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Datasheet for the decision of 29 September 2015

Case Number: T 1117/14 - 3.2.08

Application Number: 05739390.2

Publication Number: 1879525

IPC: A61F2/08, A61F2/28, A61F2/30, A61L31/14, A61F2/46

Language of the proceedings: EN

Title of invention:
SYSTEM AND IMPLANT FOR LIGAMENT RECONSTRCTION OR BONE RECONSTRUCTION

Applicant:
Mayr, Hermann

Headword:

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - after amendment
Sufficiency of disclosure - (yes)

Decisions cited:

Catchword:

Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 1117/14 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 29 September 2015

Appellant: (Applicant)	Mayr, Hermann Steinerstrasse 6 81369 München (DE)
Representative:	Ingerl, Reinhard E. Lorenz Seidler Gossel Widenmeyerstrasse 23 D-80538 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 3 January 2014 refusing European patent application No. 05739390.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	T. Kriner
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 3 January 2014 the Examining Division refused European patent application No. 05739390.2.

II. In its decision the Examining Division held that the subject-matter of the requests then on file was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

III. The appellant (applicant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

IV. Oral proceedings before the Board of Appeal were held on 29 September 2015.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the Main request submitted during oral proceedings before the Board. All previous requests were withdrawn.

V. Claim 1 of the Main request reads as follows:

"Biodegradable implant for ligament reconstruction and/or bone reconstruction, wherein the implant comprises a biodegradable material which is suitable to be remodelled into vital bone, wherein the biodegradable material has a compression strength of at least 50 N/mm^2 and/or a shear stress strength of at least 50 N/mm^2, and the biodegradable material comprises a micro pore structure characterized in that the micro pores have an average diameter ranging from 2 to 10

micrometers and in that all of said bio-degradable material has no macro pores with a diameter ranging from 100 to 500 micrometers, and wherein said biodegradable material has a porosity ranging from 25% to 50% by volume, wherein the biodegradable material is a sintered ceramic only consisting of ß-tricalcium phosphate".

VI. The following documents played a role for the present decision:

A8: G. Rizzoli, TB 03018 Less porous chronOS™ material, 2nd part, 20 July 2004;
A9: Expert declaration by Prof Bohner;
D11: WO-A-00/45867;
D12: Bohner et al, "Synthesis and characterization of porous β-tricalcium phosphate blocks", Biomaterials 26 (2005), 6099-6105;
D13: Bohner, M "Calcium Phosphate Emulsions: Possible Applications", Key Engineering Materials Vols. 192-195 (2001), pp. 765-768.

VII. The essential arguments of the appellant can be summarised as follows:

Amendments
A biodegradable implant wherein the biodegradable material is a sintered microporous ceramic only consisting of ß-tricalcium phosphate was disclosed in claims 13 and 17 as filed. Newly filed dependent claims 12 and 13 found basis on page 6, first paragraph of the description as filed.

Article 83 EPC

Although there was admittedly no detailed information in the application as filed how to produce the claimed β-TCP implant, the provision of such detailed information was not necessary, because the production of TCP implants with the claimed pore size and porosity was known to the skilled person as part of the common general knowledge. Indeed, before the date of filing, there were only very few commercially available β-TCP implants on the market, one of which was ChronOS™. The person skilled in the art of bioresorbable ceramic implants was thus well aware of this material and its manufacturing method, the "calcium phosphate emulsions" method developed by Mr. Bohner. As stated in Mr. Bohner's expert declaration (A9), the method had been published both in scientific papers, see D13, and in the patent literature, see D11, those skilled in the art at that time relying on patent documents and scientific papers with respect to production methods. It was thus part of the common general knowledge that the macroporosity reached by applying the "calcium phosphate emulsions" method was dependent on the hydrophobic liquid droplets formed in the paste. Less oil / hydrophobic liquid resulted in smaller macropores as consistently described in D13, see the abstract and Figure 3, and in D11, see page 12, lines 13-15. Provided with the task to manufacture a β-TCP implant having no macropores with a diameter ranging from 100 to 500 micrometers, the skilled person would - because of his general knowledge of the calcium phosphate emulsions method - inevitably realize that such a material could be produced using this method by simply omitting the hydrophobic liquid which is responsible for the generation of the macropores. This was also

exactly how the implants developed in the first project TB03009 had been produced, see A8, page 2, example "C".

The person skilled in the art had thus - using the common general knowledge of the calcium phosphate emulsions method together with the structural requirements defined in the application - sufficient information to carry out the invention.

Reasons for the Decision

1. The appeal is admissible.

2. Main request - Article 123(2)

Claim 1 of the Main request filed during the oral proceedings finds a basis in claims 1-4, 6, 7, 12, 13 and 17 as originally filed. Dependent claims 2-11 are based respectively on dependent claims 2, 8, 11, 18, 19, 20-24 as originally filed. Dependent claims 12 and 13 find support on page 6, first paragraph of the description as originally filed.

The set of claims of the Main request thus fulfils the requirements of Article 123(2) EPC.

3. Main request - Article 83 EPC

Uncontestedly, the application is silent about how the claimed biodegradable implant is to be produced. However, according to established case law, the skilled person may use his common general knowledge to supplement the information contained in the application. It thus has to be examined whether the skilled person - from the common general knowledge -

had at his/her disposal a method to manufacture the biodegradable implant claimed.

The appellant has submitted an expert declaration by Prof Bohner (A9). In this declaration, Prof Bohner explains (see A9, page 2, first three paragraphs) that he had developed a new method for producing porous β-TCP ceramic bodies, the so-called "calcium phosphate emulsions" method. This method had been published in the scientific (see D13) as well as in the patent literature (see D11) and formed part of the common general knowledge in the field because - at the time of filing - the method had not yet made its way into textbooks or monographs, those skilled in the art relying on articles and patent documents with respect to production methods.

The Board finds this submission convincing for the following reasons: documents D11 and D13 were published several years before the date of filing. There was thus sufficient time for the news about the method to spread in the expert community. It is also plausible that information about a new, possibly very useful manufacturing method - applied to manufacture ChronOS™, one of the few commercially available β-TCP ceramic implant materials at the time - rapidly propagated among those skilled in the art. The Board further notes that in the textbook "Bioceramics and their clinical applications" edited by T. Kokubo, first published in 2008, in Chapter 15.5.1 entitled "Sintering, processing and mechanical properties of TCP ceramics", the method is explicitly mentioned together with Prof Bohner's name, citing D13 as the relevant reference. Although post-published, this book citation supports Prof Bohner's statement that the method was well known in the field, just about to make it into the textbooks,

with the skilled person still relying on articles and patent documents. The Board is therefore convinced that at the time of filing the calcium phosphate emulsions method as disclosed in D11 and D13 was part of the common general knowledge for the preparation of macroporous β-TCP ceramic material.

With respect to the calcium phosphate emulsions method, the skilled person will have understood the functional principle of the method, i.e. that the macroporosity of the product is caused by the droplets of hydrophobic liquid in the paste, with an increase of the emulsifier concentration (resulting in smaller droplets) or a decrease of the hydrophobic liquid amount leading to a decrease of the macroporosity (e.g. D13, abstract, last sentence, and Figures 3 and 5 showing the relationship between pore diameter and oil volume fraction / emulsifier concentration; see also D11, page 12, second paragraph - page 13, second paragraph). Furthermore, the skilled person will have understood that the material also has a microporosity (see e.g. D11, page 14, example 1) which is adjustable by the amount of mixing liquid added and by the sintering parameters (D11, page 13, second paragraph).

Consequently, to carry out the invention at the date of filing, the skilled person was confronted with the task of producing a β-TCP ceramic block having no macroporosity (no pores of between 100 and 500µm) and a particular micro- and overall porosity. At the skilled person's disposal was a method to produce a macroporous β-TCP material and the knowledge that the macropore size and distribution was determined by the hydrophobic liquid volume fraction. The skilled person further had the knowledge how to influence the microporosity. The Board thus agrees with the appellant and the evaluation

by Prof Bohner that it was immediately evident to the skilled person that by omission of the hydrophobic liquid from the paste, the method's result would have no macroporosity while the microporosity remained adjustable as needed.

By applying the so modified method, common general knowledge thus allowed the skilled person to carry out the invention claimed.

There is furthermore factual evidence that with the particular structure defined in the claim (micro pores of 2-10 micrometer, no macro pores with 100 to 500 micrometers, porosity from 25-50%) a β-TCP implant produced using the common general knowledge as discussed above fulfills the mechanical requirements claimed, see D12 and A8, page 2, example C in combination with A9, pages 3, 4. As documents D12 and A8 are only cited in support of particular mechanical characteristics of the material - which do not depend on publication date or public availability - the question whether documents D12 and A8 were part of the common general knowledge or publicly available can remain open.

The Board is thus satisfied that - taking into account the common general knowledge of the skilled person - the application discloses the invention claimed in the Main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4. With the sole ground for the refusal being overcome in appeal by restriction of the claims and by provision of additional evidence (see point 17.3. of the impugned decision), the Board finds it appropriate - in

accordance with Article 111(1) EPC - to remit the case to the Examining Division 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 Examining Division for further prosecution on the basis of the Main Request filed at the oral proceedings before the Board of Appeal.

The Registrar: The Chairman:

V. Commare T. Kriner

Decision electronically authenticated