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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER HOLDINGS, INC. AND ZIMMER DENTAL INC., Petitioner

v.

FOUR MILE BAY, LLC Patent Owner

U.S. Patent No. 8,684,734

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,684,734

TABLE OF CONTENTS

				Page
I.	INTR	ODUC	CTION	1
II.	MAN	IDAT(ORY NOTICES UNDER 37 C.F.R. § 42.8	1
III.	PAY	MENT	OF FEES UNDER 37 C.F.R. §§ 42.15 AND 42.103	2
IV.			FOR STANDING AND IDENTIFICATION OF GE	2
V.	BAC	KGRO	UND	3
	A.	The '	734 Patent	4
	B.	Prose	cution History of the '734 Patent and Earlier Applications	8
		1.	The '012 Patent Prosecution (the Original Patent)	8
		2.	The '734 Patent Prosecution	10
VI.	CLA	IM CO	NSTRUCTION	12
VII.			CTIVE PRIORITY DATE OF THE '734 PATENT	19
VIII.	DET	AILED	EXPLANATION OF UNPATENTABILITY	21
	A.	Lomi	cka's Disclosure	22
	B.		nd 1: <i>Lomicka</i> Anticipates Claims 1-3, 5-10, 12-15, 17-21, 4, and 27	
		1.	Claim 1	23
		2.	Claim 2	29
		3.	Claim 3	30
		4.	Claim 5	31
		5.	Claim 6	31
		6.	Claim 7	32
		7.	Claim 8	32
		8.	Claim 9	35
		9.	Claim 10	36
		10.	Claim 12	36
		11.	Claim 13	37
		12.	Claim 14	37
		13.	Claim 15	40

TABLE OF CONTENTS

(continued)

				Page
		14.	Claim 17	40
		15.	Claim 18	40
		16.	Claim 19	41
		17.	Claim 20	41
		18.	Claim 21	44
		19.	Claim 23	44
		20.	Claim 24	45
		21.	Claim 27	45
	C.	Grou	und 2: Lomicka Renders Obvious Claim 22	48
		1.	Claim 22	48
	D.		und 3: <i>Lomicka</i> in View of <i>Bhaduri</i> Renders Obvious ms 25 and 26	49
		1.	Claim 25	
		2.	Claim 26	
IX.	STA	ТЕМЕ	ENT REGARDING CONCURRENTLY FILED PETI	TION52
X.	CON	NCLUS	SION	53

TABLE OF AUTHORITIES

Page(s)
Federal Cases
Biogen Idec., Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090 (Fed. Cir. 2013)
Fenner Invs.,LTD. v. Cellco P'ship, 778 F.3d 1320 (Fed. Cir. 2015)
Ford Motor Co. v. Vehicle Operation Techs., LLC IPR2014-00594, Paper No. 26 (P.T.A.B. Oct. 15, 2014)
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007)
Lizardtech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336 (Fed Cir. 2005)19
Lockwood v. Am. Airlines, Inc., 107 F.3d 1565 (Fed. Cir. 1997)19
Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314 (Fed. Cir. 2003)
SAP Am., Inc. v. Pi-Net Int'l, Inc., IPR2014-00414, Paper No. 11 (P.T.A.B. Aug. 18, 2014)19
Sentry Protection Products, Inc. v. Eagle Mfg Co., 400 F.3d 910 (Fed. Cir. 2005)
In re Translogic Tech., Inc., 504 F.3d 1249 (Fed. Cir. 2007)
<i>In re Yamamoto</i> , 740 F.2d 1569 (Fed. Cir. 1984)12
Statutes
35 U.S.C. § 102(b)

TABLE OF AUTHORITIES

(continued)

Page(s)

Other Authorities

37 C.F.R.	
§ 42.1(b)	53
§ 42.8	
§ 42.8(b)(1)	
§ 42.8(b)(2)	
§ 42.15	
§ 42.103	
77 Fed. Reg. 48,756 (Aug. 14, 2012)	

LIST OF EXHIBITS

No.	Description
1001	U.S. Patent No. 8,684,734 to Lyren
1002	Declaration of Dr. James Earthman
1003	Prosecution History of U.S. Patent No .7,291,012
1004	Prosecution History of U.S. Patent No. 8,684,734
1005	Four Mile Bay's Proposed Constructions and Supporting Intrinsic Evidence
1006	U.S. Patent Application Publication No. 2001/0123951 to Lomicka
1007	U.S. Patent Application Publication No. 2002/0106611 to Bhaduri et al.
1008	U.S. Patent No. 5,049,074 to Otani
1009	U.S. Patent No. 6,095,817 to Wagner et al.
1010	Excerpt from Merriam-Webster's Collegiate Dictionary (11 th ed. 2012)
1011	Prosecution History of U.S. Patent No. 8,297,974
1012	Prosecution History of U.S. Patent No. 8,043,090
1013	U.S. Patent No. 5,282,861 to Kaplan
1014	Excerpt from Webster's New World College Dictionary (4 th ed. 2004)

I. <u>INTRODUCTION</u>

Zimmer Holdings, Inc. and Zimmer Dental Inc. (collectively, "Petitioner") request *inter partes* review of claims 1-3, 5-10, 12-15, and 17-27 of U.S. Patent No. 8,684,734 ("the '734 patent") (Ex. 1001), which is assigned to Four Mile Bay, LLC ("Patent Owner"). This Petition shows that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims, and thus a trial for *inter partes* review should be instituted. This Petition also establishes by a preponderance of the evidence that claims 1-3, 5-10, 12-15, and 17-27 of the '734 patent are unpatentable under 35 U.S.C. §§ 102(b) and/or 103(a). These claims should be canceled.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

Real Party-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Zimmer Holdings, Inc., and Zimmer Dental Inc. as the real parties-in-interest.

Related Matters: Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following related matter. The '734 patent is involved in *Four Mile Bay LLC v*. *Zimmer Holdings, Inc. et al.*, No. 3:14-CV-1300 (N.D. Ind.) (JVB)-(JEM). Petitioner is concurrently filing a second petition for *inter partes* review challenging claims 1-3, 5-10, 12-15, and 17-27.

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III. PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15 AND 42.103

Petitioner submits the required fees with this petition. Please charge any additional fees required for this proceeding to Deposit Account No. 50-2613.

IV. GROUNDS FOR STANDING AND IDENTIFICATION OF CHALLENGE

Petitioner certifies that the '734 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting such review of the '734 patent on the grounds identified.

Claims 1-3, 5-10, 12-15, and 17-27 of the '734 patent are unpatentable and should be cancelled in view of the following prior art references and grounds. Specifically, as discussed in Section VII, the claims are not entitled to a priority date any earlier than the filing date of the '734 patent, and as a result, they are

invalid in view of the following prior art references and grounds:

Reference 1: U.S. Patent Application Publication No. 2011/0123951 to Lomicka ("*Lomicka*") (Ex. 1006).

Reference 2: U.S. Patent Application Publication No. 2002/0106611 to Bhaduri et al. ("*Bhaduri*") (Ex. 1007).

Ground 1: Claims 1-3, 5-10, 12-15, 17-21, 23, 24, and 27 are unpatentable under 35 U.S.C. § 102(b) as anticipated by *Lomicka*.

Ground 2: Claim 22 is unpatentable under 35 U.S.C. § 103(a) as obvious over *Lomicka*.

Ground 3: Claims 25 and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Lomicka* in view of *Bhaduri*.

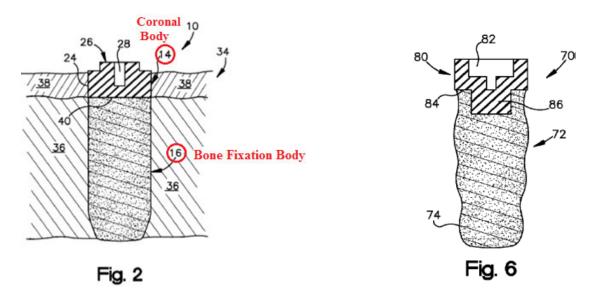
V. <u>BACKGROUND</u>

The '734 patent issued from U.S. Patent Application No. 13/571,375 ("the '375 application" or "the '734 patent application"), filed August 10, 2012, and purports to be a continuation-in-part of U.S. Patent Application No. 13/195,872 ("the '872 application"), now Patent No.8,297,974, which purports to be a continuation of U.S. Patent Application No. 11/358,375 ("the '8,375 application"), filed on February 21, 2006, now U.S. Patent No. 8,043,090, which purports to be a continuation of U.S. Patent Application No. 10/375,343 ("the '343 application" or "the original application"), filed on February 27, 2003, now Patent No. 7,291,012

("the '012 patent" or "the original patent"). Ex. 1001 at title page.

A. The '734 Patent

The '734 patent relates to dental implants, as shown in the embodiments of Figures 2 and 6, below. *See e.g.*, Ex. 1001 at 2:33-63. The disclosed dental implants include two components or bodies: a coronal body and a bone fixation body. *See e.g.*, *id.* at 2:34-37, Figs. 1 and 2; Ex. 1002 at ¶ 13. Figure 2 shows a dental implant 10 having a coronal body 14 and bone fixation body 16 embedded in a jawbone 34 of a patient:



The coronal body is formed from a solid metal piece of titanium or titanium alloy, and includes a transgingival section 24, which extends along the gum or gingival tissue 38. *See* Ex. 1001 at 2:38-41, 2:49-51, Fig. 2. It also includes a dental interface 26 extending upwardly from the transgingival section 24. *See id.* at 2:38-44, Fig. 2. Dental interface 26 is formed as a male connector (Fig. 2) or a female

connector (Fig. 6) having a polygon shape and is provided with a threaded bore 28 adapted to receive a fixation screw for connecting the implant to a dental component such as a prosthesis. *See id.* at 2:42-49 (disclosing a male hexagon connector), 4:17-19 (disclosing a female connector having a hexagon or polygon shape). In some embodiments, coronal body 14 can include a first region having a smooth outer surface and a second region having a surface treatment such as, for example, micro-texturing. *See id.* at 3:60–4:9, Figs. 3 and 4; *see also* Ex. 1002 at ¶ 14.

The specification includes an embodiment (shown in Figure 6 above) in which a distal end surface 84 of the coronal body 80 includes an elongated protrusion 86 that extends into the bone fixation body 72. *See* Ex. 1001 at 4:19-21, Fig. 6. Protrusion 86 can have any shape such as, for example, "cylindrical, square, rectangular, hexagonal, octagonal, polygonal, or other shapes." *Id.* at 4:24-27. In the embodiment shown in Fig. 6, the porous structure of the bone fixation body 72 connects to the metal coronal body at an interface that has a circular or elliptical cross-section. *See id.* at 11:40-46. According to the '734 patent, protrusion 86 is "adapted to increase the interface between the coronal body and bone fixation body." *Id.* at 4:21-23; *see also* Ex. 1002 at ¶ 15.

The bone fixation body has a generally cylindrical shape (Figs.1 and 2) or tapered shape (Figs. 3 and 4) that extends from a proximal end to a rounded distal

end. *See id.* at 2:53-55, 3:62-65, Figs. 1-4. The bone fixation body is formed from titanium and has a "completely porous structure" that "extends throughout the entire body from the proximal to distal ends [sic]." Id. at 2:55-58. "By 'porous,' it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface." Id. at 3:3-5. According to the specification, "the size and shape of the porous structure emulates the size and shape of the porous structure of natural bone." Id. at 3:10-11. In one embodiment, the '734 patent explains that the average pore diameter "is about $40\mu m$ to about 800 μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than 50-60 microns." Id. at 3:11-15; see also Ex. 1002 at ¶ 16.

The '734 patent, which is allegedly a continuation-in-part, also discloses a new embodiment—not present in the parent and grandparent applications from which the patent stems—in which "the porosity of the porous structure can be constant throughout the porous structure." *Compare* Ex. 1001 at 13:16-17 *with generally* Ex. 1003 at 160-174; Ex. 1011 at 94-107, Ex. 1012 at 238-252. Alternatively, the '734 patent explains, the porosity may "change within the porous structure." *See* Ex. 1001 at 13:17-18; *see also* Ex. 1002 at ¶ 17.

The specification alleges that the configuration of the porous structure "encourage[s] natural bone to migrate and grow into and throughout the entire

body 16." Ex. 1001 at 3:16-17. The bone fixation body can also be adapted to induce bone growth through the body. *See id.* at 4:52-54. For example, the bone fixation body can be doped with biological active substances containing pharmaceutical agents to stimulate bone growth. *See id.* at 3:53-57; *see also* Ex. 1002 at ¶ 18.

The bone fixation body can be fabricated using various techniques including sintering, casting, plasma-spraying, sputter deposition techniques, and metallic deposition techniques. *See* Ex. 1001 at 12:64-67. The coronal body can be formed using known machining techniques. *See id.* at 3:21-22. In certain disclosed embodiments, these bodies are fabricated independently and subsequently connected or fused together. *See id.* at 3:55-59; *see also* Ex. 1002 at ¶ 19.

The '734 patent includes 27 claims, of which claims 1, 8, 14, 20, 25, and 27 are independent. *See* Ex. 1001; *see also* Ex. 1002 at ¶ 20. Claims 1, 8, 14, and 20 are directed to a dental implant comprising, among other things, a coronal body and a porous body that is "uniform"/has "uniform porosity." Claims 25 and 27 are directed to a method comprising, among other things, forming a porous body having "uniform porosity." Independent claim 1 reads in full:

1. A dental implant, comprising:

a coronal body having a proximal end with a connection shaped as a polygon to receive a dental component, having a distal end surface with an elongated

protrusion that extends outwardly therefrom, and being formed of solid metal; and

an elongated cylindrical porous body formed as a porous metal structure that is uniform and that includes a proximal end that engages the distal end surface of the coronal body at an interface,

wherein the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body at the interface, and

wherein the elongated protrusion of the coronal body includes a polygonal shape that extends into an opening of the porous body such that the porous metal structure completely surrounds and engages an exterior surface of the elongated protrusion that extends into the porous body.

B. <u>Prosecution History of the '734 Patent and Earlier Applications</u>

1. The '012 Patent Prosecution (the Original Patent)

The original application, which matured into the '012 patent, included one independent claim that recited a dental implant comprising, among other aspects, "a bone fixation body . . . formed of a completely porous structure." Ex. 1003 at 169. Independent claim 1 was rejected as being anticipated and/or rendered obvious over a number of references including U.S. Patent No. 5,049,074 to Otani

("Otani"). See e.g., id. at 131-132; see also Ex. 1008. In response, Applicant amended independent claim 1 to recite that the bone fixation body was formed of a completely "uniform" porous structure and argued that the cited references do not teach a completely uniform porous structure because they teach different pore sizes. See e.g., Ex. 1003 at 112, 115-121. The Examiner maintained the rejections, and Applicant appealed the rejections to the Board. See id. at 98, 103-108.

In its decision on appeal, the Board found that some of Appellant's arguments "appear[] to be grounded on the position that the language 'completely uniform porous structure' requires that the porosity and pore size of the body [sic] fixation body is the same throughout the body." *Id.* at 39. The Board found nothing in Applicant's specification to support this position. *Id.* In particular, the Board found that "[t]he term 'uniform' is not used in Appellant's Specification, outside of [the] claims." *Id.* The Board also found that "[t]here is nothing in this description that would convey to one of ordinary skill in the art that the porosity and pore size are the same throughout the entire body." *Id.* Accordingly, the Board concluded that the phrase "completely uniform porous structure" means only "that the entire structure be porous." *Id.*

Additionally, the Board sustained a number of the Examiner's rejections including the Examiner's rejection based on *Otani*. *See id.* at 36-38. It found that

"porous layer 8 [of *Otani*] may be considered the bone fixation body" and that it is "formed of a completely uniform porous structure" because "porous layer 8 is entirely porous throughout . . . " *Id.* at 36. Based on this, the Board sustained the Examiner's rejections of claims 1, 2, 4, 5, 7-11, and 15-19 of the original application as anticipated by *Otani*. *See id.* at 37-38. In response, the Applicant conceded that *Otani* discloses an entirely porous structure and cancelled the rejected claims. *See id.* at 17-19.

2. The '734 Patent Prosecution

In the '734 patent application, which matured into the '734 patent, Applicant added new subject matter not disclosed in the original patent or any of the other intervening applications. Specifically, Applicant added that "the porosity of the porous structure can be constant throughout the porous structure" Ex. 1001 at 13:16-18. Applicant filed the '734 patent application with three independent claims broadly reciting, among other things, a "porous structure." Ex. 1004 at 123-128.

The Examiner issued a number of rejections based on *Otani*. *See id.* at 60-62. But, in a summary of an interview initiated by the Applicant, the Examiner agreed that the rejections based on *Otani* would be overcome if Applicant amended the independent claims to require the porous structure to be "uniform" based on the Applicant's representations that unlike the "uniform" porous structure of the

amended claims, "the porosity of the porous layer [in Otani] changes." Id. at 51.

Applicant subsequently amended independent claim 21 (now claim 1) to recite a "porous metal structure that is uniform," independent claims 28 and 34 (now claims 8 and 14, respectively) to recite a porous body with "uniform porosity," independent claim 40 (now claim 20) to recite "a uniform porous metal structure," and added new independent claims 45 and 47 (now claims 25 and 27, respectively) which recite a porous body with a uniform porous metal structure. Applicant argued that the amended claims and new claims See id. at 29-36. distinguish from Otani because "Otani teaches a dental implant with a porous coating that has 'a pore distribution such that the interior of the fiber material i.e. the core material side is most dense and the porosity gradually increases toward the external surface." Id. at 38-39, 41 (citing Otani at 3:35-38). Based on the Applicant's representations that (1) a "uniform" porous structure requires unchanging porosity, and (2) Otani teaches a porous layer having changing porosity, the amended and new claims were ultimately allowed and issued as independent claims 1, 8, 14, 20, 25, and 27. See Ex. 1001 at 13:49–17:6.

VI. CLAIM CONSTRUCTION

In an *inter partes* review, the Board applies the broadest reasonable interpretation ("BRI") standard to construe claim terms. Under the BRI standard, claim terms are given their "broadest reasonable interpretation, consistent with the specification." *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012). Claim terms are also "generally given their ordinary and customary meaning," which is the meaning that the term would have to a person of ordinary skill in the art. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1313 (Fed. Cir. 2005) (*en banc*)). Petitioner proposes a construction for a few of the claim terms below, but all of the claim terms in the '734 patent should be given their plain and ordinary meaning under the BRI standard.³

¹ Petitioner notes that the district courts apply a different claim construction standard and reserves its rights to make arguments based on that standard in the district court.

² A person of ordinary skill in the art would have had an undergraduate degree in a relevant engineering field (e.g., Mechanical Engineering, Materials Science Engineering, Biomedical Engineering) with 3-5 years of experience with dental

The independent claims of the '734 patent all include a "porous" feature that is "uniform," (hereinafter the "uniform porosity features"). Specifically, claim 1 recites a "porous . . . structure that is uniform." Ex. 1001 at 13:55-56. Claims 8 and 14 recite a "porous body" having "uniform porosity." *Id.* at 14:46-47, 15:9-10. And claims 20, 25, and 27 recite "a uniform porous . . . structure." *Id.* at 16:5, 32, 58-59; *see also* Ex. 1002 at ¶ 22. During prosecution of the '734 patent, the Applicant described the uniform porosity features of the independent claims similarly. *See* Ex. 1004 at 38-39, 41. In addition, the Patent Owner has grouped and construed these limitations similarly during litigation. Ex. 1005 at 1. Accordingly, these features should be construed together to have the same meaning.

In the context of the '734 patent, the broadest reasonable interpretation of implants or similar implants or a graduate degree in a relevant field with 1-3 years of experience with dental implants or similar implants. Ex. 1002 at ¶ 10.

³ Claims 2, 5, 10, and 21 do not further limit the independent claims from which they depend and/or fail to point out and distinctly claim the subject matter that is the invention. Petitioner understands that such grounds under 35 U.S.C. § 112 cannot be raised in this proceeding, but reserves the right to argue them before a district court or in another forum.

the claimed uniform porosity features is "a porous body or structure having a constant porosity throughout the body or structure." This understanding is consistent with the '734 patent's new disclosure, the plain language of the claims, and the Applicant's statements and the Office's findings during prosecution. *See* Ex. 1002 at ¶ 23.

The plain and ordinary meaning of "uniform" is "not varying or changing," or "constant." *See* Ex. 1010 at 1368; Ex. 1014 at 1561. Outside of the claims, the term "uniform" is not expressly used in the '734 patent specification. However, the new disclosure of the '734 patent, which is allegedly a continuation-in-part, discloses an embodiment with a porous body or structure having a "constant" porosity throughout. Ex. 1001 at 13:16-18. Like the term "uniform," "constant" has a plain and ordinary meaning of "unchanging," or "remaining free from variation or change" or "uniform." *See* Ex. 1010 at 267; Ex. 1014 at 312; Ex. 1002 at ¶ 24.

The '734 patent discloses a porous structure that is porous throughout. Ex. 1001 at 2:56-59 (describing a bone fixation body 16 made up of "a completely porous structure that extends through the entire body from the proximal to distal ends"); *see also id.* at 3:1-2. In the newly disclosed embodiment, the '734 patent further teaches that "the porosity of the porous structure can be **constant** throughout the porous structure." *Id.* at 13:16-18 (emphasis added); *see also* Ex.

1002 at ¶ 25.

Consistent with the plain and ordinary meaning of both "uniform" and "constant," the '734 patent contrasts the porous structure having "constant" porosity with a porous structure in which the porosity "change[s] within the porous structure." Ex. 1001 at 13:16-18 (reciting that "the porosity of the porous structure can be constant throughout the porous structure or change within the porous structure"). Unlike the porous structure having "constant" porosity, the '734 patent explains that a "porous structure can have a gradient porosity in which the porosity changes from the surface of the bone fixation body to the center of the bone fixation bode [sic] (for example, the porosity near the [external] surface of the bone fixation body is different than the porosity [near] the internal [surface of the] cavity)." Id. at 13:18-23. In another embodiment, the '734 patent discloses a nonconstant porous body in which porosity varies from 45% to 65% within the porous structure. *Id.* at 3:11-13; Ex. 1002 at ¶ 26.

The doctrine of prosecution history disclaimer further supports Petitioner's construction. This doctrine "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). The Board has considered and applied prosecution history disclaimer in construing claim terms. *See, e.g., Ford Motor Co. v. Vehicle Operation Techs., LLC*, IPR2014-00594,

Paper No. 26 at 13-19 (P.T.A.B. Oct. 15, 2014). During prosecution of the '734 patent, the Applicant advocated a construction similar to Petitioner's and clearly and unequivocally disclaimed a broader construction of the uniform porosity features in order to distinguish its claims over prior art.

In particular, the Applicant amended its claims to require the porous structure to be "uniform," and argued that the newly added limitations should have the same construction as Petitioner contends—constant porosity—to overcome *Otani*:

Independent claim 1 recites a porous metal structure that is <u>uniform</u>. Independent claim 28 recites a porous body with a <u>uniform</u> porosity. Independent claim 34 recites a porous body with a <u>uniform</u> porosity. Independent claim 40 recites a bone fixation body with a <u>uniform</u> porous metal. . . . Independent claims 45 and 47 recite a porous body with a <u>uniform</u> porous metal structure. **By contrast, Otani teaches** a dental implant with a porous coating that has a 'pore distribution such that the interior of the fiber material i.e. the core material side, is most dense and <u>the porosity gradually increases</u> toward the external surface' (col. 3, lines 35-38)."

Ex. 1004 at 38-39. The Examiner likewise noted in an interview summary that he agreed with Applicant's statements that the porous structure in *Otani* was not "uniform' because the porosity changes. *Id.* at 51. In prosecuting the original

patent the Applicant similarly distinguished references applied by the Examiner as not teaching a completely **uniform** porous structure because they disclose different pore sizes. *See* Ex. 1003 at 112, 115-121 (emphasis added).

To gain allowance of its claims, the Applicant had no choice but to clearly and unequivocally disclaim a construction of a "uniform" porous structure broad enough to encompass a structure that is no more than "entirely porous." The Board had already previously found that "[t]here is no question that the porous layer 8 [of Otani] is entirely porous throughout" Ex. 1003 at 36. And in response to Applicant's contentions that *Otani's* porous layer is not a body or structure, but simply a coating, the Board also found that Otani's porous layer is a "body," as claimed. See id. at 37 ("Otani's porous layer is a 'body"). Thus, the Applicant clearly and unmistakably distinguished Otani's changing porosity within the porous body from the claimed "uniform" porous body of the claims. See Sentry Protection Products, Inc. v. Eagle Mfg Co.,400 F.3d 910, 915 (Fed. Cir. 2005) (affirming the district court's finding that prosecution history modified the scope of the claim "term impact protection components" when Applicant "expressly disclaimed the use of multiple components to overcome a rejection"); see also Fenner Invs., LTD. v. Cellco P'ship, 778 F.3d 1320, 1325 (Fed. Cir. 2015) ("[T]he interested public has the right to rely on the inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them,

or how much weight they were given.").

Nonetheless, in litigation, Patent Owner has reversed course and contends that the uniform porosity features should be construed as "a metal structure that is porous throughout." Ex. 1005 at 1. Patent Owner's construction should be dismissed at least because it directly contradicts its statements to the Office during prosecution—including the very statements that led to the allowance of the '734 patent claims. See Biogen Idec., Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090, 1095 (Fed. Cir. 2013) ("when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered"). Patent Owner's construction is also incorrect because it is inconsistent with the '734 patent's new disclosure of a porous structure having a porosity that is "constant throughout". Ex. 1001 at 13:16-18; see also Ex. 1002 at ¶ 27. Thus, the broadest reasonable interpretation of the "uniform" porous features

⁴ The Board previously determined that a "completely uniform porous structure" simply refers to a structure in which no part is non-porous. Though the construed phrase has similarities to the uniform porosity features of the '734 patent claims, the Board's finding was made in view of the different disclosure of the original patent and thus does not apply here. *See* Ex. 1003 at 39-40.

is "a porous body or structure having a constant porosity throughout the body or structure."

VII. THE EFFECTIVE PRIORITY DATE OF THE '734 PATENT CLAIMS

The Board may consider priority in these types of proceedings. *See*, *e.g.*, *SAP Am.*, *Inc.* v. *Pi-Net Int'l*, *Inc.*, IPR2014-00414, Paper No. 11 at 11-16 (P.T.A.B. Aug. 18, 2014). Under 35 U.S.C. § 120, a claim in a U.S. application is entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the earlier filed application in accordance with the written description requirement. *See*, *e.g.*, *id.*; *Lockwood v. Am. Airlines*, *Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). To comply with the requirements of Section 112, first paragraph, the specification "must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed." *Lizardtech*, *Inc.* v. *Earth Resource Mapping*, *Inc.*, 424 F.3d 1336, 1345 (Fed Cir. 2005).

The '734 patent attempts to claim priority to several earlier filed applications, namely the '872 application, the '8,375 application, and the '343 application. *See* Ex. 1001 at 1:6-11; *see also supra* Section V.A. These earlier field applications, however, do not provide written support for at least the "uniform porosity" features of the independent claims, as required by section 112.

Accordingly, the earliest possible effective filing date of claims 1-3, 5-10, 12-15, and 17-27 is the August 10, 2012, the filing date of the '734 patent. In fact, the "uniform porosity" features were first introduced in the '734 patent application. Compare Ex. 1004 at 122, 11. 7-8 with Ex. 1003 at 160-174. The '734 patent explicitly states that "the porosity of the porous structure can be constant throughout the porous structure." Ex. 1001 at 13:16-18. By contrast, the earlierfiled applications describe a bone fixation body that is "completely porous," but with varying pore diameter and porosity throughout. See e.g., Ex. 1003 at 165 ("Preferably, the average pore diameter of body 16 is about 40µm to about 800µm with a porosity from about 45% to 65%."). The earlier applications do not describe or show a bone fixation body with the "uniform porosity" features. See generally Ex. 1003 at 160-174, Ex. 1011 at 94-107, Ex. 1012 at 238-252; see also Ex. 1002 at ¶ 28.

Indeed, the Board has confirmed that the earlier-filed applications lack written description support. During prosecution of the original patent, in response to Applicant's argument that the bone fixation body has a constant porosity, the Board found that "[t]here is nothing in [the original patent application] description that would convey to one of ordinary skill in the art that the porosity and pore size are the same through the entire body. In fact, the use of the term 'average' implies that the pores in the body vary in size." Ex. 1003 at 39. All of the earlier-filed

applications have the same disclosure as the original patent application. *Compare* Ex. 1003 at 160-174 *with generally* Ex. 1011 at 94-107, Ex. 1012 at 238-25. Thus, the challenged claims are not entitled to any priority date earlier than the filing date of the '734 patent, i.e., August 10, 2012.⁵

VIII. DETAILED EXPLANATION OF UNPATENTABILITY

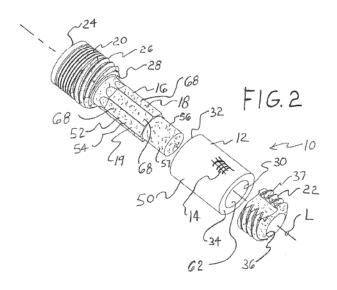
As discussed above, the broadest reasonable interpretation of the claimed uniform porous features in the context of the '734 patent is "a porous body or structure having a constant porosity throughout the body or structure." *See supra* Section VI. Given this construction, the '734 patent claims are not entitled to a priority date any earlier than the filing date of the '734 patent, August 10, 2012, (*see supra* Section VII), and are invalid in view of *Lomica* and/or *Bhaduri*. *See* Ex. 1002 at ¶ 29. *Lomicka* was published on May 26, 2011 and *Bhaduri* was published on August 8, 2002. Because the earliest effective filing date of claims 1-3, 5-10, 12-15, and 17-27 of the '734 patent is August 10, 2012, *Lomicka* and *Bhaduri* are prior art under 35 U.S.C. § 102(b).

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⁵ Petitioner does not concede that the '734 patent specification and claims comply with 35 U.S.C. § 112. Such issues cannot be raised in this proceeding. Petitioner reserves the right to argue them before a district court or in another forum.

A. <u>Lomicka's Disclosure</u>

Lomicka discloses a dental implant 10 "for insertion into a mandible or maxilla. The implant 10 is used to anchor one or more dental prostheses" See Ex. 1006 at ¶¶ [0016]-[0017], Figs. 1-4; Ex. 1002, ¶ 30. Implant 10, shown below in Figure 2, includes a coronal head 20 and core 16 extending outwardly from head 20. See e.g., id. at ¶¶ [0016]-[0018], Fig. 2. Core 16 can be integrally formed with head 20 and the structure may be formed of a solid metal such as "titanium, titanium alloy, stainless steel, zirconium[], [or] cobalt-chromium molybedenum alloy." See id. at ¶¶ [0017], [0021]. Lomicka teaches that core 16 may have a generally polygonal shape. See id. at Figs. 2, 3; see also id. at ¶¶ [0042], [0047]; Ex. 1002 at ¶ 30.



Lomicka further teaches that coronal end 24 of the head 20 is configured with a female engagement structure that receives a corresponding structure from a

separate dental component such as an abutment. *See id.* at ¶ [0018]. The female engagement structure can be shaped as a polygon to receive and retain a dental component. *See e.g.*, *id.* at Fig. 5; Ex. 1002 at ¶ 31.

Implant 10 of *Lomicka* includes an exterior portion 12 made of a porous material 14 that surrounds a surface of core 16. See Ex. 1006 at ¶¶ [0016], [0019], [0040], Fig. 2. As shown in Fig. 2, exterior portion 12 forms a cylindrical body, and includes a coronal end 32 that engages an apical end surface 28 of head 20 at an interface. See id. at Fig. 2; see also id. at ¶ [0016], [0019]. Lomicka discloses that "the porous material 14 forming the exterior portion 12 may include metal, and in one form, is a porous tantalum portion 40 which is a highly porous biomaterial useful as a bone substitute and/or cell and tissue receptive material." Id. at ¶ [0023]; see also id. at Fig. 4 (depicting the porous tantalum structure 40). The porous tantalum structure 40 "may be fabricated to virtually any desired porosity and pore size, whether *uniform* or varying, and can thus be matched with the surrounding natural bone in order to provide an improved matrix for bone ingrowth and mineralization." *Id.* at \P [0029] (emphasis added); Ex. 1002 at \P 32.

B. <u>Ground 1: Lomicka Anticipates Claims 1-3, 5-10, 12-15, 17-21, 23, 24, and 27</u>

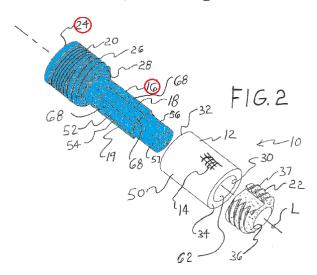
1. Claim 1

i. "A dental implant, comprising:"

Lomicka discloses a dental implant. See e.g., Ex. 1006 at ¶¶ [0004]-[0012],

[0016], [0017], Figs. 1-4. For example, *Lomicka* discloses an implant 10 "for insertion into a mandible or maxilla. The implant 10 is used to anchor one or more dental prostheses" *See id.* at ¶¶ [0016]-[0017]; Ex. 1002, ¶ 33; *see also infra* Sections VIII.B.1.ii-v.

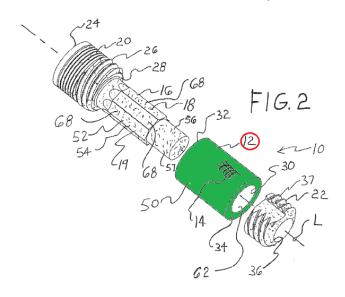
ii. "a coronal body having a proximal end with a connection shaped as a polygon to receive a dental component, having a distal end surface with an elongated protrusion that extends outwardly therefrom, and being formed of solid metal; and"



Implant 10 includes a coronal head portion or head 20, shown in blue in Fig. 2 above. *See* Ex. 1006 at ¶ [0017], Fig. 2. Head 20 has a coronal end 24 and a core 16 extending outwardly from an opposite end of head 20. *See e.g.*, *id.* at ¶ [0017]-[0018], Fig. 2. Core 16 can be integrally formed with head 20. *See id.* at ¶ [0017]. *Lomicka* discloses that head 20 and core 16 are formed of a solid metal such as "titanium, titanium alloy, stainless steel, zirconium[], [or] cobalt-chromium molybedenum alloy." *See id.* at ¶ [0021]; Ex. 1002 at ¶ 34.

Lomicka further teaches that coronal end 24 of the head 20 is configured with a female engagement structure that receives a corresponding structure from a separate dental component such as an abutment. See Ex. 1006 at ¶ [0018]. The female engagement structure can be shaped as a polygon to receive and retain a dental component, as shown in Figure 5. See e.g., id. at Fig. 5; Ex. 1002 at ¶ 35.

iii. "an elongated cylindrical porous body formed as a porous metal structure that is uniform and that includes a proximal end that engages the distal end surface of the coronal body at an interface,"



Implant 10 of *Lomicka* includes an exterior portion 12, shown in green in Fig. 2 above, made of a porous material 14. *See* Ex. 1006 at ¶ [0016]. As shown in Fig. 2, exterior portion 12 forms a cylindrical body, and includes a coronal end 32 that engages an apical end surface 28 of head 20 at an interface. *See id.* at Fig. 2; *see also id.* at ¶ [0016] ("exterior portion 12 may be placed on *or around* an interior portion [of] core 16") (emphasis added), *id.* at ¶ [0019] ("apical end

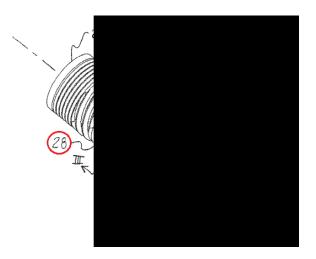
surface 28 forms a shoulder to abut and retain exterior portion 12 on the core 16" and "[a] coronal end 32 of the exterior portion 12 faces and/or abuts the apical end surface 28."); Ex. 1002 at ¶ 36.

Lomicka discloses that "the porous material 14 forming the exterior portion 12 may include metal, and in one form, is a porous tantalum portion 40 which is a highly porous biomaterial useful as a bone substitute and/or cell and tissue receptive material." Ex. 1006 at ¶ [0023]; see also id. at Fig. 4 (depicting the porous tantalum structure 40). Lomicka teaches that the porous tantalum structure 40 "may be fabricated to virtually any desired porosity and pore size, whether uniform or varying, and can thus be matched with the surrounding natural bone in order to provide an improved matrix for bone in-growth and mineralization." Id. at ¶ [0029] (emphasis added). Thus, Lomicka discloses a porous metal structure that is uniform where the porous metal structure has a constant porosity. Id.; Ex. 1002 at ¶ 37.

iv. "wherein the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body at the interface, and"

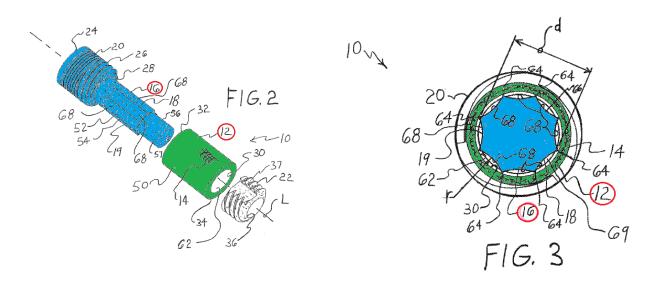
As shown in Fig. 2, apical end surface 28 of head 20 has a circular shape. See Ex. 1006 at Fig. 2; see also Ex. 1002 at ¶ 38. Likewise, coronal end 32 of exterior portion 12 has a circular shape. See Ex. 1006 at Fig. 2; see also Ex. 1002

at ¶ 38. The solid metal of the circular shape of head 20 interfaces with the porous metal structure 40 of the circular shape of exterior portion 12 as shown in Fig. 1 reproduced below.



See Ex. 1006 at \P [0019] ("[a] coronal end 32 of the exterior portion 12 faces and/or abuts the apical end surface 28."); see also Ex. 1002 at \P 38.

v. "wherein the elongated protrusion of the coronal body includes a polygonal shape that extends into an opening of the porous body such that the porous metal structure completely surrounds and engages an exterior surface of the elongated protrusion that extends into the porous body."



Lomicka teaches that "exterior portion 12 is a sleeve or collar with a bore 30 that receives the core 16" and that core 16 "has a reduced outer diameter compared to the diameter of the outer surface 26 and extends apically from an apical end surface 28 of head 20 so that apical end surface 28 forms a shoulder to abut and retain exterior portion 12 on the core 16." See Ex. 1006 at ¶ [0019]; Ex. 1002 at ¶ 39.

As shown in Fig. 3 above, porous material 14 forming exterior portion 12 completely surrounds and engages an exterior surface of core 16. *See id.* at ¶¶ [0016], [0040]; *see also* Ex. 1002 at ¶ 39. *Lomicka* discloses that, in some embodiments, core 16 has a generally polygon shape with edges 64 that cut into

and engage wall 62 of exterior portion 12. *See* Ex. 1006 at Fig. 3; *see also id.* at ¶ [0042]. *Lomicka* also teaches an embodiment in which periphery 19 of core 16 has a polygonal shape that corresponds to the polygonal shape of wall 62 to limit rotation between the components. *See id.* at ¶ [0047]; *see also* Ex. 1002 at ¶ 39.

2. Claim 2

i. "The dental implant of claim 1, wherein the elongated protrusion increases an engaging interface between the coronal body and the porous body since the coronal body engages the porous body at the exterior surface of the elongated protrusion that extends into the porous body and at the interface where the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body."

Lomicka discloses that core 16 increases an engaging interface between the coronal body, head 20 and core 16, and exterior portion 12. Ex. 1002 at ¶ 40. As discussed above in connection with claim 1, Lomicka discloses that core 16 extends apically from head 20 into a bore 30 formed in exterior portion 12 such that edges 64 of core 16 engage wall 62 of exterior portion 12. See supra Section VIII.B.1.v. Lomicka also discloses that head 20 engages exterior portion 12 at an interface where coronal end 32 of exterior portion 12 faces and/or abuts apical end surface 28 of head 20. See supra Section VIII.B.1.iv and n.3.

3. Claim 3

i. "The dental implant of claim 1, wherein the coronal body includes an exterior surface that is microtextured and an exterior surface that is smooth."

Lomicka discloses that outer surface 26 of head 20 may be treated, and that "[s]uch treatments may include macro or *micro threading*, or circumferential or annular grooves, other patterned or random recesses caused by etching (such as acid etching), blasting (such as with sand, with or without HA particles, for example), or also coating of titania (titanium oxide) or other materials that create some adhesion between soft tissues and biomaterials." Ex. 1006 at ¶ [0022] (emphasis added). Lomicka teaches that different regions of head 20 may have different treatments. See id. ("[t]he surface treatment of outer surface[] 26 . . . may or may not be the same as the surface treatment of the core 16"). Further, Lomicka teaches that portions of head 20 can be masked from treatment to produce an exterior surface that is smooth. See id. at \P [0038]. For example, "the sidewall 57 of the apical end portion 56 could be masked . . . to provide a smooth connection surface if needed." *Id.* Thus, *Lomicka* discloses that head 20 includes an exterior surface that is microtextured and an exterior surface that is smooth. Ex. 1002 at ¶ 41.

4. Claim 5

i. "The dental implant of claim 1, wherein the circular shape of the coronal body at the interface and the circular shape of the porous body at the interface include one of a shape of a circle and a shape of an oval."

As discussed above in connection with claim 1, *Lomicka* discloses that the circular shape of apical end 28 of head 20 and the circular shape of exterior portion 12 at the interface where head 20 abuts exterior portion 12 includes a shape of a circle. *See supra* Section VIII.B.1.iv and n.3; *see also* Ex. 1002 at ¶ 42.

5. Claim 6

i. "The dental implant of claim 1, wherein the porous body has one of a continuous taper shape in a side view and a straight cylindrical shape in the side view."

Lomicka discloses that exterior portion 12 has a straight cylindrical shape in the side view. See e.g., Ex. 1006 at Fig. 1, ¶ [0019] ("[i]n one specific form, the exterior portion 12 is a sleeve or collar with a bore 30 that receives the core 16."); Ex. 1002 at ¶ 43. Lomicka also teaches that while implant 10 is shown having a generally cylindrical outer surface, "implant 10 may also have a morse-type taper so that its diameter decreases as it extends apically to further increase friction with surrounding bone when implant 10 is pressed or threaded into a bore in the bone." Ex. 1006 at ¶ [0048]; Ex. 1002 at ¶ 43.

6. Claim 7

i. "The dental implant of claim 1, wherein the porous body is not a coating but is made separately from the coronal body and then attached to the coronal body at the interface."

Lomicka discloses fabricating exterior portion separately from head 20 and then attaching exterior portion 12 to head 20. See e.g., Ex. 1006 at ¶¶ [0021], [0039]; see also Ex. 1002 at ¶ 44. In particular, Lomicka teaches positioning core 12 in bore 30 of exterior portion 12 and mounting an anchor 22 onto core 16 to attach exterior portion 12 to head 20 at the interface where head 20 abuts exterior portion 12. See Ex. 1006 at ¶¶ [0019], [0020]. Anchor 22 is mounted to core 16 and "secured thereon by laser welding, threading, or other permanent connection." Id. at ¶ [0039].

7. Claim 8

i. "A dental implant, comprising:"

As discussed above in connection with claim 1, *Lomicka* discloses a dental implant. *See supra* Section VIII.B.1.i; *see also* Ex. 1002 at ¶ 45, *infra* Sections VIII.B.7.ii-v.

ii. "a coronal body formed of solid metal and including a proximal end with a connection shaped to connect with a dental component and a distal end surface with an elongated protrusion that extends outwardly from the distal end surface; and"

As discussed above in connection with claim 1. Lomicka discloses a head 20

formed of solid metal such as "titanium, titanium alloy, stainless steel, zirconium[], [or] cobalt-chromium molybedenum alloy," having a coronal end 24 with a connection shaped to connect to a dental component and a core 16 extending outwardly from an opposite end of head 20. *See* Ex. 1006 at ¶ [0021]; *supra* Section VIII.B.1.ii; *see also* Ex. 1002 at ¶ 46.

iii. "an elongated cylindrical porous body having a proximal end engaged with the distal end surface of the coronal body at an interface and having an interconnected porous structure;"

As discussed above in connection with claim 1, implant 10 of *Lomicka* includes a generally elongated cylindrical exterior portion 12 made of a porous material 14 having a coronal end 32 that engages with an apical end surface 28 of head 20 at an interface. *See supra* Section VIII.B.1.iii; *see also* Ex. 1002, ¶ 47. *Lomicka* teaches that "the porous material 14 forming the exterior portion 12 may include metal, and in one form, is a porous tantalum portion 40" *Id.* at ¶ [0023]. As shown in Fig. 4, porous tantalum structure 40 includes a large plurality of interconnected members defining open spaces therebetween. *See id.* at ¶ [0024].

iv. "wherein the interconnected porous structure includes metal, the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and at the interface the circular shape of the coronal body includes the solid metal that interfaces with the circular shape of the porous body that includes the interconnected porous structure, and"

As discussed above in connection with claim 1, *Lomicka* discloses apical end surface 28 of head 20 made of a solid metal having a circular shape that interfaces with a circular shape of the porous tantalum structure 40 at coronal end 32 of exterior portion 12. *See supra* Section VIII.B.1.iv; *see also* Ex. 1002 at ¶ 48.

v. "wherein the porous body is made separately from the coronal body to have a uniform porosity and subsequently attached to the coronal body at the interface such that the elongated protrusion of the coronal body extends into an opening at the proximal end of the porous body such that the interconnected porous structure surrounds and engages the elongated protrusion that extends into the opening of the porous body."

Lomicka discloses fabricating exterior portion 12 separately from head 20 and then attaching exterior portion 12 to head 20. See e.g., Ex. 1006 at [0021], [0039]; see also Ex. 1002 at ¶ 49. Lomicka teaches that the porous tantalum structure 40 of exterior portion 12 "may be fabricated to virtually any desired porosity and pore size, whether *uniform* or varying, and can thus be matched with the surrounding natural bone in order to provide an improved matrix for bone ingrowth and mineralization." *Id.* at ¶ [0029] (emphasis added); see supra Section

VIII.B.1.iii. Thus, *Lomicka* discloses the "uniform porosity" features. Ex. 1002 at ¶ 49. As discussed above in connection with claim 1, *Lomicka* also teaches that exterior portion 12 surrounds and engages core 16, which extends into the opening of exterior portion 12. *See supra* Section VIII.B.1.v.

As discussed above in connection with claim 7, *Lomicka* teaches positioning core 12 in bore 30 of exterior portion 12 and mounting an anchor 22 onto core 16 to attach exterior portion 12 to head 20 at the interface where head 20 abuts exterior portion 12. *See supra* Section VIII.B.6; Ex. 1002 at ¶ 50.

8. Claim 9

i. "The dental implant of claim 8, wherein the porous body has a size and shape that emulate a size and shape of natural human bone."

Lomicka teaches that implant 10 is a dental implant "for insertion into a mandible or maxilla." See Ex. 1006 at ¶ [0017]. Lomicka discloses that implant 10 is placed in a bore of formed in the patient's jaw, and teaches that implant 10 can have any shape to facilitate insertion into the bore. See Ex. 1006 at ¶¶ [0040], [0048]. Once placed in the bore, bone can grow on an exterior surface 50 of implant 10 radially into exterior portion 12. See id. at ¶ [0024]. Lomicka teaches that the structure of exterior portion 12 of implant 10 "closely resembles the structure of natural cancellous bone, thereby providing a matrix into which cancellous bone may grow to anchor implant 10 into the surrounding bone "

See id.at \P [0025]; Ex. 1002 at \P 51.

9. Claim 10

i. "The dental implant of claim 8, wherein the circular shape of the coronal body at the interface and the circular shape of the porous body at the interface include one of a shape of a circle and a shape of an oval."

As discussed above in connection with claim 5, *Lomicka* further discloses that the circular shape of apical end 28 of head 20 and the circular shape of exterior portion 12 at the interface where head 20 abuts exterior portion 12 includes a shape of a circle. *See supra* Section VIII.B.4 and n.3; Ex. 1002 at ¶ 52.

10. Claim 12

i. "The dental implant of claim 8, wherein an exterior surface of the coronal body includes a first region with a smooth outer surface and a second region with a microtextured surface that is contiguous and adjacent the first region."

As discussed above in connection with claim 3, *Lomicka* further discloses that head 20 includes a first region with a smooth outer surface and a second region with a microtextured surface. *See supra* Section VIII.B.3. *Lomicka* teaches that second region with a microtextured surface is contiguous and adjacent the first region with a smooth outer surface. *See* Ex. 1006 at ¶ [0022] (disclosing that the micro threading surface treatment of outer surface 26 may or may not be the same as the surface treatment of core 16, which is contiguous and adjacent to it), *id.* at ¶ [0038] (disclosing that an apical end portion 56 of core 16 can be masked when

core 16 is treated to produce a smooth outer surface); see also Ex. 1002 at ¶ 53.

11. Claim 13

i. "The dental implant of claim 8, wherein the elongated protrusion is shaped as one of a square, a rectangle, a hexagon, and an octagon."

Lomicka discloses an embodiment in which core 16 is shaped as an octagon. See e.g. Ex. 1006 at Fig. 3; see also Ex. 1002 at ¶ 54.

12. Claim 14

i. "A dental implant, comprising:"

As discussed above in connection with claim 1, *Lomicka* discloses a dental implant. *See supra* Section VIII.B.1.i; *see also* Ex. 1002 at ¶ 55, *infra* Sections VIII.B.12.ii-vi.

ii. "a cylindrical coronal body formed of solid metal, including a proximal end with an abutment-engaging end, and including a distal end surface with an elongated protrusion that extends outwardly therefrom; and"

As discussed above in connection with claim 1, *Lomicka* discloses a cylindrical head 20 formed of solid metal such as "titanium, titanium alloy, stainless steel, zirconium[], [or] cobalt-chromium molybedenum alloy," having an abutment-engaging coronal end 24 and a core 16 extending outwardly from an opposite end of head 20. *See supra* Section VIII.B.1.ii; *see also* Ex. 1002 at ¶ 56.

iii. "an elongated cylindrical porous body having a uniform porosity and having a proximal end engaged with the distal end surface of the coronal body at an interface and having an interconnected porous structure that includes metal,"

As discussed above in connection with claim 1, implant 10 of *Lomicka* includes an elongated cylindrical exterior portion 12 having a coronal end 32 that engages an apical end surface 28 of head 20. *See supra* Section VIII.B.1.iii. *Lomicka* discloses that exterior portion 12 is formed of a porous material 14 that is "in one form, [] a porous tantalum portion 40 which is a highly porous biomaterial useful as a bone substitute and/or cell and tissue receptive material." Ex. 1006 at ¶ [0023]; *see also id.* at Fig. 4 (depicting the porous tantalum structure 40). *Lomicka* teaches that the porous tantalum structure 40 "may be fabricated to virtually any desired porosity and pore size, whether *uniform* or varying." *Id.* at ¶ [0029]. Thus, *Lomicka* discloses that porous tantalum structure 40 of exterior portion 12 has a constant porosity throughout the structure. *Id.*; Ex. 1002 at ¶ 57.

iv. "wherein the distal end surface of the coronal body at the interface has a circular shape that is the solid metal, the proximal end of the porous body at the interface has a circular shape that is the interconnected porous structure, and the circular shape of the coronal body engages with the circular shape of the porous body at the interface,"

As discussed above in connection with claim 1, *Lomicka* discloses apical end surface 28 of head 20 having a circular shape that interfaces with a circular

shape of the metal porous tantalum structure 40 at coronal end 32 of exterior portion 12. *See supra* Section VIII.B.1.iv; *see also* Ex. 1002 at ¶ 58.

v. "wherein the elongated protrusion of the coronal body includes an elongated polygon that extends into an opening of the porous body such that the interconnected porous structure surrounds and engages an exterior surface of the elongated polygon that extends into the porous body, and"

As discussed above in connection with claim 1, *Lomicka* teaches that head 20 includes a core 16 that extends into a bore 30 such that porous tantalum structure 40 of exterior portion 12 surrounds and engages an exterior surface of core 16, which extends into exterior portion 12. *See supra* Section VIII.B.1.v; *see also* Ex. 1002 at ¶ 59.

vi. "wherein the elongated protrusion increases an interface between the coronal body and the porous body since the coronal body engages the porous body at the exterior surface of the elongated polygon that extends into the porous body and at the interface where the solid metal of the circular shape of the coronal body interfaces with the interconnected porous structure of the circular shape of the porous body."

As discussed above in connection with claim 2, core 16 increases an interface between head 20 and exterior portion 12 because head 20 engages exterior portion at (1) an exterior surface of core 16 that extends into bore 30 of exterior portion 12, and (2) an interface where an apical end surface 28 of head 20 engages a coronal end 24 of exterior portion 12. *See supra* Section VIII.B.2; *see*

also Ex. 1002 at ¶ 60.

13. Claim 15

i. "The dental implant of claim 14, wherein the porous body has a porous structure that emulates a porous structure of natural human bone."

Lomicka discloses that exterior portion 12 has a porous tantalum structure 40 that emulates a porous structure of natural human bone. See e.g. Ex. 1006 at [0025] (disclosing that "porous tantalum is a lightweight, strong porous structure which . . . closely resembles the structure of natural cancellous bone"); supra Section VIII.B.8; see also id. at ¶ [0029]; Ex. 1002 at ¶ 61.

14. Claim 17

i. "The dental implant of claim 14, wherein the porous body has one of a shape of a continuous taper in a side view and a straight cylinder in the side view."

As discussed above in connection with claim 6, *Lomicka* discloses that exterior portion 12 can have a straight cylindrical or tapered shape in a side view. *See supra* Section VIII.B.5; *see also* Ex. 1002 at ¶ 62.

15. Claim 18

i. "The dental implant of claim 14, wherein the elongated polygon of the elongated protrusion is shaped as one of a square, a rectangle, a hexagon, and an octagon."

As discussed above in connection with claim 13, *Lomicka* discloses an embodiment in which core 16 is shaped as an octagon. *See supra* Section

VIII.B.11; *see also* Ex. 1002 at ¶ 63.

16. Claim 19

i. "The dental implant of claim 14, wherein the porous body is made separately from the coronal body and then attached to the coronal body at the interface and at the exterior surface of the elongated polygon."

As discussed above in connection with claim 7, *Lomicka* discloses fabricating exterior portion separately from head 20 and then attaching exterior portion 12 to head 20 by positioning core 12 in bore 30 of exterior portion 12 and mounting an anchor 22 onto core 16 to secure exterior portion 12 between head 20 and anchor 22. *See supra* Section VIII.B.6; *see also supra* Section VIII.B.1.v; Ex. 1002 at ¶ 64.

17. Claim 20

i. "A dental implant, comprising:"

As discussed above in connection with claim 1, *Lomicka* discloses a dental implant. *See supra* Section VIII.B.1.i; *see also* Ex. 1002 at ¶ 65; *infra* Sections VIII.B.17.ii-vii.

ii. "a coronal body that includes a proximal end engageable with a dental component, includes an end surface with an elongated protrusion that extends outwardly from the end surface, and is solid metal; and"

As discussed above in connection with claim 1, *Lomicka* discloses a cylindrical head 20 formed of solid metal such as "titanium, titanium alloy,

stainless steel, zirconium[], [or] cobalt-chromium molybedenum alloy," having a coronal end 24 engageable with a dental component, and a core 16 extending outwardly from an end of head 20 opposite coronal end 24. *See supra* Section VIII.B.1.ii; *see also* Ex. 1002 at ¶ 66.

iii. "an elongated cylindrical bone fixation body that includes a porous metal structure with a proximal end that engages the end surface of the coronal body at an interface,"

As discussed above in connection with claim 1, implant 10 of *Lomicka* includes a cylindrical exterior portion 12 having a coronal end 32 that engages an apical end surface 28 of head 20 at an interface. *See supra* Section VIII.B.1.iii; *see also* Ex. 1002 at ¶ 67. *Lomicka* discloses that exterior portion 12 is formed of a porous material 14 that is "in one form, [] a porous tantalum portion 40 which is a highly porous biomaterial useful as a bone substitute and/or cell and tissue receptive material." Ex. 1006 at ¶ [0023]; *see also id.* at Fig. 4 (depicting the porous tantalum structure 40).

iv. "wherein the end surface of the coronal body has a shape, the proximal end of the bone fixation body has a shape, and the solid metal of the shape of the coronal body engages with the porous metal structure of the shape of the bone fixation body at the interface,"

As discussed above in connection with claim 1, *Lomicka* discloses apical end surface 28 of head 20 having a shape that interfaces with a shape of the metal

porous tantalum structure 40 at coronal end 32 of exterior portion 12. *See supra* Section VIII.B.1.iv; *see also* Ex. 1002 at ¶ 68.

v. "wherein the elongated protrusion of the coronal body extends into an opening of the bone fixation body such that the porous metal structure surrounds and engages an exterior surface of the elongated protrusion that extends into the bone fixation body,"

As discussed above in connection with claim 1, *Lomicka* teaches that head 20 includes a core 16 that extends into a bore 30 such that porous tantalum structure 40 of exterior portion 12 surrounds and engages an exterior surface of core 16. *See supra* Section VIII.B.1.v; *see also* Ex. 1002 at ¶ 69.

vi. "wherein the bone fixation body is made separately from the coronal body to have a uniform porous metal structure and then attached to the coronal body at the interface and at the exterior surface of the elongated protrusion, and"

As discussed above in connection with claim 7, *Lomicka* discloses fabricating exterior portion 12 separately from head 20 and then attaching exterior portion 12 to head 20 by positioning core 12 in bore 30 of exterior portion 12 and mounting an anchor 22 onto core 16 to secure exterior portion 12 between head 20 and anchor 22. *See supra* Section VIII.B.6; *see also* Ex. 1002 at ¶ 70. *Lomicka* also teaches that the porous tantalum structure 40 of exterior portion 12 "may be fabricated to virtually any desired porosity and pore size, whether *uniform* or varying" Ex. 1006 at ¶ [0029] (emphasis added); *supra* Section VIII.B.1.iii.

Thus, Lomicka discloses the "uniform porosity" feature. Ex. 1002 at ¶ 70.

vii. "wherein the porous metal structure of the bone fixation body emulates a porous structure of natural human bone."

As discussed above in connection with claim 15, porous tantalum structure 40 emulates a porous structure of natural human bone. *See supra* Section VIII.B.13; *see also* Ex. 1002 at ¶ 71.

18. Claim 21

i. "The dental implant of claim 20, wherein the porous body has a structure that emulates a structure of natural human bone."

As discussed above in connection with claim 15, porous tantalum structure 40 emulates a porous structure of natural human bone. *See supra* Section VIII.B.13 and n.3; Ex. 1002 at ¶ 72.

19. Claim 23

i. "The dental implant of claim 20, wherein the elongated protrusion has a polygonal shape and increases an interface between the coronal body and the bone fixation body."

As discussed above in connection with claim 1, core 16 has a polygon shape. *See supra* Section VIII.B.1.v. As further discussed above in connection with claim 2, core 16, which extends from head 20, increases an interface between the coronal body, head 20 and core 16, and the exterior portion 12. *See supra* Section VIII.B.2; Ex. 1002 at ¶ 73.

20. Claim 24

i. "The dental implant of claim 20, wherein the coronal body has an outer surface with a first region adjacent a second region in which the first region is smooth and the second region is non-porous and microtextured."

As discussed above in connection with claims 3 and 12, *Lomicka* discloses that head 20 includes a first region with a smooth outer surface that is adjacent to a second region with a microtextured surface. *See supra* Sections VIII.B.3, VIII.B.10. *Lomicka* further teaches that the second region can be non-porous and microtextured. *See* Ex. 1006 at ¶ [0022] (disclosing that head 20 and core 16 are made of a metal such as titanium, titanium alloy, stainless steel, zirconium, and cobalt-chromium molybedenum alloy and may be non-porous and micro-textured); Ex. 1002 at ¶ 74.

21. Claim 27

i. "A method, comprising:"

Lomicka discloses the claimed method. See, e.g., 1006 at ¶¶ [0021], [0029]-[0040]; see also Ex. 1002 at ¶ 75; infra Sections VIII.B.21.ii-v.

ii. "forming a coronal body of a dental implant from solid metal with a proximal end having a connection that engages a dental component and with a distal end surface having an elongated male protrusion that extends outwardly therefrom;"

Lomicka discloses forming a coronal head portion or head 20 of an implant 10 from solid metal. See Ex. 1006 at ¶ [0021] ("head 20 . . . [is] made of a suitable

biocompatible material such as titanium, titanium alloy, stainless steel, zirconium[], [or] cobalt-chromium molybdenum alloy"). A coronal end 24 of head 20 is formed with a connection that engages a dental component, and a core 16 that extends outwardly from an opposite end of head 20. *See id.* at ¶¶ [0017]-[0018], Fig. 2; *see also supra* Section VIII.B.1.ii; Ex. 1002 at ¶ 76.

iii. "forming, separately from the coronal body, a porous body of the dental implant having a uniform porous metal structure and having a non-tapering cylindrical shape with a central opening at a proximal end; and"

Lomicka discloses fabricating an exterior portion 12 of implant 10 separately from head 20. See e.g., Ex. 1006 at ¶¶ [0021], [0039]; see also supra Section VIII.B.6; Ex. 1002 at ¶ 77. Lomicka teaches an embodiment in which exterior portion 12 is a sleeve having a generally cylindrical shape with a bore 30. See Ex. 1006. at ¶ [0019], Figs. 2, 3. Exterior portion 12 is made of a porous material 14 that is "in one form, [] a porous tantalum portion 40 which is a highly porous biomaterial useful as a bone substitute and/or cell and tissue receptive material." Ex. 1006 at ¶ [0023]; see also id. at Fig. 4 (depicting the porous tantalum structure 40). Lomicka further teaches that the porous tantalum structure 40 of exterior portion 12 "may be fabricated to virtually any desired porosity and pore size, whether *uniform* or varying." *Id.* at ¶ [0029] (emphasis added); *see supra* Section VIII.B.1.iii. Thus, Lomicka discloses the "uniform porosity" feature. Ex. 1002 at ¶ 77.

iv. "engaging, after the coronal body and the porous body are separately formed from each other, the porous body to the coronal body to form the dental implant with an elongated cylindrical shape such that the elongated male protrusion of the coronal body extends into the central opening of the porous body and forms a core for the porous body,"

Once head 20, core 16, and exterior portion 10 are separately formed, *Lomicka* teaches engaging exterior portion 12 and head 20 to form a generally cylindrical implant 10 by positioning core 16 in bore 30 of exterior portion 12. *See e.g.*, Ex. 1006 at ¶ [0016] ("[t]he exterior portion 12 may be placed on or around an interior portion or core 16 that supports the exterior portion"), *id.* at ¶ [0017] ("[a] separate anchor 22 . . . is configured to engage the core 16 so that head 20 and the anchor 22 cooperatively retain the porous exterior portion 14 therebetween on the implant 10"); *see also supra* Section VIII.B.1.v; Ex. 1002 at ¶ 78.

v. "wherein the elongated male protrusion of the coronal body has a cylindrical shape with a polygonal external surface that extends into the central opening of the porous body such that the porous metal structure surrounds and engages the polygonal external surface that extends into the porous body."

Lomicka teaches that core 16 has a cylindrical shape with a polygonal external surface. See e.g., Ex. 1006 at Fig. 2 (illustrating core 16 having a generally cylindrical shape), id. at ¶ [0042] (describing a periphery 19 of core 16 as having a generally polygon shape). As discussed above in connection with claim 1, core 16 extends into bore 30 of exterior portion 12 such that porous tantalum

structure 40 of exterior portion 12 surrounds and engages an exterior surface of core 16. *See supra* Section VIII.B.1.v; *see also* Ex. 1002 at ¶ 79.

C. Ground 2: Lomicka Renders Obvious Claim 22

1. Claim 22

i. "The dental implant of claim 20, wherein the coronal body is fabricated independently from the bone fixation body and is subsequently fused to the bone fixation body."

As discussed above, *Lomicka* discloses fabricating exterior portion 12 independent from head 20, and then securing exterior portion 12 onto core 16 between head 20 and anchor 22. See supra Sections VIII.B.6, VIII.B.17.vi. Lomicka does not explicitly disclose fusing exterior portion 12 to head 20. However, it would have been obvious to do so based on the knowledge of one of ordinary skill in the art and the teachings of Lomicka. Ex. 1002 at ¶ 80. In particular, Lomicka teaches welding core 16 into anchor 22 along a seam 58 at an apical end portion 60 of anchor 22. See Ex. 1006 at ¶ [0017]. It would have been obvious to also weld apical end surface 28 of head 20 to coronal end 32 of exterior portion 12. Ex. 1002 at ¶ 80. One of ordinary skill in the art would have been motivated to do so to prevent rotation of exterior portion 12 relative to head 20. *Id*. One of skill would have additionally understood that welding exterior portion 12 to head 20 would have eliminated relative movement between the two structures, minimizing wear damage and fatigue at their interface. Id. Furthermore, one of

ordinary skill in the art would have realized that fusing exterior portion 12 to head 20 would have amounted to nothing more than applying known techniques to a known method to yield predictable results. *Id.*; *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Welding or fusing two components was well-known and within the skill of art at the time of the alleged invention, as evidenced by *Lomicka's* teaching of welding. Ex. 1002 at ¶ 80.

D. Ground 3: Lomicka in View of Bhaduri Renders Obvious Claims 25 and 26

1. Claim 25

i. "A method, comprising:"

Lomicka and Bhaduri teach the claimed method. See, e.g., 1006 at \P [0021], [0029]–[0040]; Ex. 1007; see also Ex. 1002 at \P 81; infra Sections VIII.D.ii-v.

ii. "machining a coronal body of a dental implant that is formed of solid metal to include a proximal end with a connection shaped to receive a dental component and a distal end surface with an elongated protrusion that extends outwardly therefrom;"

As discussed above in connection with claim 27, *Lomicka* discloses forming a coronal head portion or head 20 of an implant 10 including a coronal end 24 with a connection shaped to receive a dental implant and core 16 extending from apical end surface 28. *See supra* Section VIII.B.21.ii. While *Lomicka* discloses forming head 20 from a solid metal (*see* Ex. 1006 at ¶ [0021]), *Lomicka* does not explicitly

disclose machining head 20. However, it would have been obvious to one of ordinary skill in the art to machine head 20 based on the knowledge of one of ordinary skill in the art and the teachings of *Bhaduri*. Ex. 1002 at ¶ 82. In particular, one of skill would have understood that it was common practice to create implants through machining in 2012. *Id.* One of skill would have further understood that the implant would have undergone a final machining even if it were formed through other methods. *Id.* For instance, a coronal body created through casting (i.e., the pouring of a material into a mold) would still have undergone a surface machining to ensure exact dimensions were achieved. *Id.*

Bhaduri likewise teaches that in 2002, dental implants were commonly machined, stating that "[p]resently, titanium dental implants are machined out of titanium and titanium alloys." See Ex. 1007 at ¶ [0006]. As a result, one of ordinary skill in the art would have realized that machining head 20 would have amounted to nothing more than applying known techniques to a known method to yield predictable results. Ex. 1002 at ¶ 83; see KSR, 550 U.S. at 417.

iii. "fabricating, separately from the coronal body, a porous body of the dental implant having an elongated cylindrical shape with a uniform porous metal structure that extends throughout the porous body and with a central opening at a proximal end of the porous body; and"

As discussed above in connection with claim 27, *Lomicka* discloses fabricating separately from head 20, an exterior portion of implant 10 having an

elongated cylindrical shape and a bore 30. *See supra* Section VIII.B.21.iii; *see also supra* Sections VIII.B.1.v, VIII.B.6; Ex. 1002 at ¶ 84. Exterior portion 12 is made of a porous material 14 that is "in one form, [] a porous tantalum portion 40 which is a highly porous biomaterial useful as a bone substitute and/or cell and tissue receptive material." Ex. 1006 at ¶ [0023]; *see also id.* at Fig. 4 (depicting the porous tantalum structure 40). *Lomicka* teaches that the porous tantalum structure 40 of exterior portion 12 "may be fabricated to virtually any desired porosity and pore size, whether *uniform* or varying." *Id.* at ¶ [0029] (emphasis added); *see supra* Section VIII.B.1.iii. Thus, *Lomicka* discloses forming a porous tantalum structure 40 having constant porosity throughout the structure. Ex. 1002 at ¶ 84.

iv. "attaching, after the porous body is separately fabricated from the coronal body, the porous body to the coronal body to create the dental implant with an elongated cylindrical shape such that the elongated protrusion of the coronal body extends into the central opening of the porous body,"

As discussed above in connection with claim 27, *Lomicka* discloses attaching, after exterior portion 12 is separately fabricated from head 20, exterior portion to head 20 by position core 16 within bore 30 to create implant 10. *See supra* Section VIII.B.21.iv; *see also supra* Sections VIII.B.1.v, VIII.B.6. As shown in Fig. 2, implant 10 has a generally cylindrical shape. *See* Ex. 1006 at Fig. 2; Ex. 1002 at ¶ 85.

v. "wherein the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the circular shape of the porous body when the elongated protrusion of the coronal body extends into the opening of the porous body."

As discussed above in connection with claim 27, *Lomicka* discloses that apical end surface 28 of head 20 has a circular shape that interfaces with a coronal end 32 of exterior portion 12 having a circular shape when core 16 is positioned in bore 30. *See supra* Sections VIII.B.21.v, VIII.B.1.iv; Ex. 1002 at ¶ 86.

2. Claim 26

i. "The method of claim 25 further comprising: fusing the porous body to the coronal body after the porous body is separately fabricated from the coronal body."

As discussed above in connection with claims 22 and 25, *Lomicka and Lomicka* in view of *Bhaduri* renders these features obvious. *See supra* Section VIII.B.6; *see also supra* Sections VIII.C.1, VIII.D.1. As a result, because claim 26 depends from claim 25, *Lomicka* in view of *Bhaduri* renders obvious claim 26. One of ordinary skill would have combined *Lomicka* and *Bhaduri* for the same reasons provided above for claim 25.

IX. STATEMENT REGARDING CONCURRENTLY FILED PETITION

As noted, Petitioner is filing another petition concurrently with this petition.

This petition presents grounds based on intervening prior art, i.e., *Lomicka* and/or

Bhaduri, because the claims are not entitled to the earlier priority date. The

concurrently filed petition presents grounds based on non-intervening prior art, i.e.,

Otani and U.S. Patent No. 5,282,861 to Kaplan (Ex. 1013), and/or U.S. Patent

6,095,817 to Wagner et al. (Ex. 1009), that apply even if the Board finds that the

challenged claims are entitled to the earlier priority date.

The Board should institute review based on both petitions. Petitioner has

attempted to streamline the petitions by raising only one primary reference in each

petition. This achieves the goal of "just, speedy and inexpensive resolution"

consistent with 37 C.F.R. § 42.1(b). In addition, the two petitions present

independent, distinctive, and non-redundant grounds because the grounds are based

on whether the claims are entitled to the earlier priority date and rely on different

references.

X. <u>CONCLUSION</u>

For the reasons given above, Petitioner requests inter partes review and

cancellation of claims 1-3, 5-10, 12-15, and 17-27 of the '734 patent.

Respectfully submitted,

Dated: April 16, 2015

By: /Naveen Modi/

Naveen Modi (Reg. No. 46,224)

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Zimmer Dental Inc.

53

CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2015, a copy of the foregoing **Petition for** *Inter Partes* **Review of U.S. Patent No. 8,684,734** was served by express mail on the Patent Owner at the following correspondence address of record for the patent-at-issue and at the following correspondence address for Patent Owner's litigation counsel:

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Matthew M. Wawrzyn Stephen C. Jarvis WAWRZYN LLC 233 South Wacker Drive, 84th Floor Chicago, Illinois 60606

Dated: April 16, 2015 By: /Naveen Modi/

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