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**Datasheet for the decision
of 9 January 2014**

Case Number: T 0139/10 - 3.3.10

Application Number: 01996400.6

Publication Number: 1351722

IPC: A61L27/32, A61L27/06,
A61L27/10, A61F2/30, A61C8/00

Language of the proceedings: EN

Title of invention:
ENDOSSEOUS IMPLANT

Patent Proprietor:
UNIVERSITE DE GENEVE
Ecole Polytechnique Fédérale de Lausanne (EPFL)

Opponent:
BIOMET Deutschland GmbH

Headword:
Endosseous implant /Université de Genève

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 54, 56

Keyword:
Fresh objection raised at the appeal stage (not admitted)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
T 0823/96

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0139/10 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 9 January 2014

Appellant: BIOMET Deutschland GmbH
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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
30 October 2009 concerning maintenance of the
European Patent No. 1351722 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The Appellant (Opponent) lodged an appeal against the interlocutory decision of the Opposition Division maintaining European patent No. 1 351 722 according to the then pending main request.
- II. The Appellant's notice of opposition requested revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step pursuant to Article 100(a) EPC and of insufficient disclosure of the invention pursuant to Article 100(b) EPC.
- Inter alia* the following documents were submitted in opposition proceedings:
- (1) WO-A-99/11202
 - (3) US-A-5 733 564 and
 - (7) WO-A-02/13872.
- III. According to the Opposition Division the patent-in-suit as amended according to the then pending main request met the requirements of Articles 123(2) and (3). The subject-matter of the claims of this request was novel over documents (1), (3) and (7). Document (3) represented the closest prior art to the invention. The skilled person had no incentive to apply phosphonate compounds to uncoated metallic implants or to specific ceramic substrates, since document (3) taught that metallic substrate was normally coated with apatite or hydroxyapatite to promote the bone bonding process. The subject-matter of the claims of the then pending main request involved therefore an inventive step.

Furthermore, the objection of insufficiency of disclosure against the packaging material of claim 22 as granted was unfounded.

IV. With the statement setting out the grounds of appeal, the Appellant filed inter alia documents

(16a) Helsen & Breme, "Metals as Biomaterials", 1998, John Wiley & Sons Ltd, Chichester, England, Chapters 1,2 and 8, pages 1 to 71 ,

(16b) Helsen & Breme, "Metals as Biomaterials", 1998, John Wiley & Sons Ltd, Chichester, England, Chapters 1,2 and 8, pages 219 to 264 and,

(17) Park & Lakes, "Biomaterials: An introduction", 1992, 2nd Edition, Plenum Press, New York.

According to the written submissions of the Appellant the invention was not sufficiently disclosed in view of the interpretation of the formula $A_2-[PO(OH)_2]$ made by the Respondents in the opposition proceedings and followed by the Opposition Division in the contested decision. Compounds according to that formula could not be prepared when A_2 represented an amino acid without a terminal alkyl group, or a sequence of amino acids of a protein or of a polypeptide.

The formula $A_2-[PO(OH)_2]$ in claim 1 did not exclude the presence of a linker between the peptide or protein and the phosphonate groups and thus comprised the compounds disclosed in document (7). Furthermore, the use of the specific metals, metal alloys and ceramics recited in claim 1 for implants was common general knowledge as shown in document (16) and (17). These surfaces were therefore implicitly disclosed in documents (3) and

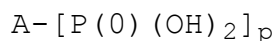
(7). Hence, the subject-matter of the claims maintained by the Opposition Division was not novel with respect to documents (3) and (7). The subject-matter of these claims lacked an inventive step starting from document (3) as the closest prior art to the invention. The subject-matter of claim 1 maintained by the Opposition Division differed from document (3) only on account of the material used to make the implant. No technical effect was shown by using a different material. Accordingly, the technical problem underlying the patent-in-suit was the provision of alternative implants. The solution of using the specific metals, metal alloys and ceramics recited in claim 1 for making an implant was obvious from documents (1), (16) and (17). The claimed subject-matter lacked therefore an inventive step. Alternatively, the claimed subject-matter lacked an inventive step starting from document (1) combined with document (3).

The appellant did not file any comments with respect to the claims of the auxiliary requests filed with letter dated 22 July 2010 in reply to statement of grounds of appeal.

- V. During the oral proceedings held on 9 January 2014 before the Board, the Respondents (Proprietors of the patent) withdrew the main request and auxiliary requests 1 to 3 and 5 to 9 and defended the maintenance of the patent in suit solely on the basis of claims 1 to 17 of the auxiliary request 4 filed with the letter dated 22 July 2010. This request is the sole request, henceforth referred to as the main request.

Claim 1 of this main request read as follows:

"1. Endosseous implant to be applied to a human or animal bone, said implant having a surface made from a selected metal or a selected metal alloy or a ceramic, whereby said metal resp. metal alloy is selected from chromium, niobium, tantalum, vanadium, zirconium, aluminium, cobalt, nickel, stainless steels or an alloy thereof, whereby said ceramic is selected from oxide surfaces, carbide surfaces, nitride surfaces, oxynitride surfaces, carbonitride surfaces or oxycarbide surfaces of chromium, niobium, tantalum, vanadium, zirconium, cobalt, nickel, stainless steels or alloys thereof or said ceramic is selected from titanium carbide, titanium nitride, titanium oxynitride, titanium carbonitride and/or titanium oxycarbide, said surface having a smooth or rough texture, characterized in that said surface has been treated with at least one pharmaceutically acceptable organic compound carrying at least one phosphonic acid group or a derivative thereof, which is a pharmaceutically acceptable ester, amide or salt thereof, corresponding to the general formula (I):



wherein A means A₁ or A₂, and

A₁ is a residue of a linear, branched or cyclic, saturated or unsaturated, hydrocarbon residue with n carbon atoms, whereby said residue may be substituted by carboxyl and optionally further interrupted by one or more oxygen and/or sulphur and/or nitrogen atoms, carrying p phosphonic acid groups, wherein

n is a number from 1 to 70 and

p is 3, 4, 5 or 6, or

A means A_2 and A_2 is a residue of an amino acid or of a sequence of amino acids respectively of a protein or of a polypeptide; or a residue of a specific drug molecule, wherein each residue A_2 carries p phosphonic acid groups, and p is 3 to 6 when A_2 is a residue of an amino acid or of a sequence of amino acids, of a protein of a polypeptide; or

p is 3, 4, 5 or 6, when A_2 is a residue of a specific drug molecule originally not bearing any phosphonic group, optionally falling under the definition given for A_1 ."

The Respondents objected to the introduction of the fresh Appellant's objection of sufficiently of disclosure submitted for the first time at the stage of the appeal proceedings. This fresh objection was unfounded. In support of its argumentation they filed document

(27) Seki et al. "A Facile preparation of Amino(diethoxyphosphoryl)acetic Esters: Transformation of Phosphoranes to Phosphonic Esters", Synthesis, 1996, vol. 5, pages 580 to 582

describing the preparation of a phosphonic acid modified glycine, thereby showing that the compounds defined in claim 1 could be prepared by the skilled person.

The subject-matter of claim 1 was novel over documents (3) and (7) both with respect to the surface to be treated and the chemical structure of the phosphonic acid compounds. As regards inventive step, the skilled

man starting from document (3) as the closest prior document would not have contemplated the use of phosphonate compounds having 3 to 6 phosphonate moieties to treat implant surfaces in view of their huge structural differences with respect to the biphosphonates disclosed in document (3), and since these compounds were not known in the field of bone medicine. The subject-matter of claim 1 was therefore novel and involved an inventive step.

- VI. The Appellant requested that the decision under appeal be set aside and the patent be revoked.

The Respondents requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request (sole request), filed as the fourth auxiliary request with letter dated 22 July 2010.

- VII. Oral proceedings were held in the absence of the Appellant, which after having been duly summoned by letter dated 24 September 2013, informed the Board that it will not attend. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. *Fresh objection submitted with the statement of the grounds of appeal*

In the notice of opposition, the Appellant raised an objection under Article 100(b) EPC concerning the packaging material of claim 22 of the patent as granted. This objection was rejected by the opposition

division in the decision under appeal. The decision of the opposition division on this objection was not contested in the appellant's grounds of appeal.

However, in the statement of grounds of appeal, the Appellant raised a fresh objection against claim 1 under Article 100(b) EPC based on an alleged impossibility of preparing the compounds of formula (I) when A_2 is an amino acid having no free terminal alkyl group, such as glycine, methionine, or a sequence of aminoacids respectively of a protein or of a polypeptide. The Respondent objected to the admissibility of this new objection against claim 1.

The Appellant justified the introduction of this fresh objection at the stage of the appeal proceedings by the fact that the Opposition Division interpreted in the contested decision formula (I) of claim 1 as requiring that the rest A_2 was directly linked to the phosphonate group.

However, this cannot justify the late filing of this objection, since the logical interpretation of the compounds of the formula (I) at least includes the possibility that the phosphonates are directly attached to the residue A_2 .

Apart from the unjustified late filing, the Board fails to see *a priori* reasons why a skilled person could not prepare compounds of formula (I), where A is A_2 . The fresh Applicant's objection is mainly based on the allegation that it is not possible to prepare amino acids having a phosphonate group if they lack a free terminal alkyl group, such as glycine. This allegation is *a priori* unfounded, as proven by document (27) which shows the preparation of the glycine substituted with a

phosphonate group (see compound 10, page 580, right-hand column), i.e. a compound of formula (I) wherein a phosphonate group is directly linked to an amino acid without a terminal alkyl group.

Therefore, pursuant to Article 12(4) RPBA, the Board considers it appropriate not to admit this new objection at the stage of the appeal proceedings.

