtain a composition as claimed, *i.e.* a composition comprising a composite comprising a discontinuous phase comprising a plurality of elongated calcium carbonate inclusions having a length dimension of 5 microns to 20 microns. According to the respondent, this was demonstrated by Figures 3B and 4B of the patent. In support of its argumentation, the respondent referred to the disclosure of document D13.

10. The respondent also submitted that the objection relating to claim 9 of the main request has only been raised during the oral proceedings before the opposition division. Since there was no change in the proceedings before filing the objection, it was late filed and thus inadmissible. The respondent further submitted that the description of the contested patent, in particular the examples 1 to 4, as well as the common general knowledge, provided the skilled person with sufficient information how to perform the method according to claim 9, in particular with respect to the

maximum temperature of 825°C.

11. The board observes that the contested patent contains examples which, according to the respondent, described methods for the preparation of compositions according to claim 1, as well as for the method according to claim 9. Although the appellant argued that compositions according to claim 1 cannot be obtained by following the teaching of the patent, there is no evidence on file to support this allegation. This also applies to the method according to claim 9, in particular in view of the disclosure of paragraphs [0002], [0029] and [0030] of the patent in suit, which disclose not to heat above 825°C during the sintering step. It is not apparent to the board, why the killed person would not be able to follow this teaching. For the claimed invention to be sufficiently disclosed, it is not necessary that this temperature be included in claim 9.

12. For these reasons, the board concludes that the main request meets the requirements of Article 83 EPC.

13. Document D13, submitted by the respondent during the opposition proceedings, was not admitted into the proceedings by the opposition division. The opposition division did not consider the document to provide any new information relevant to the outcome of the opposition proceedings. Since the board follows the respondent's argumentation without having to rely on D13 (see the previous point), there is no need to decide on its admission into the appeal proceedings.

Inventive step (Article 56 EPC)

14. The opposition division, in agreement with both parties, considered documents D2 and D7 to be the closest prior art for the subject-matter of claims 1, and 9 to 13, respectively.

According to the opposition division, the composition according to claim 1 of the main request differed from compositions disclosed in D2 in the presence of a matrix phase comprising sintered hydroxyapatite, and a discontinuous phase comprising calcium carbonate, and in the length dimension of 5 microns to 20 microns of the calcium carbonate inclusions. According to the opposition division, sintering was an obvious measure for the skilled person, and this feature did not contribute to inventive step. On the other hand, the provision of a powder comprising a matrix phase and a discontinuous phase according to claim 1 was not apparent from the disclosure of D2. The opposition division therefore concluded that the provision of a composition according to claim 1 of the main request was based on an inventive step.

With respect to claim 9, the opposition division defined two differing features between the claimed method and the method disclosed in document D7. Those were the presence of an extraneous carbonatable calcium component in the hydroxyapatite material, and the treatment of the hydroxyapatite material with a carbon dioxide source after the sintering step, rather than during sintering. According to the opposition division, the resulting technical problem of providing an alternative method for preparing a carbonated hydroxyapatite composition was solved in a non-obvious way, in particular because D7 taught away from the solution provided according to claim 9 of the main request. According to the opposition division, the

presence of extraneous carbonatable material led to the two-phase carbonated hydroxyapatite composition prepared by the method of claim 9. Document D7, however, disclosed that a single phase was obtained, and that products which were not substantially single phase were not desirable.

The opposition division concluded that the main request met the requirements of Article 56 EPC.

15. The appellant contested this finding, and considered all three independent claims not to be inventive.

15.1 With regard to claim 1, the appellant argued, by reference to documents D16, D6 and D7, that document D2 also disclosed a matrix phase comprising sintered hydroxyapatite, and a discontinuous calcium carbonate phase. The only remaining difference was thus the length dimension of the calcium carbonate inclusions. Since this feature did not lead to a surprising technical effect, the solution to the resulting technical problem of providing an alternative composite material was obvious for the skilled person.

15.2 Concerning claim 9, the appellant argued that document D7 also disclosed an extraneous carbonatable calcium component in the hydroxyapatite material and that the only difference between the method of claim 9 of the main request and the method disclosed in claims 1 and 3 of document D7 was that the carbon dioxide treatment was carried out after the sintering step. This difference did not lead to a surprising technical effect, in particular not to the formation of the second - discontinuous - phase, as shown by paragraphs [0021] and [0029] of the contested patent. The resulting technical problem was thus only the provision

of an alternative method for producing a composite material. The appellant submitted that the claimed alternative, treating the hydroxyapatite material with a carbon dioxide source after the sintering step rather than during, was obvious in view of the skilled person's common general knowledge. This was already demonstrated by example 5 of the contested patent.

15.3 The appellant furthermore considered the method of independent claim 13 of the main request not to be inventive either. According to the appellant, document D7 was the closest prior art. The differing feature was that hydroxyapatite material and a carbonatable compound were sintered, wherein the Ca/P ratio of the sintered material was greater than 1.67. Using elongated carbonate inclusions as such did not lead to a particular technical effect, and claim 13 did furthermore not contain a feature directed to a two-phase material. Document D8 suggested to add calcium carbonate in order to increase the compressive strength of hydroxyapatite/calcium carbonate composites. Variation and modification of a known method was obvious and a matter of routine operation for the person skilled in the art. No inventive activity could thus be acknowledged, in particular not for the whole scope of the claim.

16. The respondent disagreed with the arguments provided by the appellant for all three independent claims.

16.1 The respondent argued that document D2 did not disclose a two-phase composite comprising a matrix phase comprising a sintered hydroxyapatite, in particular not sintered hydroxyapatite comprising a Ca/P ratio of 1.67. Instead, the document disclosed substituted hydroxyapatite, which was not sintered and wherein part

of the phosphorus was replaced by calcium, leading to a higher Ca/P ratio. According to the respondent, the document did also not disclose a discontinuous phase comprising a plurality of elongated calcium carbonate inclusions, and in particular not such inclusions having a length dimension of 5 microns to 20 microns. The combination of these four differing features led to a denser material, which was, due to the Ca/P ratio of hydroxyapatite, biocompatible and easy to resorb. Since document D2 did not provide any hint towards the differing features, the composition according to claim 1 of the main request was inventive.

16.2 The respondent, by reference to page 5, lines 22 to 24 of document D7, that the document did not disclose a bi-phasic material, but rather a material which was substantially single phase. The document did furthermore not disclose a method wherein a sintering step was performed on hydroxyapatite before the thus formed sintered material was treated with a carbon dioxide source. According to D7, in particular claim 1, treatment with an atmosphere comprising carbon dioxide happened during the heating step. As a consequence, the method according to D7 led to an exchange of phosphate or hydroxy groups in the hydroxyapatite phase by carbonate groups, whereas the method according to claim 9 of the main request led to the formation of a second phase during the last step, which contained calcium carbonate. The material was thus different, *i.e.* bi-phasic, and had improved properties. The formation of the second phase was achieved by the treatment of the hydroxyapatite material with a carbon dioxide phase after the sintering step. With this step replacement of phosphate or hydroxy groups of hydroxyapatite was avoided, since these groups were made inaccessible after sintering. The formation of the different single

phase compositions was, however, at the core of document D7. The skilled person would thus not have envisaged a change in the preparation method disclosed in D7 in order to obtain a different material. According to the respondent, the formation of different materials was also not put into question by the spectroscopic data provided in D7 and in the contested patent. The respondent concluded that inventive step had to be acknowledged for the method of claim 9.

16.3 The respondent concurred that document D7 was the closest prior art for the method according to claim 13 of the main request, and that a differing feature between the claimed method and the method disclosed in document D7 was the treatment with the carbon dioxide source after the sintering step. The respondent contested the appellant's conclusion that claim 13 did not relate to a two-phase system, because the claimed method comprised a step wherein the sintered hydroxyapatite material was contacted with a carbon dioxide source to provide elongated carbonate inclusions randomly oriented within the hydroxyapatite material, thus forming a second phase within the hydroxyapatite matrix phase. The respondent argued that the claimed method was inventive for essentially the same reasons as the method according to claim 9 of the main request.

17. The board comes to the following conclusions:

The contested patent

18. The patent relates to two-phase composites comprising sintered hydroxyapatite and a discontinuous phase comprising elongated calcium carbonate inclusions. The composites are intended for use as scaffolds for bone

growth in bone grafting (see paragraphs [0001], [0004] and [0008]). Particular problems mentioned in the description concern the strength of the composite material, its biocompatibility and remodeling rate (see paragraphs [0001], [0004], [0018] and [0022]). In order to address these problems, the patent provides a composite material according to claim 1, a method of preparing a two-phase carbonated hydroxyapatite composition according to claim 9, and a method of using elongated carbonate inclusions to affect strength of a hydroxyapatite material according to claim 13.

19. *Claim 1*

The closest prior art

19.1 The parties concurred with the opposition division that document D2 represents the closest prior art. The board sees no reason to differ. The document discloses heterophase composite biomaterials in the hydroxyapatite-calcite system, and their use as bone grafting materials (see the title and the left-hand column on page 151).

Differing feature

19.2 The parties agreed that document D2 did not disclose the length dimension of calcium carbonate crystals of 5 microns to 20 microns. The parties disagreed whether D2 disclosed a matrix phase comprising sintered hydroxyapatite comprising a Ca/P ratio of 1.67, and whether D2 discloses a discontinuous phase comprising calcium carbonate.

19.3 The board notes that document D2 discloses composite materials comprising various ratios of hydroxyapatite

(HA) and calcium carbonate (CC). According to the last sentence of the left-hand column on page 151, compositions in the series from HA to CC are formed following replacement of phosphate groups by carbonate groups. This disclosure is repeated at the end of the first paragraph of the right-hand column on page 152, and at the end of the first paragraph of the left-hand column on page 154. As a consequence, due to this replacement of phosphate groups by carbonate groups, the materials disclosed in document D2 comprise, in addition to a calcium carbonate phase, a hydroxyapatite phase with a Ca/P ratio higher than 1.67.

19.4 The composition according to claim 1 of the main request thus differs from the composition disclosed in D2 at least in the length dimension of calcium carbonate inclusions in the discontinuous phase, *i.e.* 5 microns to 20 microns rather than up to 4 µm (see page 154, left-hand column, line 18), and in that the hydroxyapatite comprises a Ca/P ratio of 1.67, rather than higher than 1.67.

19.5 The appellant submitted that the argument concerning the stoichiometry of the hydroxyapatite phase was raised for the first time during the oral proceedings before the board and should therefore not be admitted into the proceedings.

19.6 The board does not agree. In their reply to the notice of appeal, the respondent referred to the disclosure of document D2 in the context of inventive step (see page 11, after the reaction scheme copied from document D2). The respondent argued that the *"... process leads to powders of hydroxyapatite substituted by carbonate ions both on its hydroxyl (A) and phosphate (B) sites, i.e. AB-carbonated hydroxyapatite (see page 152, right*

column, end of first paragraph), in addition to calcium carbonate." Following the argument of the respondent, the process thus inevitably leads to a Ca/P ratio of the hydroxyapatite of more than 1.67. This will be appreciated by the person skilled in the art, even if the opposition division, in the contested decision, did not rely on that differing feature. The board notes that this argument has also already been submitted by the respondent - in the context of novelty of claim 1 of the patent as granted - with their reply to the notice of opposition, (see page 5 of the respondent's submission of 20 October 2020, point 3.2.1.a) after the reaction scheme copied from document D2). Furthermore, the Ca/P ratio of the hydroxyapatite phase was also discussed the in the context of added subject-matter (see point 5.2 of this decision).

Technical problem

19.7 The contested patent does not disclose any comparative data with respect to the disclosure of document D2. There is also no other proof on file showing an increase in density, biocompatibility or ease of resorption of the composite material, and in particular not with respect to the material disclosed in document D2. The objective technical problem is thus the provision of an alternative composition to the compositions disclosed in D2, which can be used as scaffolds for bone growth in bone grafting.

Solution to the technical problem

19.8 According to claim 1 of the main request, this technical problem was solved by the provision of a composition, wherein the sintered hydroxyapatite comprised in the matrix phase comprises a Ca/P ratio of

1.67, and wherein a discontinuous phase comprises a plurality of elongated calcium carbonate inclusions having a length dimension of 5 microns to 20 microns. The board is satisfied that the solution according to claim 1 solves the technical problem of providing an alternative composition for the intended use. This was not disputed.

Inventiveness of the claimed solution

19.9 Document D2 teaches the person skilled in the art to introduce carbonate groups into hydroxyapatite materials. According to D2, the carbonate groups of carbonate-containing hydroxy apatite (CHA) increase the resorbability of hydroxy apatite (HA), making CHA a promising material. The document further discloses a series of compositions from HA to CC, wherein phosphate groups have been replaced by carbonate groups (see the left-hand column on page 151, the end of first paragraph of the right-hand column on page 152, and lines 4 to 8 of the right-hand column on page 153). According to the document these materials can find use in the development of new ceramic materials with controlled resorption kinetics meant for cellular engineering of bone tissue regeneration. The document thus suggests the person skilled in the art to provide composite biomaterials comprising hydroxyapatite wherein some of the phosphate groups have been replaced by carbonate groups. This will increase the Ca/P ratio of the hydroxyapatite to more than 1.67. The document does not suggest to provide compositions comprising a composite material comprising *i.a.* a matrix phase comprising hydroxyapatite comprising a Ca/P ratio of 1.67. The appellant did not rely on any other documents in this respect.

19.10 The board comes, already for these reasons, to the conclusion that the provision of a composition according to claim 1 of the main request is based on an inventive step within the meaning of Article 56 EPC.

20. *Claim 9*

Closest prior art

20.1 Both parties concurred with the opposition division that document D7 represents the closest prior art. The board sees no reason to differ. The document discloses a process for the preparation of a carbonate-substituted hydroxyapatite, which is intended to be used as a bone replacement material (see page 1, lines 10 to 13). Claim 9 of the main request also relates to a method for the preparation of a two-phased carbonated hydroxyapatite composition, which can be used for the same purpose.

Differing feature

20.2 The process disclosed in document D7 comprises heating a hydroxyapatite having a Ca/P molar ratio greater than 1.67 at a temperature of from 600 to 1200°C in an atmosphere comprising CO_2 (see claim 1). The parties agreed that the claimed method differs from this method in that the hydroxyapatite material is treated with a carbon dioxide source after the sintering step, rather than heating the hydroxyapatite in an atmosphere comprising CO_2.

20.3 The appellant argued that document D7 did not disclose the preparation of a different material, since the method disclosed therein essentially used the same starting material and comprised the same steps as the

method according to claim 9 of the main request. According to the appellant, D7 therefore disclosed a two-phase material, which was also disclosed in the figures of D7, when compared to the data provided in the figures of the contested patent.

20.4 The board comes to the conclusion that document D7 does not disclose a two-phase carbonated hydroxyapatite composition according to claim 9 of the main request. The document does not contain any indication for a two-phase material. It discloses in various parts of the description that the carbonated hydroxyapatite compositions were substantially of a single phase (see page 1, lines 4 to 9; page 5, lines 5 to 9 and lines 22 to 24 and page 9, lines 16 to 18). The document further discloses that a material not in a single-phase was undesired (see page 9, lines 23 to 30). The document furthermore discloses that the carbonate-substituted hydroxyapatite prepared according to the method of the invention had a carbonate substitution predominantly on the phosphate site of hydroxyapatite. It thus discloses hydroxyapatite material with a Ca/P ratio of more than 1.67. It is also noted that the method disclosed in D7 is not identical to the method according to claim 9 of the main request, already because of the treatment with a carbon dioxide source during, rather after the heating step. Finally, a comparison of figure 1 of D7 and figure 2C of the contested patent, as referred to by the appellant, does not provide evidence for the equivalence of the compositions studied. Although both spectra show signals below 30 degrees, the exact position is different. Furthermore, as submitted by the respondent, the signal may well be based on the presence of carbonate groups, but may not necessarily reflect the exact position of such groups in the

material.

20.5 In summary, the method according to claim 9 of the main request differs from the method disclosed in document D7 in that the treatment of the hydroxyapatite material with a carbon dioxide source is done after sintering of the hydroxyapatite material, rather than heating the hydroxyapatite material in an atmosphere comprising carbon dioxide. It further differs in that the process leads to a product, which essentially differs from the product disclosed in D7 in that the hydroxyapatite has a Ca/P ratio of 1.67 (claim 9 of the main request), compared to more than 1.67 (claim 1 of document D7). The product also differs in that it is a two-phase carbonated hydroxyapatite composition (claim 9), rather than a composition consisting of a single phase (D7).

Technical problem

20.6 The appellant argued that the treatment of the hydroxyapatite with carbon dioxide, or a carbon dioxide source, during or after the heating step, respectively, did not lead to a different product, in particular not to a product which comprised a separate discontinuous calcium carbonate phase within the hydroxyapatite phase. The appellant further argued, by reference to paragraph [0029] of the contested patent, that sintering and treatment with carbon dioxide only led to the conversion of calcium oxide to calcium carbonate.

20.7 The respondent argued that sintering the hydroxyapatite material before treatment with a carbon dioxide source made it more difficult or even impossible to replace phosphate groups within the hydroxyapatite phase. Claim 9 of the main request made it clear that the treatment step led to the conversion of at least part of the

carbonatable portion - which was provided as extraneous carbonatable calcium component with the hydroxyapatite material - to the discontinuous calcium carbonate phase within the hydroxyapatite phase.

20.8 The board notes that, according to paragraph [0029] of the contested patent, sintering of hydroxyapatite with a calcium precursor leads to the conversion of calcium oxide to calcium carbonate. However, the board also finds it credible that the treatment of hydroxyapatite with a carbon dioxide source after the sintering step leads to a product which is different from the product disclosed in D7, because - as argued by the respondent - the formation of the calcium carbonate phase happens without affecting the Ca/P ratio of the already sintered hydroxyapatite phase.

20.9 The objective technical problem can thus be seen in the provision of a process for the preparation of a carbonated hydroxyapatite composition, which differs from the product disclosed in document D7 at least in that the hydroxyapatite has a Ca/P ratio of 1.67, and in that it is a two-phase carbonated hydroxyapatite composition.

Solution to the technical problem

20.10 The board is satisfied that the technical problem is solved by the method according to claim 9 of the main request. The appellant has not provided any evidence that the claim extends to subject-matter which does not solve the technical problem.

Inventiveness of the claimed solution

20.11 Document D7 discloses the preparation of a different material, which is essentially in a single-phase form and which comprises hydroxyapatite having a Ca/P ratio of more than 1.67 (see point 20.5 of this decision and claim 3 of D7). The document also discloses that the provision of a material not in a single-phase is undesired (see page 9, lines 23 to 30). The document does therefore not suggest the skilled person to modify the step comprising sintering hydroxyapatite in an atmosphere comprising carbon dioxide (see claim 1) and provide a method comprising two separate steps, *i.e.* sintering hydroxyapatite material comprising an extraneous carbonatable calcium component and subsequent treating the sintered material with a carbon dioxide source, in particular not with the aim to convert at least a portion of the carbonatable calcium component to a discontinuous calcium carbonate phase within the hydroxyapatite phase. The appellant has not made reference to any other document in that respect.

20.12 The board, for these reasons, comes to the conclusion that the provision of a method according to claim 9 of the main request is based on an inventive step within the meaning of Article 56 EPC.

21. *Claim 13*

21.1 Both parties consider document D7 to be closest prior art for the same reasons as for claim 9. The board sees no reason to differ.

21.2 During the course of the oral proceedings before the board, the parties agreed that the method according to claim 13 inherently comprised the steps of the method according to claim 9. The appellant contested, however, that the claimed method included the provision of a

two-phase material. The appellant furthermore argued that there was no data available to support any surprising technical effect, and since the term "affect" used in the claim could mean improvement as well as deterioration of the properties of the hydroxyapatite material, the technical problem could only be seen in the provision of an alternative method. According to the appellant, the modification of individual steps of a known method was obvious to the person skilled in the art wishing to optimise a production method. The claimed method was thus not based on an inventive step.

21.3 The respondent considered the arguments with respect to inventive step of claim 9 to apply *mutatis mutandis* to claim 13.

21.4 The board comes to the conclusion that the provision of the method according to claim 13 is based on an inventive step within the meaning of Article 56 EPC. The reasons are as follows.

21.5 The claim is directed to a method of using elongated carbonate inclusions to affect the strength of a hadroxyapatite material. The method comprises a step of providing a sintered hydroxyapatite material comprising a carbonatable calcium component. The method further comprises contacting said hydroxyapatite material and a carbon dioxide source. This contacting has to be at least partially sufficient to provide elongated carbonate inclusions, these inclusions being randomly-oriented within said hydroxyapatite material. Since the claimed method thus requires the formation of elongated carbonate inclusions *"within"* the hydroxyapatite material, the resulting material comprises two phases, *i.e.* a hydroxyapatite phase, and a phase formed by the

elongated carbonate inclusions. Therefore, the claimed method includes the provision of a two-phase material, as does the method according to claim 9. Since the claim inherently also comprises the remaining steps of claim 9, as agreed by the parties, the claimed method is based on an inventive step for the same reasons as claim 9 of the main request.

Conclusion

22. In summary, the board comes to the conclusion that the reasons brought forward by the appellant do not prejudice the maintenance of the patent as maintained by the opposition division. There is thus no need to consider any of the auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated