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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte T. TAIT ROBB, BRUCE BERCKMANS III,
ROSS W. TOWSE, and ROBERT L. MAYFIELD

Appeal 2015-000454
Application 13/558,037
Technology Center 3700

Before JENNIFER D. BAHR, LINDA E. HORNER, and
EDWARD A. BROWN, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

T. Tait Robb et al. (Appellants)¹ seek our review under 35 U.S.C. § 134 of the Examiner’s decision, as set forth in the Final Office Action, dated July 31, 2013 (“Final Act.”), rejecting claims 41–53.² We have jurisdiction under 35 U.S.C. § 6(b).

¹ Appellants identify the real party in interest as Biomet 3i, LLC. Appeal Br. 2.

² Appellants canceled claims 21–27 in an amendment filed after the Final Action; the Examiner entered this amendment in an Advisory Action dated July 24, 2014.

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We REVERSE and enter a NEW GROUND OF REJECTION pursuant to our authority under 37 C.F.R. § 41.50(b).

CLAIMED SUBJECT MATTER

Appellants' claimed subject matter "relates to roughened surfaces provided on dental implants to improve the osseointegration of the implant surface with the bone, thereby shortening the time between initial insertion of the implant and the installation of a prosthetic tooth." Spec. 2, ll. 15–18. Claims 41 and 48 are independent. Claim 41 is reproduced below.

41. A method of producing a uniformly roughened surface on Ti 6/4 alloy for contact with living bone comprising:

treating least a portion of the implant surface for a suitable period of time to create a first surface; and

contacting the first surface with a first aqueous solution including hydrofluoric acid and hydrochloric acid for a suitable period of time to create a second surface having a topography for osseointegration of the implant with living bone.

Independent claim 48 also is directed to a method of producing a uniformly roughened surface on a Ti 6/4 alloy implant and recites the same "contacting" step as claim 41. Appeal Br. A2 (Claims App.).

REJECTIONS

The Final Action includes the following grounds of rejection:

1. Claims 41 and 44–47 under 35 U.S.C. § 103(a) as unpatentable over Leitao (US 6,069,295, issued May 30, 2000).

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2. Claims 42, 43, and 48–53 under 35 U.S.C. § 103(a) as unpatentable over Leitao and Lazzara (US 5,863,201, issued January 26, 1999).

RELATED PROCEEDING

The application presently on appeal claims priority under 35 U.S.C. § 120 to Application 10/843,916, filed May 12, 2004 (“the ’916 application”). The ’916 application came before the Board of Patent Appeals and Interferences in an appeal from an adverse Examiner’s decision, and the Board issued a decision reversing the Examiner’s decision. *Ex parte Robb*, Appeal 2010-001525 (BPAI January 24, 2012) (attached to Appeal Brief as Exhibit A). The claims on appeal in the related application were of different scope than the claims before us in the present appeal, and the Examiner relied on several prior art references in the rejection in the related application that differ from the prior art references relied upon in the Examiner’s rejections in the present appeal. *See id.* at 1–2. In the appeal in the related application, Appellants relied on the Declaration of Keith D. Beaty Under 37 C.F.R. § 1.132 (“Beaty Decl.”) and the Declaration of Richard J. Lazzara Under 37 C.F.R. § 1.132 (“Lazzara Decl.”) to show patentability of the appealed claims over the prior art. *See id.* at 4 (FF 2, 3). Appellants submitted these same declarations in the present application to rebut the Examiner’s obviousness determinations of the presently appealed claims. Appeal Br., Exhibits B and C.

ANALYSIS

First Ground of Rejection

The Examiner found that Leitao discloses a process for surface roughening of an implant comprised of Ti 6/4 alloy including etching the implant first surface with acid to produce surface roughening. Final Act. 5 (citing Leitao, col. 1, ll. 60–64, col. 2, ll. 66–67, col. 7, ll. 44, 51). In particular, the Examiner relied on Example 3 of Leitao, which discloses the use of hydrochloric acid (HCl) and sulphuric acid (H₂SO₄) to etch the surface of a Ti 6/4 alloy. *Id.* The Examiner found, “however, Leitao explicitly states that “[t]he chemical surface treatment may e.g. be a treatment with a strong, preferably mineral, acid solution, such as **hydrofluoric, hydrochloric**, sulphuric, nitric, perchloric acid **or combinations thereof**” (column 2, lines 49–52, emphasis added).” *Id.* The Examiner determined “[t]o have etched the Leiteo [sic] [Ti 6/4 alloy] implant [of Example 3] with a combination of hydrofluoric and hydrochloric acid as is explicitly suggested by Leiteo [sic] would have been obvious to one of ordinary skill in the art.” *Id.* at 5–6.