3. *Amendments*

The Appellant did not contest the finding of the Opposition Division that the then pending main request met the requirements of Article 123(2) and (3) EPC. The Board on its own does not see any reason to take a different view. Hence, it is unnecessary to go into more detail in that respect.

Compared to the set of claims of the main request maintained by the Opposition Division, claim 1 of the present main request has been further amended in that "p" has been restricted to "3 to 6" according to *inter alia* the disclosure of page 6, lines 9, 17 and 20 of the application as filed. Dependent claims 2 and 4 have been adapted accordingly. Claims 12 and 15 have been deleted.

The requirements of Article 123(2) and (3) EPC are thus satisfied.

4. *Novelty*

4.1 *Document (7)*

Document (7) is a Euro-PCT application published on 21 February 2002. It is a state of the art pursuant to

Article 54(3) and (4) EPC, i.e. only for the purpose of novelty.

Document (7) discloses peptide compounds comprising 2 or 4 phosphonate moieties which can be used on biocompatible surfaces of e.g. implants. The biocompatible surfaces can be metal surfaces such as titanium or titanium alloys or can be cation-containing surfaces, such as amorphous or sintered calcium phosphate (hydroxyl-apatite, bones, teeth) or calcium phosphate cements (see claim 1 and the paragraph bridging pages 2 and 3).

The specific metals, metal alloys or ceramics recited in present claim 1 from which the surface of the endosseous implant is made is, however, not disclosed in document (7).

The Appellant nevertheless challenged the novelty of the claimed subject-matter with regard to document (7) arguing that the metal and metal alloys recited in claim 1 were implicitly disclosed in document (7) by virtue of the knowledge of the skilled person, who would have considered them as suitable surfaces for implants, as illustrated in documents (16) and (17).

The Board observes that it is a generally applied principle that for concluding lack of novelty, there must be a direct and unambiguous disclosure, either explicit or implicit, in the state of the art which would inevitably lead the skilled person to subject-matter falling within the scope of what is claimed. In this context "implicit disclosure" means disclosure which any person skilled in the art would objectively consider as necessarily implied in the explicit content, e.g. in view of general scientific laws. In

this respect, the term "implicit disclosure" should not be construed to mean matter that does not belong to the content of the technical information provided by a document but may be rendered obvious on the basis of that content. Whilst common general knowledge must be taken into account in deciding what is clearly and unambiguously implied by the explicit disclosure of a document, the question of what may be rendered obvious by that disclosure in the light of common general knowledge is not relevant to the assessment of what is implied by the disclosure of that document. The implicit disclosure means no more than the clear and unambiguous consequence of what is explicitly mentioned (see T 823/96, point 4.5 of the reasons, not published in OJ EPO).

In the present case, applying the peptide compound on a biocompatible surface according to the disclosure of document (7) does not necessarily imply that said surface is made of a material as recited in claim 1, since as argued by the respondent, it can be made of titanium, titanium allows or amorphous or sintered calcium phosphate (hydroxyl-apatite, bones, teeth) or calcium phosphate cements, as explicitly disclosed in document (7).

Thus, since the feature in present claim 1 that surface of the implant is made from specific materials is not disclosed in document (7), either explicitly or implicitly, the Board concludes that the subject-matter of claim 1 is novel with respect to document (7).

4.2 *Document (3)*

Document (3) discloses a method of treating endo-osteal materials with an aqueous solution comprising of a

bisphosphonate compound (see claim 1). This document does not disclose any compound having 3 to 6 phosphonate moieties, as required by claim 1 of the main request. The subject-matter of claim 1 is therefore novel with respect to document (3).

5. *Inventive step*

The Appellant objected to inventive step against the subject-matter of the claims maintained by the Opposition Division based on document (3), either as the closest prior document and combined with document (1), (16) or (17) or in combination with document (1). The Appellant, which was not present at the oral proceedings before the Board, did not take position in writing on the claims of the auxiliary request 4 which was already filed with the letter dated 22 July 2010 in reply to the statement of grounds of appeal.

The inventive step objection raised by the Appellant in the grounds of appeal against claim 1 maintained by the Opposition Division does not apply to claim 1 of the present request, since claim 1 has been restricted to implants treated with a compound of formula (I) having from 3 to 6 phosphonates groups. Those compounds are not envisaged in document (3), or in documents (1), (15) and (17). Accordingly document (3) taken in combination with either of documents (1), (16) or (17) does not render the claimed subject-matter obvious.

Hence, the subject-matter of independent claim 1, that of dependent claims 2 to 13 and 15, which include all the feature of claim 1, and by the same token that of independent claim 14 which is directed to a process for producing an implant according to one of the claims 1 to 13, that of claims 16 and 17, which is directed to a

packaging material containing an implant according to claim 15, involves an inventive step in the light of the cited documents.

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 claims 1 to 17 (main, sole request), filed as the fourth auxiliary request with letter dated 22 July 2010, and a description yet to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated