

The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAN EIRIK ELLINGSEN and GUNNAR ROLLA

Appeal 2007-1526
Application 11/035,534
Technology Center 1700

Decided: June 29, 2007

Before PETER F. KRATZ, JEFFREY T. SMITH, and
LINDA M. GAUDETTE, *Administrative Patent Judges*.

KRATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal from the Examiner's final rejection of claims 5-7, 21, 28, 35, 42, and 79-87.¹ We have jurisdiction pursuant to 35 U.S.C. § 6.

The subject application for a patent presents an invention directed to a process of treating a metallic bone implant with a hydrofluoric acid solution.

¹ An oral hearing was held on June 06, 2007. Counsel for Appellants appeared via telephone.

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According to Appellants (the named inventors), the treatment enhances the biocompatibility of the implant, that is, the rate of attachment of bone tissue to the implant and the strength of the implant bond (Specification 4 and 5).

Claim 79 is illustrative and reproduced below:

79. A process of treating a metallic bone implant consisting essentially of treating the metallic bone implant with a solution of hydrofluoric acid in which the concentration of hydrofluoric acid is 0.01% to 0.5%.

The Examiner relies on the following prior art references as evidence in rejecting the appealed claims:

Kasuga	US 4,871,384	Oct. 3, 1989
Haruyuki (as translated)	JP 3-146679	Jun. 21, 1991
Kiyoshi (as translated)	JP 5-285213 A	Nov. 2, 1993

Claims 5-7, 21, 28, 35, and 79-84 stand rejected under 35 U.S.C.

§ 103(a) as being unpatentable over Haruyuki. Claims 42, 85, and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki in view of the admitted prior art (APA). Claims 42, 85, and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki in view of Kiyoshi. Claim 87 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki in view of Kiyoshi and Kasuga.

Concerning the Examiner's first stated rejection, Appellants group claims 5, 28, 35, 79-81, and 84 together, and put claims 6, 7, 82, and 83 in a second claim grouping. Hence, we select claim 79 as the representative claim for the first claim grouping and claim 6 as the representative claim for the second grouping of claims. Claim 21 is argued separately.

Claims 5, 28, 35, 79-81, and 84

Representative claim 79 is drawn to a process for treating a metallic implant for bone. The process is recited as consisting essentially of treating

the implant with a hydrofluoric acid solution of a concentration between 0.01% and 0.5%.

The Examiner found that Haruyuki discloses, *inter alia*, that treating a metallic bone implant made of titanium or titanium alloy with hydrofluoric acid at a concentration of 1% to 6% improves adhesion of the implant to bone tissue (Answer 4). Haruyuki reports that the HF treatment, at the above-noted concentration levels, forms “a large number of irregularly shaped microscopic depressions with an average diameter of 1 to 10 μm and an average depth of 0.5 to 5 μm ” (Haruyuki 4, left column, ll. 3-6). Haruyuki teaches that “sharp edges and spines” due to this treatment can be smoothed by a post treatment of the implant with a hydrogen peroxide and hydrofluoric acid mixed aqueous solution (Haruyuki 4, right column, ll. 5-9). Haruyuki discloses that it is known to roughen the surface of titanium implants to improve adhesion of the implant to bone and that even “the formation of ultrafine, 10 nm to 1,000nm (0.01 μm to 1 μm) pores in the surface of metal repair members” are known, albeit “the bonding force with cells is still not always adequate” (Haruyuki 3, left col., ll. 17-23).

The Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the HF treatment process of Haruyuki by using a concentration of HF in the treating solution, as called for in representative claim 79, to improve the adhesion of an implant to bone (Answer 3 and 4). In this regard, Haruyuki teaches that the concentration of the HF in the treating solution and the treatment time are result-effective variables in treating implants (Haruyuki 4, left col., ll. 6-9). The Examiner is basically asserting that an ordinarily skilled artisan would have recognized using lower concentrations of HF acid was a

workable option from these teachings of Haruyuki. This is because, in the Examiner's view, the formation of depressions in the implant surface for improving bone cell binding therewith, even if perhaps of somewhat smaller size, would have been recognized as predictable and within the reach of such an ordinarily skilled artisan by using lower concentrations of HF acid in the treatment of an implant surface. The Examiner contends that the existence of a prima facie case of obviousness can be supported when the claimed range and a disclosed prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have substantially the same or similar properties. *See Titanium Metals Corp. v. Banner*, 778 F.2d 775, 783, 227 USPQ 773, 779 (Fed. Cir. 1985).

Appellants, on the other hand, refer to several passages of Haruyuki and, based thereon, contend that:

Haruyuki clearly teaches:

- (i) treatment with HF having a concentration less than 1% provides pore sizes below 1 μm , and
- (ii) an implant surface comprising pore sizes below 1 μm gives an inadequate anchoring effect and is thus not desirable.

Therefore, a person of ordinary skill in the art would have no reason to use or further explore the treatment containing less than 1% HF concentrations.

Br. 6 and 7.

Furthermore, Appellants contend in their Briefs that the process of representative claim 79 is attended by unexpected results.

Thus, the dispositive issues before us with respect to the Examiner's obviousness rejection of representative claim 79 are: (1) Have the Appellants identified reversible error in the Examiner's assertion that a prima facie case of obviousness has been presented based on the teachings

found in Haruyuki, as they would be understood by one of ordinary skill in the art?; (2) If not, have Appellants established unexpected results for the representative claim 79 process or otherwise furnished secondary indicia of unobviousness of such character and weight as to warrant reversal of the Examiner's obviousness holding of representative claim 79?

We answer both questions in the negative and affirm the Examiner's obviousness rejection of representative claim 79 and the rejected claims grouped together therewith.

Appellants argue to the effect that one of ordinary skill in the art would have had no reason to employ a lower acid concentration in the HF solution treatment of Haruyuki, because Haruyuki teaches or would have led one of ordinary skill in the art to the conclusion that using an acid concentration of less than 1% will result in inadequate bonding of the implant to bone tissue. This line of argument is not persuasive and is undercut not only by a full reading of Haruyuki, but also by the admitted background prior art information provided in Appellants' Specification.²

For example, Haruyuki discloses that forming ultrafine pores in the implant is beneficial even though the cell bonding force is not always adequate (Haruyuki 3, col. 1, ll. 14-23). Moreover, Appellants acknowledge that titanium implants have been available since 1950, and that the force of the bond between titanium and bone tissue is relatively strong albeit

² It is axiomatic that admitted prior art, including prior art found in an applicant's specification, may be used in determining the patentability of a claimed invention, and that consideration of the prior art cited by the Examiner may include consideration of the admitted prior art found in the Specification. *In re Nomiya*, 509 F.2d 566, 570-571, 184 USPQ 607, 611-612 (CCPA 1975); *In re Davis*, 305 F.2d 501, 503, 134 USPQ 256, 258 (CCPA 1962).

enhancements in strength may be desirable for some implant applications (Specification 2: 10-17). Also, Appellants acknowledge that methods of enhancing the physical or chemical properties of an implant surface to stimulate bone growth and the repair process for better attachment thereof, including the formation of micro-pitted surfaces are known (Specification 2: 18 - 3: 3).

Against this prior art factual background, we agree with the Examiner that it would have been prima facie obvious for one of ordinary skill in the art to use lower concentrations of HF acid, such as within the here-claimed range, in treating the titanium implants of Haruyuki depending on the application desired for the implant. After all, one of ordinary skill in the art would understand that the value for adequate bond strength will differ depending on the particular implant application. Haruyuki, read in isolation, may have suggested that the relative bond strength for an implant treated with a lower concentration of the acid would be lower than for an implant treated with HF concentrations of from 1-6%. However, this suggestion by Haruyuki, would not have dissuaded an ordinarily skilled artisan from employing such lower concentrations range acids in treating the implant for use in applications where the bond strength required is relatively low. In addition, taking the disclosure of Haruyuki in light of the admitted prior art set forth in Applicants' Specification, an ordinarily skilled artisan would have recognized the value of adding smaller depression or pits in the surface of the implant in furnishing a suitable implant material. Thus, we do not agree with Appellants' argumentation suggesting one of ordinary skill in the art would have been dissuaded from such a modification of the HF concentration in the treating solution of Haruyuki (Reply Br. 1 and 2).

In addition, we note that the argued “obvious to try” is not inimical to an obviousness determination.

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

KSR Int'l. Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742, 82 USPQ2d 1382, 1397 (2007).

As a further point, we are aware that the representative claim includes the transition “consisting essentially of” (Claim 79). However, this term does not render the process of representative claim 79 closed to other steps or the use of other treatment materials for the implant. In this regard, the “phrase ‘consisting essentially of’ limits the scope of a claim to the specified ingredients and those that do not *materially affect* the *basic and novel* characteristic(s) of a composition.” *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976); *see also PPG Indus., Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998) (“By using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention”).

However, it is also the case that during examination, "claims ... are to be given their broadest reasonable interpretation consistent with the specification, and ... claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art."

In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364, 70 USPQ2d 1827, 1830 (Fed. Cir. 2004). In assessing a broadest reasonable claim construction wherein a potentially exclusionary “consisting essentially of” transitional phrase is involved, it is appropriate that Appellants bear the burden of: (1) showing the basic and novel characteristics of their claimed invention, and (2) establishing how those characteristics would be materially changed by any allegedly excluded component of an applied reference. *See In re DeLajarte*, 337 F.2d 870, 873-74, 143 USPQ 256, 258 (CCPA 1964); *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (BPAI 1989).

Here, Appellants have not carried this burden by their unsubstantiated arguments to the effect that representative claim 79 would exclude the post treatment step of Haruyuki with hydrogen peroxide and hydrogen fluoride in solution. In this regard, we note that claim 42, which depends from claim 79, provides for a further treatment step following the hydrofluoric acid treatment. Thus, claim 79 is not closed to other treatment steps, which may beneficially affect the implant biocompatibility. Moreover, Appellants expressly indicate that they do not consider their inventive contribution to be bound by the theory or their thoughts that biocompatibility is enhanced by retention of fluoride on the implant surface (Specification 4: 31- 5: 2).³

Furthermore, and assuming that such a post treatment step were excluded by representative claim 79, it is our view that it would have been

³ Indeed, U.S. Patent No. 4,330, 891, of record (referenced in the Specification at 2) would appear to suggest that the presence of fluoride ions was known to be beneficial to tissue growth around an implant surface (col. 4, ll. 8-28). In the event of further prosecution of the subject matter of this application before the Examiner, the Examiner should consider whether this patent together with other prior art of record would render any pending claims unpatentable.

obvious to one of ordinary skill in the art to forego the post treatment step of Haruyuki, with its function, especially where lower concentrations of acid are employed in the hydrofluoric acid initial treatment step. This is because one of ordinary skill in the art would expect less sharp edges and sharp spines to be formed with the lower depths of any depressions formed when using lower acid concentrations as taught/suggested by (Haruyuki 4, col. 1, ll. 26-31). Consequently, we do not find Appellants arguments with respect to the post treatment step option of Haruyuki to be persuasive of reversible error in the Examiner's obviousness rejection.

For the foregoing reasons and those stated in the Answer, we determine that the Examiner has established a prima facie case of obviousness in view of the reference evidence. Appellant has argued that unexpected results have been demonstrated substantially throughout the Brief and Reply Brief. Therefore, we begin anew and consider the evidence for and against obviousness. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

The question as to whether unexpected advantages have been demonstrated is a factual question. *In re Johnson*, 747 F.2d 1456, 1450-60, 223 USPQ 1260, 1263 (Fed. Cir. 1984). Thus, it is incumbent upon Appellants to supply the factual basis to rebut the prima facie case of obviousness established by the examiner. *See, e.g., In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972). Appellants, however, do not refer to an adequate factual showing in the specification to support a conclusion of unexpected advantages. Appellants' evidence of nonobviousness is significantly short of being commensurate in scope with

representative claim 79 and cannot overcome the rejection of the claims. *See In re Boesch*, 617 F.2d 272, 277, 205 USPQ 215, 220 (CCPA 1980); *In re Payne*, 606 F.2d 303, 315-16, 203 USPQ 245, 256 (CCPA 1979). The Specification Examples do not even furnish a single test conducted with an implant treated near the lower limit of the claimed acid concentration. For example, the tested 0.2 percent acid concentration (Examples 1 and 2) is 20 times greater in acid concentration than the 0.01% acid concentration lower limit of representative claim 79. While Example 3 includes one calcium phosphate precipitation induction test conducted at a 0.05% acid concentration, that test included a relatively long 180 second treatment time and still included five times the minimum claimed acid strength. Moreover, representative claim 79 is inclusive of any metallic implant. Hence, the representative claim is not limited to the tested titanium implants. Nor is claim 79 limited to the specific testing conditions employed. Moreover, Appellants have not satisfied their burden of explaining how the results reported for the limited tests presented can be extrapolated to substantiate Appellants' contentions for the invention as broadly claimed.

Furthermore, Appellants have not explained why the comparative examples are considered to be the closest prior art. *See In re Burckel*, 592 F.2d 1175, 1179, 201 USPQ 67, 71 (CCPA 1979). Also, Appellants have not asserted unexpectedness for the claimed subject matter in the Specification, much less persuasively explained why the reported results are considered "unexpected." Based on the totality of the record, including consideration of Appellants' arguments and evidence, we determine that the preponderance of evidence weighs most heavily in favor of obviousness

within the meaning of § 103(a). Therefore, we affirm the obviousness rejection of representative claim 79 and the claims grouped therewith.

Claims 6, 7, 82, and 83

Representative claim 6 further requires that the treatment of claim 79 is carried out for at least 10 seconds. Appellants additionally maintain that Haruyuki's disclosure of treatment times from 30 seconds to 3 minutes is not shown to be attended by the new and unexpected results that the claimed invention is alleged to be associated with. For reasons discussed above, however, we do not find that Appellants have established unexpected results for the claimed subject matter. Thus, we shall also affirm the Examiner's obviousness rejection as to claims 6, 7, 82, and 83.

Claim 21

Appellants maintain that the "same morphology" limitation for the product implant surface added by dependent claim 21 patentably distinguishes claim 21 from the teachings of Haruyuki. We disagree.

As argued by Appellants (Br. 13), the claim 21 "same" limitation in question is inclusive of minor surface changes. Taking this construction of claim 21 as being consistent with Appellants' Specification and how that claim would be understood by one of ordinary skill in the art, we determine that one of ordinary skill in the art would have expected the implant surface changes to be minor when low acid concentrations and treatment times are employed based on the above-discussed teachings of Haruyuki. While we agree with Appellants that Haruyuki does not describe or exemplify an acid treatment process with such a "same" morphological result (Br. 13-15,

Reply Br. 4-6), we nevertheless agree with the Examiner that such a process was within the ambit of one of ordinary skill of the art based on the overall teachings of Haruyuki. The claim 21 process is attended by morphological features of the implant that would have been expected by an ordinarily skilled artisan when treating the implant with extremely dilute HF acid solution. On this record, we determine that one of ordinary skill in the art would have found the subject matter of claim 21 an obvious matter of choice depending on the implant surface properties desired.

Concerning the Examiner's separate rejections of dependent claims 42, 85, 86, and 87, Appellants limit their arguments against the Examiner's obviousness rejections of these claims to the arguments made against the Examiner's obviousness rejection of representative claim 79 (Br. 15 and 16). It follows that we shall also sustain the Examiner's separate rejections of these dependent claims on this record.

CONCLUSION

The Examiner's decision to reject claims 5-7, 21, 28, 35, and 79-84 under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki; to reject claims 42, 85, and 86 under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki in view of the admitted prior art (APA); to reject claims 42, 85, and 86 under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki in view of Kiyoshi; and to reject claim 87 under 35 U.S.C. § 103(a) as being unpatentable over Haruyuki in view of Kiyoshi and Kasuga is affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

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