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Datasheet for the decision of 23 June 2016

Case Number: T 0211/13 - 3.3.10

Application Number: 06125422.3

Publication Number: 1800700

IPC: A61L27/30, A61L27/56

Language of the proceedings: EN

Title of invention:
Implant with laser-produced porous surface

Patent Proprietor:
Howmedica Osteonics Corp.

Opponent:
DMV Marketing+Vertriebs GmbH

Headword:
Implant / Howmedica Osteonics Corp.

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(3)

Keyword:
New objection raised during oral proceedings - admitted (no)
Inventive step - main request (yes)

Decisions cited:

Catchword:

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Case Number: T 0211/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 23 June 2016

Appellant I: (Patent Proprietor)	Howmedica Osteonics Corp. 325 Corporate Drive Mahway, NJ 07430 (US)
Representative:	Regimbeau 20, rue de Chazelles 75847 Paris Cedex 17 (FR)
Appellant II: (Opponent)	DMV Marketing+Vertriebs GmbH Postfach 10 08 85663 Hohenbrunn (DE)
Representative:	Popp, Eugen Meissner Bolte Patentanwälte Rechtsanwälte Partnerschaft mbB Widenmayerstraße 47 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 14 November 2012 concerning maintenance of the European Patent No. 1800700 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	J.-C. Schmid
	F. Blumer

Summary of Facts and Submissions

I. Appellant I (Proprietor of the patent) and Appellant II (opponent) both lodged an appeal against the interlocutory decision of the Opposition Division maintaining European patent No. 1 800 700 according to the then pending auxiliary request 3. Independent claim 1 of the then pending auxiliary request 2, which corresponds to independent claim 12 of the patent as granted, reads as follows.

"1. A method of forming a three-dimensional porous tissue in-growth structure with varying pore characteristics and having a first surface and a second surface, said method comprising:
determining the varying pore characteristics of said three-dimensional porous tissue in-growth structure;
providing a file component representation of said three-dimensional porous tissue in-growth structure comprising said varying pore characteristics;
determining a layered configuration of unit cells and portions thereof corresponding to said file component representation such that each layer corresponds to said pore characteristics in that layer, said layered configuration having a first layer configuration and successive layer configurations;
depositing a first layer of metal powder onto a substrate;
scanning said first layer of metal powder with a laser beam to form said unit cells and portions thereof in said metal powder corresponding to said first layer configuration;
depositing successive layers of metal powder onto a previous layer, wherein each layer or portion thereof

is scanned using said laser beam and forms unit cells corresponding to each successive layer configuration;
depositing and scanning said metal layers to form said three-dimensional porous tissue in-growth structure which resembles said file component representation and has varying pore characteristics corresponding to said file component representation;
placing a flowable polymer against said second surface of said three-dimensional porous tissue in-growth structure; and
solidifying said flowable polymer to form a bearing surface adjacent said three-dimensional porous tissue in-growth structure,

wherein said three-dimensional porous tissue in-growth structure has a gradient porosity from the second surface to the first surface including at least an inner layer that is porous, an intermediate layer that is almost non-porous, an outer layer that is porous such that said flowable polymer cannot leech through said intermediate layer from said inner layer to said outer layer when said flowable liquid polymer is placed in contact with said inner layer".

Independent claim 1 of the then pending auxiliary request 3 is based on claim 1 of the auxiliary request 2 and contains the following further limitation at the end of the claim: "said outer layer having a porosity between 60% to 80% and said inner layer having a porosity higher than 80%".

II. Notice of opposition had been filed by Appellant II requesting the revocation of the patent in its entirety on the grounds of lack of inventive step (Article 100(a) EPC), and extension of the subject-matter of the patent in suit beyond the content of the application as

filed (Article 100(c) EPC). In the opposition proceedings inter alia the following documents were cited:

(3) EP-A-1 418 013 and

(4) US-B-6 682 567.

