UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RICHARD J. LAZZARA, THOMAS S. HEYLMUN, and KEITH D. BEATY

Appeal 2007-0192
Application 09/237,605
Technology Center 3700

Decided: May 30, 2007

Before MURRIEL E. CRAWFORD, JENNIFER D. BAHR, and LINDA E. HORNER, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants seek our review under 35 U.S.C. § 134 of the Examiner's final rejection of claims 51 and 60-75, which are all of the claims now pending.[1] We have jurisdiction under 35 U.S.C. § 6(b) (2002).

SUMMARY OF DECISION

We REVERSE and ENTER A NEW GROUND OF REJECTION UNDER 37 C.F.R. § 41.50(B).

THE INVENTION

Appellants' claimed invention is to a dental implant for insertion into a hole in a living jawbone for eventual support of artificial teeth (Specification 1:6-7). Claim 51, reproduced below, is representative of the subject matter on appeal.

> 51. A dental implant made of titanium metal, comprising:
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> a smooth head portion for receiving a dental restoration component;
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> a lowermost end opposing said head portion;
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> a threaded portion for engaging bone between said head portion and said lowermost end; and
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> a roughened region for facilitating osseointegration with said bone located on said threaded portion and

[1] The Final Rejection, dated July 23, 2004, also included a rejection of claims 11-16 and 57-59. Appellants canceled these claims in an Amendment filed with the Appeal Brief on August 16, 2005. The Examiner entered this Amendment on April 5, 2006 (Answer 2).

> extending to said lowermost end of said implant, said roughened region being uniformly acid etched with a second acid solution after a native oxide layer had been removed by contact with a first acid solution with minimum consumption of said titanium metal to produce a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns.

THE REJECTION

The Examiner relies upon the following as evidence of unpatentability:

Haruyuki	JP 3-146679	Jun. 21, 1991
Niznick	US 5,571,017	Nov. 5, 1996

The Examiner rejected claims 51 and 60-75 under 35 U.S.C. § 103(a) as unpatentable over Haruyuki and Niznick. Appellants seek our review of this rejection.

ISSUE

Appellants contend Haruyuki's roughened surface does not "inherently" correspond to Appellants' claimed roughened region, Haruyuki's surface cannot be duplicated (Appeal Br. 7-9; Exhibit I), and Niznick and Haruyuki teach away from their combination (Appeal Br. 10). Appellants further provide a Declaration from Dr. Stephan S. Porter purporting to evidence secondary considerations of non-obviousness (Appeal Br. 15-17; Exhibit J).

The Examiner found that there is no clear difference between the surfaces resulting from Haruyuki's treatment method and the claimed treatment method (Answer 5) and the claimed treatment steps are broad such that they are not

commensurate in scope with the process used to make Appellants' test samples (Answer 6). The Examiner further contends "the fact that Haruyuki wants to optimize pores size and depth to promote cell attachment does not teach away from Niznick, but instead teaches a way of achieving what both references desire: cell attachment and ongrowth" (Answer 6).

The issue before us is whether the combination of Haruyuki and Niznick renders obvious the invention of claims 51 and 60-75.

FINDINGS OF FACT

Independent claims 51, 63, and 68 recite a roughened region (claim 51) or an acid-etched surface (claims 63 and 68) "having a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns."

Haruyuki discloses titanium and titanium alloy biorepair members used in medicine for, e.g., dental surgery and more particularly implant members such as artificial dental roots and false teeth (Haruyuki[2] 2: Technical Field). In particular, Haruyuki discloses a biorepair member where at least the surface of the embedded portion of the member is provided by means of acid treatment with irregularly shaped microscopic depressions having an average depth of 0.5 to 5 μm (Haruyuki 3: Means Solving the Problems). Haruyuki discloses a two-step acid etching process, which includes a pretreatment step, in which the surface of the embedding portion is dipped in 1 to 6 weight% aqueous hydrofluoric acid (HF)

[2] Our references to Haruyuki throughout this Opinion refer to the English translation of Haruyuki provided by the PTO and attached as Exhibit B to Appellants' Appeal Brief.

solution for 30 seconds to 3 minutes, followed by a posttreatment comprising dipping for 10 to 60 seconds in an aqueous mixed solution of 1 to 6 weight% aqueous hydrofluoric acid solution and 1 to 10 weight% hydrogen peroxide (H_2O_2) solution (Haruyuki 3: Means Solving the Problems). Haruyuki discloses that the pretreatment step functions to thoroughly remove the oxide film present on the surface of the Ti and Ti alloy biorepair members (Haruyuki 3: Function). Haruyuki further discloses that depression size and depth can be changed, and hence the surface roughness can be adjusted, by varying the HF concentration and dipping time (Haruyuki 4: Function). Haruyuki discloses, "an average depth in excess of 5 μm, although providing a high anchoring effect, tends to result in the appearance of sharp spines and sharp edges at the ridge lines between depressions, which can cause tissue irritation (possibly a trigger for cancer)" (Haruyuki 4: Function). Haruyuki teaches, "Dipping in a mixed aqueous solution of HF and H_2O_2 in the posttreatment functions to smooth the sharp edges and sharp spines that appear at the microscopic depressions produced during the pretreatment" (Haruyuki 4: Function).

Niznick discloses externally-threaded, endosseous dental implants with generally cylindrical-shaped bodies and self-tapping threads at or near the distal end of the implant (Niznick, col. 4, ll. 14-16). Niznick discloses that the external surface of the neck of the implant is preferably unthreaded, uncoated and relatively smooth to allow maintenance of oral hygiene should the neck become exposed to the oral environment (Niznick, col. 4, ll. 41-44). In particular, Niznick discloses "the neck portion of the implant is sufficiently smooth to minimize adherence of

dental plaque that can cause an adverse mucosal tissue reaction if exposed to the oral environment as a result of crestal bone loss or otherwise" (Niznick, col. 4, l. 65 – col. 5, l. 2). Niznick discloses that the external surface of the threaded distal end of the implant is preferably uncoated and has a smooth enough surface to maintain sharp cutting threads for self-tapping insertion (Niznick, col. 4, ll. 44-47). Niznick discloses that the external surface of the middle, preferably threaded, portion of the implant is roughened or coated, or both, to increase the percentage of the surface in contact with bone, thus enabling the implant to better withstand biting forces (Niznick, col. 4, ll. 48-52).

PRINCIPLES OF LAW

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (internal quotation marks omitted). "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product... . Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same ...[footnote omitted]." The burden of proof is similar to that required

with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (*quoting In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. *See, e.g., In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294, 227 USPQ 657, 665 (Fed. Cir. 1985).

Further, since in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. *In re Weber*, 405 F.2d 1403, 1407, 160 USPQ 549, 553 (CCPA 1969). Where the affidavit or declaration presented asserts that the reference relied upon is inoperative, the claims presented by applicant must distinguish from the alleged inoperative reference disclosure. *In re Crosby*, 157 F.2d 198, 200, 71 USPQ 73, 75 (CCPA 1946).

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). *See also In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). In so doing, the examiner is expected to make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. In addition to these factual determinations, the examiner must also provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir 2006) (*cited with approval in KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007)). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *See Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444. *Id.* at 1445, 24 USPQ2d at 1444. *See also Piasecki*, 745 F.2d at

1472, 223 USPQ at 788. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444; *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986) (citations omitted).

> Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid. When a word of degree is used the [factfinder] must determine whether the patent's specification provides some standard for measuring that degree. The [factfinder] must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.

Seattle Box Co. v. Indust. Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed. Cir. 1984) (affirming the trial court's determination that an expert would know the limitations of the claims because the specification clearly sets forth a standard for measuring the degree used in the claim language). Even if a person of ordinary skill would need to experiment so as to determine the limits of a patent's claims, the claims would not be invalid under section 112. See, e.g., *W.L.*

Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983).

A prior art rejection of a claim, which is so indefinite that "considerable speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is needed, is likely imprudent. *See In re Steele*, 305 F.2d 859, 862, 134 USPQ 292, 298 (CCPA 1962) (holding that the examiner and the board were wrong in relying on what at best were speculative assumptions as to the meaning of the claims and basing a rejection under 35 U.S.C. § 103 thereon.)

ANALYSIS

The Examiner based his rejection on the dental implant of Haruyuki having a roughened surface produced by applying Haruyuki's surface treatment method to a titanium implant. Haruyuki's disclosure focused on the surface treatment method. As such, it did not provide detailed disclosure of the different parts of a conventional dental implant. Rather, Haruyuki merely stated that its surface treatment method could be used to create "irregularly shaped microscopic depressions" on "at least the surface of the embedded portion of the titanium or titanium alloy biorepair member." The Examiner thus combined the surface treatment method of Haruyuki with the disclosure of Niznick, which shows the conventional components of a dental implant, including a head portion, a lowermost end, and a threaded portion, as claimed. The crux of the dispute revolves around the roughened surface that results from applying the surface

treatment method of Haruyuki to an implant, and whether this resulting surface is comprised of "a substantially uniform array of irregularities" as claimed.

Appellants provided a Declaration of Prabhu Gubbi, which purported to compare "a titanium dental implant [that] was given a treatment according to the method described in this patent application to produce an Osseotite® surface" with "titanium implants [that] were exposed to the two-step procedure described in ... Haruyuki." (Gubbi Decl., ¶D). Dr. Gubbi attached copies of SEM photographs of the sample implants along with three-dimensional representations of each surface (Gubbi Decl., Exhibits A & B). Dr. Gubbi concluded,

> From these SEM photographs and the three-dimensional representations of the surfaces, it appears that exposure of titanium implants to hydrofluoric acid treatments produced less roughening than reported by [Haruyuki]. In fact, the machining marks are still visible on many of the surfaces. Further, the post-treatment with hydrofluoric acid and hydrogen peroxide appears to smoothen the surface, which is consistent with the teaching at column 2 on page 4 of the translation of [Haruyuki]. Finally, the treatments of [Haruyuki] produced surfaces that do not resemble the surface achieved by the methodology of the subject patent application, as shown in Exhibit A (Gubbi Decl. ¶ H).

Although the Specification provides no specific discussion of the claimed "substantially uniform array of irregularities," it incorporates by reference a preferred method of roughening the surface, as disclosed in U.S. Patent No. 5,876,453 to Beaty[3] (Specification 3:23-25). Our review of the '453 Beaty patent

[3] The present application is also a continuation-in-part of the '453 Beaty patent

does not, however, uncover any description of a standard for measuring the degree of uniformity such that one of ordinary skill in the art would understand what is claimed when the claim is read in light of the Specification. The '453 Beaty patent discloses, "Because of the prior removal of the native oxide layer, even a mild second treatment of the implant surface can produce a substantially uniform effect over substantially the entire bone-interfacing surface of the implant" (Beaty '453, col. 5, ll. 57-61). It further discloses, "The same degree of uniformity was found in all the samples, and from sample to sample, at magnifications of 2,000 and 20,000, as compared with similar samples subjected to bulk etching without prior removal of the native oxide...." (Beaty '453, col. 8, ll. 21-25). This seems to imply that the uniformity of the irregularities is made possible by the pretreatment step, during which the native oxide layer is removed. As we found *supra,* the two-step method of Haruyuki includes a similar first step of removing the native oxide layer, followed by a second step of acid etching. As such, it is not clear how the resulting surface of Haruyuki's implant would not have the "substantially uniform array of irregularities" as claimed.

The Gubbi Declaration is of no assistance in further defining the claim language so as to distinguish the claimed surface from the prior art surface. Dr. Gubbi fails to state in his declaration that the Osseotite® surface, used for comparison with the prior art, was made according to the "claimed invention." Rather, Dr. Gubbi's declaration states merely that "a titanium dental implant was given a treatment according to the method described in this patent application to

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(Specification 1:3,4).

produce an Osseotite® surface" (Gubbi Decl., ¶D). Further, the declaration fails to reach a conclusion that the prior art sample surfaces do not contain "substantially uniform arrays of irregularities." Rather, the Dr. Gubbi merely concludes that "the treatments of the Japanese patent application produced surfaces that do not resemble the surface achieved by the methodology of the subject patent application, as shown in Exhibit A [the Osseotite® surface]" (Gubbi Decl., ¶H).

Further, one having ordinary skill in the art would not be able to discern the metes and bounds of the claim scope based on the SEM photographs and the three-dimensional representations of the surfaces attached to Dr. Gubbi's declaration. For example, any critical difference in the degree of uniformity is doubtful when one compares the irregularities shown in the Osseotite® surface and the surface shown in Example 3 of Exhibit B made using the prior art Haruyuki method. Dr. Gubbi does not provide an explanation in his Declaration of why this prior art surface fails to contain a "substantially uniform array of irregularities." As such, we are left to compare the three-dimensional representations for ourselves, and in doing so, we do not see a discernable difference in the uniformity of the array of irregularities on these surfaces.

Further, the remainder of the claim fails to provide any assistance in determining the scope of the indefinite limitation. Although the claims further recite that the substantially uniform array of irregularities have "peak-to-valley heights not greater than about 10 microns," this recitation provides only an upper limit on the size of the irregularities but does not aid one in determining whether a particular array of irregularities is "substantially uniform." For example, a peak-

to-valley height of zero or 0.01 microns would fall within this claim limitation, so that an array of irregularities of widely varying heights might be present on the roughened surface. The claims also recite the acid-etching process, including removing a native oxide layer and then uniformly acid etching with a second acid solution. This general description of the treatment method is insufficient to define what is meant by "substantially uniform array of irregularities" because, if it was, then Haruyuki would inherently contain such an array as it follows the same two-step treatment process. Appellants have chosen to make "substantially uniform array of irregularities" the critical and defining limitation of the claim. As such, it must be clear as to what falls within its scope.

"Substantially" is a broad term. *See In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960) (affirming the Board's rejection of a claim reciting a "substantially homogeneous and ferritic" steel structure because it was, at best, a change in degree from the "substantially ferritic" steel of the prior art and the specification failed to provide a standard to determine what degrees are included within the broad term "substantially.") In this case, the Specification fails to provide a standard for measuring the claimed degree of uniformity. Therefore, one of ordinary skill would not know what degree of roughness would fall within the claim scope and what would not. Further, we do not see how one skilled in the art would be able to determine the claim scope by experimentation. This is because the Specification does not even provide a measure of the enhancement of bonding of the implant to the bone as compared to prior art implants.

As such, we enter a new ground of rejection of claims 51 and 60-75 under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regard as their invention.

Based on the indefiniteness of the claims, as set forth *supra*, we find it improvident to decide on the propriety of the Examiner's rejection of the claims in view of the prior art, because it would require the Board to engage in speculative assumptions as to the meanings of the claims. *See In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962). As such, we do not reach the issue of combinability of the references or the evidence presented in the Declaration of Dr. Porter, raised in Appellants' Brief.

CONCLUSIONS OF LAW

We conclude that claims 51 and 60-75 are indefinite because one skilled in the art would not be able to ascertain what is claimed when the claims are read in light of the Specification. As such, we conclude that the Examiner's rejection of claims 51 and 60-75 as unpatentable over Haruyuki and Niznick was imprudently made in view of the indefiniteness of the claims.

DECISION

The decision of the Examiner to reject claims 51 and 60-75 under 35 U.S.C. § 103(a) is reversed. We enter a new ground of rejection of claims 51 and 60-75 under 35 U.S.C. § 112, second paragraph as being indefinite.

This decision contains a new ground of rejection pursuant to 37 C.F.R.

§ 41.50(b) (2006). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds 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 proceeding will be remanded to the Examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . .

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) (2006).

REVERSED; 37 C.F.R. § 41.50(b)

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