Appellants argue that Leitao does not suggest etching a Ti 6/4 alloy using hydrofluoric (HF) and hydrochloric (HCl) acids (Appeal Br. 6–7), and that one skilled in the art would be led away from the inclusion of hydrofluoric acid in an etching solution for Ti 6/4 alloy. Appeal Br. 6–7, 12–13 (Appellants arguing Leitao’s specific teaching of etching Ti 6/4 alloy excludes the use of hydrofluoric acid).

Leitao discloses generally that the substrate of the implant can be of various materials, including metals, organic natural and synthetic polymers, and ceramic materials. Leitao, col. 1, l. 66 – col. 2, l. 9. Leitao discloses that the invention provides a process of subjecting the solid implant substrate material to a mechanical or chemical surface treatment until a desired surface roughness is obtained. *Id.*, col. 2, ll. 36–40. Leitao describes “[t]he chemical surface treatment may e.g. be a treatment with a strong, preferably mineral, acid solution, such as hydrofluoric, hydrochloric, sulphuric, nitric, perchloric acid or combinations thereof.” *Id.*, col. 2, ll. 49–52. Leitao’s disclosure of a list of possible substrate materials and a list of possible chemical surface treatment materials does not provide any specific guidance in this portion of the disclosure in column 2 as to which chemical surface treatment materials would work with the various substrate materials.

In Example 3, Leitao discloses a “new two-step chemical treatment for preparing an implant with a specific surface roughness, resulting in a metallic surface that allows fast precipitation of biomimetic calcium phosphate (Ca-P) coatings from in vitro super-saturated calcification solutions (SCS).” *Id.*, col. 7, ll. 28–33. Leitao discloses that that the two-step chemical treatment “was performed on the metallic implant materials, i.e. commercially pure titanium (cp.Ti), annealed Ti6Al4V and porous tantalum (Ta).” *Id.*, col. 7, ll. 42–45. Leitao teaches that the pure titanium and annealed titanium alloy samples were treated with a mixture of HCl and H₂SO₄, and the tantalum implant samples were treated with a mixture of HCl, H₂SO₄ and HF. *Id.*, col. 7, ll. 50–54. Notably, Leitao does not suggest

using hydrofluoric acid in the treatment mixture for the titanium samples. Further, Leitao discloses that “[t]he procedure of the treatments for titanium implants and tantalum could not be exchanged, otherwise no CA-P coating was acquired.” *Id.*, col. 8, ll. 32–34. We find that Leitao’s omission of hydrofluoric acid from the treatment mixture used with the Ti 6/4 alloy implant, and Leitao’s disclosure that the tantalum treatment mixture which included hydrofluoric acid would not work on the Ti 6/4 alloy implant to achieve the CA-P coating, would have led one having ordinary skill in the art away from using hydrofluoric acid to treat the Ti 6/4 alloy implant. For this reason, we do not sustain the rejection of claim 41, and its dependent claims 44–47, under 35 U.S.C. § 103(a) as unpatentable over Leitao.

Second Ground of Rejection

The second ground of rejection relies on the same determination of obviousness regarding use of hydrofluoric acid in the treatment mixture for the Ti 6/4 alloy based on Leitao that we found deficient in the first ground of rejection. Final Act. 7–8 (relying on Lazzara for teaching surface roughening on a threaded portion of an implant and for the initial step of removing native oxide with hydrofluoric acid prior to etching). For the reasons provided *supra* in our analysis of the first ground of rejection, we likewise do not sustain the rejection of claims 42 and 43, which depend from claim 41, and independent claim 48, and its dependent claims 49–53, under 35 U.S.C. § 103(a) as unpatentable over Leitao and Lazzara.

NEW GROUND OF REJECTION

As noted by the Examiner (Ans. 6), independent claim 41 is broad and does not limit the claimed method to producing the Osseotite® surface described in the Specification. Spec. 6, ll. 21–27 (describing the Osseotite® surface as having a “generally uniform set of sharp peaks with a maximum peak-to-valley height of 10 μm or less” and an “average peak-to-peak distance is about 1–3 μm ” and which is “clinically demonstrated to achieve *enhanced* osseointegration” (emphasis added)). Rather, claim 41 simply calls for contacting the first surface of the implant with an aqueous solution including HF and HCl “for a suitable period of time to create a second surface having a topography for osseointegration of the implant with living bone.” Appeal Br. A1 (Claims App.). We understand the Specification to describe that application of the specific two-step treatment method discussed on page 9, line 29 through page 10, line 18 of the Specification to a Ti 6/4 alloy implant resulted in *improved* osseointegration of the implant to the bone. We further understand the Specification to describe that implants having roughened surfaces other than the Osseotite® surface still achieve osseointegration of the implant with the bone, but not as quickly as achieved with an implant having the Osseotite® surface. Spec. 3, ll. 20–22 (describing the Osseotite® surface as “having reduced the time required for osseointegration of the titanium implant with bone”). Further, we understand the claim, as written, to require only that the contacting step produce a roughened surface having a topography capable of

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osseointegration of the implant with living bone, as the claim is directed to a method of producing the implant and not a method of using the implant.

Based on the scope of claim 41, we enter a new ground of rejection of claim 41 under 35 U.S.C. § 102(b) as anticipated by Hama (U.S. Patent Number 4,818,559, issued April 4, 1989). Hama discloses “[a] method of producing a uniformly roughened surface on Ti 6/4 alloy for contact with living bone,” as recited in the preamble of claim 41. In particular, Hama discloses using Ti 6/4 alloy material as artificial material for tooth roots. Hama, col. 2, l. 64 – col. 3, l. 7. Hama further discloses the surface of the metallic core material is made rough to a specific maximum surface roughness in the range of 15 μm to 100 μm . *Id.*, col. 3, ll. 28–32.

Hama discloses “treating [at] least a portion of the implant surface for a suitable period of time to create a first surface,” as recited in the first step of claim 41. In particular, Hama discloses “[t]he metallic material is formed into the desired shape by conventional methods, such as cutting, casting, forging, punching, electro arc machining, laser-processing, and powdered metal techniques.” Hama, col. 3, ll. 25–28. As noted by the Examiner in the Final Action, “whether the implant is machined, cast or made in some other way[,] it would necessarily have had a surface that was shaped (i.e.,] treated) over a period of time to have a first surface.” Final Act. 5. We find that the methods for shaping the metallic implant material disclosed in Hama, such as cutting, forging, punching, and machining, constitute treating a portion of the implant surface for a suitable period of time to create a “first surface.”

Hama further discloses “contacting the first surface with a first aqueous solution including hydrofluoric acid and hydrochloric acid for a suitable period of time to create a second surface having a topography for osseointegration of the implant with living bone,” as recited in the second step of claim 41. In particular, Hama describes that in order to make the surface rough, the metallic core material is subjected to chemical etching, which is “carried out by using mineral acid, such as sulfuric acid, hydrochloric acid, hydrofluoric acid, which are used alone or in a combination of two or more thereof.” Hama, col. 3, ll. 41–45, 51–55. Thus, Hama discloses, to achieve the desired surface roughness of 15 μm to 100 μm , the metallic core material, which is preferably made of Ti 6/4 alloy, is subjected to chemical etching by contact with an aqueous solution that includes sulfuric acid, hydrochloric acid, and hydrofluoric acid.³ We note that Hama is not concerned with the acid being too aggressive because it is not trying to achieve a surface roughness of less than 10 μm . *See, e.g.*, Beaty Decl., para. 8 and Lazzara Decl., para. 9 (stating that Hama teaches using hydrochloric acid and hydrofluoric acid to etch an implant surface to obtain a surface topography of up to 100 μm). While such a roughened surface may not be capable of the *improved* osseointegration achieved by Appellants’ Osseotite® surface described in the Specification, this roughened surface nonetheless provides a topography capable of osseointegration of the implant with living bone, as called for in claim 41.

³ Claim 41 does not exclude sulfuric acid in the claimed solution.

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Finally, we find it of no moment that Hama additionally teaches spraying the roughened surface with a ceramic material because the claim uses the transitional term “comprising” and is thus broad enough to include additional steps. For these reasons, we enter a new ground of rejection of claim 41 under 35 U.S.C. § 102(b) as anticipated by Hama.

DECISION

The decision of the Examiner to reject claims 41–53 is REVERSED.

We enter a NEW GROUND OF REJECTION of claim 41 under 35 U.S.C. § 102(b) as anticipated by Hama.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” Section 41.50(b) also provides:

When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.

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(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

REVERSED; 37 C.F.R. § 41.50(b)