According to the opposition division the amendments made to independent claim 1 of the patent as granted extended the subject-matter of the patent beyond the content of the application as filed, while claim 1 of the then pending auxiliary request 1 extended the protection conferred by the patent as granted. Claim 1 of auxiliary request 2 corresponded to claim 12 of the patent as granted. Document (3) disclosed a method of producing a three dimensional porous tissue ingrowth structure comprising an iterative laser-sintering process of metal powder lavers. This document represented the closest prior art for the subject-matter of the claims according to auxiliary request 2. The claimed method differed from the method disclosed in document (3) by the presence of a polymer layer on a surface of the porous metallic structure and by the presence of an intermediate almost non-porous layer between the porous inner and outer layer such that said flowable polymer cannot leach through said intermediate layer. The technical problem was to provide a modification of the method described in document (3) in order to allow the implant to bear against the surface of an additional articulating element. Document (4) disclosed an acetabular cup comprising a ceramic shell having multiple layers and a polymer liner formed integrally with the shell. The skilled man would have thus found in that document the hint to place a polymeric liner on the inner surface of the metal

porous layer. Therefore he would have modified the method described in document (3) in order to allow the insertion of an intermediate almost non-porous layer between the inner and outer porous surface in order to provide a barrier to prevent migration of the liner through the metal porous material thereby arriving to the proposed solution. The subject-matter of claim 1 of the then pending auxiliary request 2 lacked therefore an inventive step. It was however not obvious in the light of the prior art to increase the porosity of the inner layer to values higher than 80%. The subject-matter of claim 1 of the then pending auxiliary request 3 involved therefore an inventive step.

III. During the oral proceedings held on 23 June 2016 before the Board, Appellant I defended the patent in suit on the basis of a main request, filed as auxiliary request 2 during the oral proceedings before the board, and on the basis of auxiliary requests 3 to 14 filed with a letter dated 25 March 2013. Appellant II contended for the first time in these opposition/appeal proceedings that the subject-matter of claim 1 of the main request, which corresponds to claim 12 as granted, extended beyond of the content of the application as filed.

IV. According to Appellant I, the late objection raised by Appellant II during the oral proceedings before the Board concerning added subject-matter in granted claim 12 should not be admitted in the proceedings. Claims 1 to 7 of the main request were identical to claims 12 to 18 of the patent as granted. Former auxiliary request 2 differed from the main request filed as auxiliary request 2 during the oral proceedings only on account of a minor amendment made in dependent claim 2 in order to address an issue under Rule 80 EPC. The main request should therefore be admitted into the proceedings.

Document (3) represented the closest prior art to the invention. This document related to a laser-produced porous surface on a prosthesis for use as a tissue ingrowth surface. The method disclosed in document (3) differed from the claimed method in four aspects, namely there was no control of the unit cells forming the different layers, there was only one functional surface, there was no variation of the gradient of porosity and there was no polymer on the bearing surface. The technical problem solved by the patent-in-suit was the provision of a method of forming an improved three-dimensional porous tissue in-growth structure. The porous tissue in-growth structure was improved with respect to that disclosed in document (3) inter alia by the presence of a second functionalized surface. Furthermore the intermediate non-porous layer excluded any leaching of a flowable polymer from the inner layer to the outer layer. Document (4) was directed towards a method for forming an orthopaedic implant using a sintering process. The process described in document (4) was therefore very different to that of laser scanning metal powder disclosed in document (3). Accordingly, the skilled person would not have turned to document (4) to find a solution to this problem. Even if he had turned to document (4), he would not have arrived to the subject-matter of claim 1 by combining the disclosure of documents (3) and (4).

Accordingly, the subject-matter of claim 1 of the main request involved an inventive step.

V. According to Appellant II the main request should not be admitted in the proceedings since it was filed belatedly. The issue of Article 100(c) EPC with respect to claim 1 of the main request raised during the oral proceedings should be admitted on account of its prima

facie relevance. It immediately appeared that the two first features of claim 1 of the main request were not based on the content of the application as filed. Document (3) represented the closest prior art to the invention. This document disclosed a method for producing a three-dimensional structure wherein unit cells forming the different layers were built with a defined level of porosity. This document disclosed all the features of the method of claim 1 except the presence of a polymer on the bearing surface of the prosthesis. The proposed solution to coat the second surface with a polymer to form a bearing surface was obvious in the light of document (4). This document disclosed a method for providing orthopaedic prosthesis for implantation into a bone of a patient. The prosthesis comprised a shell component which included three layers consisting of an interior layer that is porous and received a polymeric layer, an exterior layer that was porous and engaged the bone when implanted, and an intermediate non porous layer between the inner and the outer porous layers. The shell may be made of metal. The polymeric liner was integrated onto the porous interior layer by placing a polymer powder thereto, melting the polymer and applying a pressure to the system to ensure the formation of the liner. Accordingly, the person skilled in the art would have arrived at the claimed subject-matter by combining the teachings of document (3) and (4). The subject-matter of claim 1 of the main request lacks therefore an inventive step.

VI. Appellant I (Proprietor of the patent) requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 7 of the main request filed as auxiliary request 2 during the oral proceedings before the Board, or subsidiarily, on the

basis of any of auxiliary requests 1 to 12 filed with the letter dated 25 March 2013 as auxiliary requests 3 to 14.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

VII. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeals are admissible.

2. *Admissibility of the main request submitted at the oral proceedings*

Appellant II objected to the admissibility of this request for being late filed.

The set of claims of the main request differs from the corresponding former set of claims filed with a letter dated 25 March 2013 only in that an amendment made in dependent claim 2 of the previous request was withdrawn in response to the remark of the Board at the oral proceedings that said amendment may not comply with Rule 80 EPC. Claims 1 to 7 of the main request are now identical to claims 12 to 18 of the patent as granted.

Furthermore, the minor modification made in dependent claim 2 during oral proceedings did not modify the main point of discussion in the decision under appeal and in the statement of the grounds of appeal, namely the question of inventive step of the subject-matter of independent claim 1.

The main request is thus admitted into the proceedings.

3. *Late-filed objection*

During the oral proceedings before the Board, Appellant II argued for the first time that the subject-matter of claim 1 of the main request, which is identical to independent claim 12 of the patent as granted, extended beyond the content of the application as filed.

According to Article 12(2) of the RPBA, the statement setting out the grounds of appeal and the reply to the statement setting out the grounds of appeal of the other party (Appellant I) should contain the Appellant II's complete case. Any amendment to a party's case may only be admitted under the board's discretion (Article 13(1) RPBA). In the present case, the Board considers that Appellant I has been caught by surprise by this newly raised issue during the oral proceedings before the Board and thus could not be expected to provide arguments on this issue, with the consequence that the oral proceedings would have been postponed if this objection were to be admitted into the proceedings. Furthermore, the Appellant II’s argument for justifying the lateness of this issue that it had only realised shortly before the oral proceedings before the Board that independent claim 12 may be objected under Article 100(c) EPC does not play in favour of a *prima facie* relevance of this issue.

The board, therefore, decided not to admit this late objection into the proceedings (Article 13(3) RPBA).

Main request

4. Inventive step

4.1 Closest prior art

The Board considers, in agreement with the parties that document (3) represents the closest prior art to the invention, and, hence takes it as the starting point in the assessment of inventive step.

This document discloses a method of producing a three dimensional porous tissue ingrowth structure. The method comprises depositing a first layer of a metal powder onto a substrate, scanning a laser beam over said first layer, depositing at least one layer of said powder onto the first layer and repeating said laser scanning steps for each successive layer until a desired web height is reached (see claim 1). For example, a laser beam with predetermined settings scans the powder layer causing the powder to remelt and subsequently solidify with a decreased density, resulting from an increase in porosity as compared to a solid metal (see paragraph [0006]). Many scanning strategies are possible, such as a waffle scan, all of which can have interconnecting porosity if required (see page 5, lines 18 and 19).

4.2 *Technical* problem underlying the patent-in-suit

In view of this state of the art, the Appellant submitted that the technical problem to be solved by the invention was the provision of a method of forming an improved three-dimensional porous tissue in-growth structure.

4.3 *Solution*

The solution proposed by the patent-in-suit is the method of claim 1 characterized by forming a three-dimensional porous tissue in-growth structure which has a gradient porosity from the second surface to the first surface including at least an inner layer that is porous, an intermediate layer that is almost non-porous, an outer layer that is porous such that said flowable polymer cannot leech through said intermediate layer from said inner layer to said outer layer when said flowable liquid polymer is placed in contact with said inner layer, and placing a flowable polymer against second surface of said three-dimensional porous tissue in-growth structure; and solidifying said flowable polymer to form a bearing surface adjacent said three-dimensional porous tissue in-growth structure.

