BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 1 February 2010

Case Number: T 1314/06 - 3.3.05

Application Number: 96940322.9

Publication Number: 0859737

IPC: C01B 25/32

Language of the proceedings: EN

Title of invention:
Low temperature calcium phosphate apatite and a method of its manufacture

Applicant:
ETEX CORPORATION

Headword:
HIGH STRENGTH APATITE/ETEX

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 54(1)(2), 56, 84

Keyword:
"Main request: novelty (yes)"
"Main request: inventive step (yes) - evidence showing alleged effects"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1314/06 - 3.3.05

D E C I S I O N
of the Technical Board of Appeal 3.3.05
of 1 February 2010

Appellant: ETEX CORPORATION
University Park at MIT,
38 Sidney Street,
The Clark Building
Cambridge, MA 02139 (US)

Representative: Gambell, Derek
Graham Watt & Co LLP
St Botolph's House
7-9 St. Botolph's Road
Sevenoaks
Kent TN13 3AJ (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 March 2006 refusing European patent application No. 96940322.9 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: G. Raths
Members: J.-M. Schwaller
S. Hoffmann

Summary of Facts and Submissions

I. This appeal lies from the decision of the examining division refusing European patent application No. 96 940 322.9, with claim 1 of the main request reading as follows:

"*1. A method of preparing a low crystallinity calcium phosphate apatite of high mechanical strength, comprising:*
precipitating a low crystallinity calcium phosphate from an aqueous solution comprising calcium and phosphate ions, and optionally further comprising carbonate ions;
collecting the low crystallinity calcium phosphate from the solution;
casting the low crystallinity calcium phosphate into a mold; and
dehydrating the low crystallinity calcium phosphate in a relative humidity of 55 to 99% and at a temperature of 1 to 50°C to obtain a high strength calcium phosphate apatite block solid.",

II. In the contested decision, the examining division held the subject-matter of above claim 1 as lacking an inventive step in the light of document

D1: WO 94/02412.

It argued in particular that the dehydrating conditions defined in said claim to obtain the desired low crystallinity apatite did not substantially differ from those that the skilled person would select in the process according to D1 for producing the bone mineral

in vivo. Using a mold for carrying out the dehydrating step was furthermore not regarded as involving an inventive step.

III. With the grounds of appeal dated 26 July 2006, the appellant filed eight amended sets of claims as a main request and as 1st to 7th auxiliary requests, respectively.

Claim 1 of the main request read as follows (differences with the subject-matter of above claim 1 emphasized by the board):

"1. A method of preparing a low crystallinity calcium phosphate apatite of high mechanical strength, comprising:
precipitating a low crystallinity calcium phosphate from an aqueous solution comprising calcium and phosphate ions, and optionally further comprising carbonate ions;
collecting the precipitated low crystallinity calcium phosphate from the solution;
maturing the low crystallinity calcium phosphate;
mixing the matured low crystallinity calcium phosphate to form a homogenized gel;
casting ~~low crystallinity calcium phosphate~~ the homogenized gel into a mold; and
dehydrating the ~~low crystallinity calcium phosphate~~ homogenized gel in said mold in a humidity chamber at a relative humidity of 55 to 99% and at a temperature of 1 to 50°C to obtain a high strength calcium phosphate apatite block solid."

IV. In a communication under Rule 100(2) EPC, the board objected to above claim 1 under Articles 123(2), 84 and 56 EPC.

The board held in particular that it was essential for the problem being solved - namely for obtaining a calcium phosphate of high mechanical strength - that, on the one hand, the low crystallinity calcium phosphate was obtained by precipitation under conditions where initial precipitation was rapid, and on the other hand, that the homogenized gel be dehydrated slowly, namely for at least one week.

V. Under cover of a letter dated 22 September 2009, the appellant cancelled the former requests and submitted two sets of amended claims as main request and auxiliary request, respectively.

Claim 1 of the main request reads as follows (differences with claim 1 of the main request filed with the grounds of appeal emphasized by the board):

"*1. A method of preparing a low crystallinity calcium phosphate apatite of high mechanical strength, comprising:*
rapidly *precipitating a low crystallinity calcium phosphate from an aqueous* ***mother*** *solution comprising calcium and phosphate ions, and optionally further comprising carbonate ions;*
collecting the ***precipitated*** *low crystallinity calcium phosphate from the solution;*
maturing the low crystallinity calcium phosphate ***in an aqueous solution****;*

mixing the matured low crystallinity calcium phosphate to form a homogenized gel;
casting the homogenized gel into a mold; and
***slowly** dehydrating the homogenized gel in said mold in a humidity chamber at a relative humidity of 55 to 99% and at a temperature of 1 to 50°C **for at least one week to** obtain a high strength calcium phosphate apatite block solid."*

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of the sets of claims filed with letter dated 22 September 2009 as a main request and as a first auxiliary request, respectively.

Reasons for the Decision

1. Main request - Amendments

Amended claims 1 to 11 of this request find their support in the application as filed as follows:

Claim 1: claims 1, 2, 5, 20; page 9, lines 24 to 26; page 11, lines 4 to 8 and lines 24 to 29; page 12, lines 7 to 9; page 13, line 1 to 4; Figure 1.

Claim 2: claims 3 and 4

Claim 3: claims 6 and 7

Claim 4: claims 8 and 9

Claim 5: claim 10

Claim 6: claims 11, 12 and 13

Claim 7: claims 14 to 17

Claim 8: claims 18 and 19

Claim 9: claim 22

Claim 10: claim 25

Claim 11: claims 26 to 29

The requirements of Article 123(2) EPC are thus met.

2. Main request - Clarity

The board notes that claim 1 at issue recites the relative terms "*low crystallinity*", "*rapidly precipitating*", "*slowly dehydrating*", "*high strength*", but since these terms do not affect the determination of the scope of protection thus conferred by the claim and - as can be seen from items 3. and 4. hereinbelow - do not prevent the invention from being unambiguously distinguished from the prior art with respect to novelty and inventive step, the wording of the claim is thus in compliance with the clarity requirement of Article 84 EPC 1973.

3. Main request - Novelty

In the contested decision, the examining division did not contest the novelty of the process then claimed.

The scope of protection of claim 1 of the present request is furthermore substantially restricted in comparison to the process claims on which the decision was based, and the board is satisfied that its subject-matter fulfills the requirements of Article 54 (1) and (2) EPC 1973, in particular over the process disclosed in document D1, which neither discloses the casting of the homogenized gel into a mold nor the dehydration procedure of at least one week defined in claim 1 at issue.

4. Main request - Inventive step

4.1 The present application concerns in its independent claim 1 a process for preparing a calcium phosphate apatite having low crystallinity and high mechanical strength.

4.2 The closest state of the art - as acknowledged by both the examining division and the appellant - is represented by document D1 which aims at preparing in particular a substantially amorphous material that can be transformed under controlled conditions into crystalline bone material (D1, page 1, first and third paragraphs).

At its simplest, the amorphous material is described as a precursor composition containing calcium and phosphate ions as primary constituents together with inhibitor components (notably magnesium and/or pyrophosphate ions) which inhibit its transformation into a crystalline form, generally hydroxyapatite. In use, i.e. in vivo, the precursor composition is applied to a site where bone growth is required and where it

gradually loses the inhibitor component(s) by leaching action to ambient body fluids, and undergoes transformation into crystalline hydroxyapatite (page 2, line 32 to page 3, line 6).

In the Examples of D1, the synthetic precursor material is prepared by buffering calcium chloride solutions to maintain the pH at about 7.4, adding magnesium chloride to produce a Mg/Ca mole ratio ranging from 1:1 to 0.01:1, and adding a buffered phosphate solution. The total concentrations are selected to approximate to "natural" conditions with an ion strength of about 0.15 and a pH of about 7.4. The solutions are stirred and the resulting precipitates are collected by centrifugation, washed and dried at 60°C (page 4, lines 3 to 13).

The transformation of the amorphous material into bone mineral is described as being "slow, e.g. taking days" (page 3, lines 17 and 18).

4.3 The problem to be solved in the light of the above disclosure might be seen - as described at page 4, lines 23 to 25 of the application - in the provision of a process for preparing a low crystallinity calcium phosphate apatite which mimics the properties of natural bone and is in the form of a high mechanical strength ceramic block.

4.4 As a solution to this problem, the application proposes the process according to claim 1, characterized in particular in that the low crystallinity calcium phosphate is rapidly precipitated and the gel is cast into a mold and slowly dehydrated in said mold in a

humidity chamber at a relative humidity of 55 to 99% and at a temperature of 1 to 50°C for at least one week.

4.5 The board is satisfied that the problem underlying the invention has been successfully solved having in particular regard to Table 1 of the application as filed (reproduced hereinafter)

Table 1. Preparation of block solid apatite using varying drying times.

No.	temperature (°C)	relative humidity (%)	dehydration time (days)	hardness (VHN)
2	4	85-95	~14	17
3	25	60-70	~8	17
4	50	20-30	~3	microcracks

which shows that the dehydration time is at issue, a rapid dehydration time of about three days (No. 4) - in comparison to dehydration times falling within the ambit of claim 1 at stake - resulting in deterioration of the block solid mechanical properties (microcracks).

Table 1 furthermore shows that the temperature and humidity conditions can be varied within the ranges defined in present claim 1 without deterioration of the mechanical strength of the block solid. The board is therefore satisfied that the problem is solved over the whole breadth of claim 1 at issue and that all the features essential for the problem to be solved are now recited in claim 1 at issue.

4.6 It remains to be decided whether the proposed solution to the technical problem, namely the process according to claim 1 at issue, is obvious or not in view of the prior art.

4.6.1 The examining division argued that the dehydrating conditions indicated in claim 1 at issue in the contested decision - namely a relative humidity of 55 to 99% and a temperature of 1 to 50°C - did not substantially differ from those existing in human bodies.

4.6.2 The board observes that the subject-matter of claim 1 at issue is substantially restricted in comparison to that of the claim the examining division rejected under Article 56 EPC in the contested decision in the light of document D1.

D1 moreover does not disclose that a calcium phosphate apatite is produced ex vivo as a **block** solid, nor that the dehydration is carried out **for at least one week** with the purpose of obtaining a solid that exhibits increased mechanical strength.

4.6.3 Furthermore, none of the other publications cited in the search report teaches or suggests the method steps recited in claim 1 at issue, in particular that the homogenized gel be cast into a mold and slowly dehydrated in said mold in a humidity chamber at a relative humidity of 55 to 99% and at a temperature of 1 to 50°C for at least one week, in order to produce a low crystallinity calcium phosphate apatite block solid that exhibits increased mechanical strength.

4.6.4 In view of the above considerations, the skilled person faced with the problem indicated in item 4.3 above thus had no indication to arrive at the subject-matter of claim 1 at issue in the light of the above state of the art documents.

4.7 It is therefore concluded that having regard to the state of the art, the subject-matter of claim 1 of this request (and of the claims 2 to 11, which all depend on claim 1) is not obvious to a person skilled in the art and, therefore, it involves an inventive step within the meaning of Article 56 EPC 1973.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the set of claims 1 to 11 according to the main request filed with letter of 22 September 2009 and a description to be adapted to these claims.

The Registrar: The Chairman:

C. Vodz G. Raths