According to Appellant II, the solution proposed by the patent-in-suit was **only** characterized by the presence of a polymer on the bearing surface, all other features of the claimed method were disclosed in document (3), in particular in paragraphs [0007], [0009], [0016], [0025] and [0027].

Paragraph [0007] of document (3) referred to by Appellant II discloses that a metallic powder is deposited onto a metallic solid base or core and fused thereto. Successive powder layers of the same or different materials are added in a layer-by-layer fashion. The porosity may be increased as the structure is built, resulting in a graded profile in which the mechanical properties will also be reduced outwards from the core. According to paragraph [0009], at least one additional layer of powder is deposited and then

the laser scanning steps for each successive layer are repeated until a desired web height is reached, with an interconnecting or non-interconnecting porosity. Paragraph [0016] discloses that a three-dimensional structure with or without a solid base or core can be built using a direct laser remelt process. The process can be used to build on a solid base or core with an outer porous surface, the porosity of which is constant or varies. An all-porous structure with grade pore size to interact with more than one type of structure may be formed. Paragraph [0025] discloses that successive powder layers can differ in porosity by varying factors used for laser scanning powder layers. According to Paragraph [0027] the additional scan lines may be at any angles to the first scan to form a structure with a defined porosity, which may be regular or random. Irregular porous constructs may be produced with a defined level of porosity.

Accordingly, none of the passages of document (3) referred to by Appellant II discloses a porous structure having an inversion of the porosity gradient, i.e. a porosity which increases and then decreases from the second surface to the first surface. Therefore, document (3) does not disclose a three dimensional porous tissue ingrowth structure having an almost non-porous layer between two porous layers.

Accordingly, the Appellant II's argument should be rejected.

4.4 *Success*

The claimed method provides a three-dimensional porous structure having a second functionalized surface and a variation in the gradient of porosity between the two

surfaces impairing the leaching of a flowable polymer from the inner layer to the outer layer. Hence, the Board is satisfied that the claimed method provides an improved three-dimensional porous tissue in-growth structure.

4.5 *Obviousness*

Finally, it remains to be decided whether or not the proposed solution to this technical problem is obvious in view of the state of the art.

Appellant II exclusively addressed document (4) in order to object to obviousness. This document relates to a method for providing a shell component incorporating a porous ingrowth material and a liner (see column 1, lines 7 to 12), such as an acetabular cup (column 1, lines 59 to 63). This document is mainly concerned with ceramic material. The shell portion may be formed from a ceramic material that includes three integrally formed regions, i.e. an inner and an outer porous region and therebetween a non-porous region. A liner may then be interdigitated into the inner porous region of the shell to be held firmly in place (see column 2, line 3 to 8).

The sole section of document (4) relating to metallic prostheses is found in column 4, lines 32 to 35 and discloses that "the shell may be formed of other material such as metal wherein the inner and outer surfaces of a metal shell may be made porous".

Accordingly, the sole teaching in document (4) relating to the production of a metallic three-dimensional porous tissue in-growth structure instructs to start

with a metallic structure and to modify it by making the inner and outer surface porous.

Document (4) thus does not provides any hint to the skilled person how to modify the method disclosed in document (3), let alone to vary the gradient of the porosity in the successive metallic layers formed with laser scanning such as to provide an intermediate almost non-porous layer.

The Opposition Division statement in the contested decision in point 5.1.13 that the skilled person led by the teaching of document (4) would also have modified the method of document (3) as to allow the insertion of an intermediate almost non-porous layer in order to provide a barrier to prevent the migration of the liner, thus arriving at the claimed method is neither based on a prior art disclosure, nor on the general knowledge of the skilled person, and thus can only be seen as the result of an *ex post facto* analysis, i.e. an interpretation made with the knowledge of the invention in mind and with the aim of reconstructing on purpose the claimed method.

The Board is not aware of any further documents cited in the appeal proceedings which render the proposed solution obvious.

Therefore, the Board comes to the conclusion that the subject-matter of claim 1 of the main request, and for the same reason, that according to dependent claims 2 to 7, involves an inventive step within the meaning of Article 56 EPC.

5. Auxiliary requests 2 to 12

Since the main request is considered to be allowable, it is not necessary to decide on the lower-ranking auxiliary requests.

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 with the order to maintain the patent on the basis of the main request filed as auxiliary request 2 during the oral proceedings before the Board and a description yet to be adapted.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated