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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OTICON MEDICAL AB; OTICON MEDICAL LLC; WILLIAM DEMANT HOLDING A/S
Petitioner

v.

COCHLEAR LIMITED
Patent Owner of
U.S. Patent No. 9,838,807 to L. Jinton et al.
Issued December 5, 2017

Case IPR2019-00975

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-12, 14, 16, 17, 25, 28, 33-35, 37-41 AND 45-47 OF U.S. PATENT NO. 9,838,807 PURSUANT TO 35 U.S.C. § 311

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I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-42.80 and 42.100-42.123, OTICON MEDICAL AB, OTICON MEDICAL LLC, and WILLIAM DEMANT HOLDING A/S (hereinafter "Petitioner") submit this Petition to institute an *Inter Partes* Review (IPR) of claims 1-12, 14, 16, 17, 25, 28, 33-35, 37-41 and 45-47 ("challenged claims") of U.S. Patent 9,838,807 ("the '807 Patent") (Ex. 1001). This Petition demonstrates that the challenged claims are unpatentable over the prior art and that Petitioner has a reasonable likelihood of prevailing in this proceeding.

II. MANDATORY REQUIREMENTS, NOTICES AND FEES

A. Real Party-In-Interest

Petitioner OTICON MEDICAL AB, OTICON MEDICAL LLC, and WILLIAM DEMANT HOLDING A/S are the sole real parties-in-interest.

B. Related Matters - 37 C.F.R. § 42.8(b)(2)

The '807 Patent is subject to concurrent litigation of: Civil Action No. 3:18-cv-06684, filed April 13, 2018, in the United States District Court for the District of New Jersey. OTICON MEDICAL LLC was served on April 19, 2018, and OTICON MEDICAL AB was served on April 23, 2018.

Otherwise, to the best of Petitioner's knowledge, as of the filing date of this petition, there are no other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding.

C. Lead and Back-Up Counsel - 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner appoints:

Lead Counsel: D. Richard Anderson, Reg. No. 40,439 (email: dra@bskb.com).

Back-up Counsel: Lynde F. Herzbach, Reg. No. 74,886 (email: Lynde.Herzbach@bskb.com); Chad D. Wells, Reg. No. 50,875 (email: cdw@bskb.com); and Jason W. Rhodes, Reg. No. 47,305 (email: jwr@bskb.com).

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Lead Counsel and Back-Up Counsel can all be reached by telephone at (703) 205-8000; facsimile number: (703) 205-8050.

D. Service Information - 37 C.F.R. § 42.8(b)(4)

As identified in the attached Certificate of Service, a copy of the present petition, in its entirety, including a declaration, all Exhibits and a power of attorney, is being served by Federal Express, costs prepaid, to the address of the

attorney or agent of record for the '807 Patent: Pilloff & Passino LLP. Petitioner may be served at the lead counsel address provided in Section **II.C** of this Petition. Petitioner consents to electronic service by email at the email addresses above.

E. Power of Attorney

A power of attorney is being filed concurrently with the designation of counsel in accordance with 37 C.F.R. § 42.10(b).

F. Fees – 35 U.S.C. § 312(1) and 37 C.F.R. § 42.15

The required fees are submitted herewith in accordance with 37 C.F.R. § 42.103(a) and § 42.15, as required by 35 U.S.C. § 312(a)(1). If necessary, the Director is hereby authorized in this, concurrent, and future filings to charge any fees required during these proceedings or credit any overpayment to Deposit Account No. 02-2448.

III. REQUIREMENTS FOR INTER PARTES REVIEW UNDER 37 C.F.R. § 42.104

A. Grounds for Standing – 37 C.F.R. § 42.104(a)

Petitioner certifies that the '807 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an IPR for the challenged claims of the '807 Patent.

B. Identification of the Challenge under 37 C.F.R. § 42.104(b)

Petitioner respectfully requests *inter partes* review of claims 1-12, 14, 16, 17, 25, 28, 33-35, 37-41 and 45-47 of the '807 Patent on the grounds set forth below. Petitioner asks that the Board cancel each challenged claim as unpatentable. In support of the proposed grounds for unpatentability, this Petition is accompanied by a Declaration of Dr. Wilson Hayes (Ex. 1002).

1. The Specific Art on Which the Challenge is Based

The '807 Patent issued from U.S. Application No. 14/922,604 ("the '604 application"), which was filed on October 26, 2015. The '604 application was filed as a Continuation of U.S. Application No. 12/177,083, filed July 21, 2008, and claimed priority to U.S. Provisional Application Nos. 60/951,163 and 60/951,169, both filed July 20, 2007. Each reference relied on herein precedes the earliest claimed priority date of the '807 Patent. Thus, Petitioner need not address whether the '807 Patent is entitled to its claimed priority date, and reserves the right to challenge the priority claims of the '807 Patent. Petitioner relies on the following prior art.

Exhibit 1003 (Westerkull'794) - U.S. Patent No. 7,116,794 to P. Westerkull ("Westerkull'794"), issued October 3, 2006, filed on November 4, 2004 as U.S. Patent Application No. 10/981,340 ("the '340 application")

The '340 application was published on May 4, 2006 as U.S. Patent Application No. 2006/0093175, and is provided herein as Ex. 1004. Westerkull'794 is prior art at least under pre-AIA 35 U.S.C. §§ 102(a) and 102(e). Further, U.S. Patent Application Publication No. 2006/0093175 (Ex. 1004) is prior art under pre-AIA 35 U.S.C. § 102(b).

Exhibit 1005 (Choi) - U.S. Patent No. 6,981,873 to K. Choi et al. ("Choi") issued January 3, 2006. Choi is prior art under pre-AIA 35 U.S.C. § 102(b).

Exhibit 1006 (Håkansson) - WO Publication No. 98/55049 to B. Håkansson et al. ("Håkansson") published December 10, 1998. Håkansson is prior art under pre-AIA 35 U.S.C. § 102(b).

Exhibit 1007 (Westerkull'222) - U.S. Patent No. 7,074,222 to P. Westerkull ("Westerkull'222") issued July 11, 2006. Westerkull'222 is prior art under pre-AIA 35 U.S.C. § 102(b).

Exhibit 1008 (Brånemark) - WO Publication No. 2006/065205 to R. Brånemark et al. ("Brånemark") published on June 22, 2006. Brånemark is prior art under pre-AIA 35 U.S.C. § 102(b).

2. The Specific Grounds on Which the Challenge is Based

Petitioner respectfully requests cancellation of the challenged claims on the following grounds:

Ground	**'807 Patent Claims**	**Basis**
No. 1	1-12, 14, 16, 25, 28, 33-35, 38, 39, 45 and 46	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Westerkull'794* (Ex. 1003) in view of *Choi* (Ex. 1005)
No. 2	17	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Westerkull'794* (Ex. 1003) in view of *Choi* (Ex. 1005) and *Håkansson* (Ex. 1006)
No. 3	37 and 47	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Westerkull'794* (Ex. 1003) in view of *Choi* (Ex. 1005) and *Westerkull'222* (Ex. 1007)
No. 4	28, 40 and 41	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Westerkull'794* (Ex. 1003) in view of *Choi* (Ex. 1005) and *Brånemark* (Ex. 1008)

Each reference relied upon in the grounds set forth above qualifies as prior art under at least one of pre-AIA 35 U.S.C. §§ 102(a), 102(b) and 102(e). This

Petition and the Declaration of Dr. Wilson Hayes (Ex. 1002), submitted herewith, cite additional prior art materials to provide background of the relevant technology and, in some instances, to further explain why one of ordinary skill in the art would have found it obvious combine the cited references to arrive at the claimed invention.

IV. THE '807 PATENT AND THE PERSON OF ORDINARY SKILL IN THE ART

A. Embodiment(s) of the '807 Patent

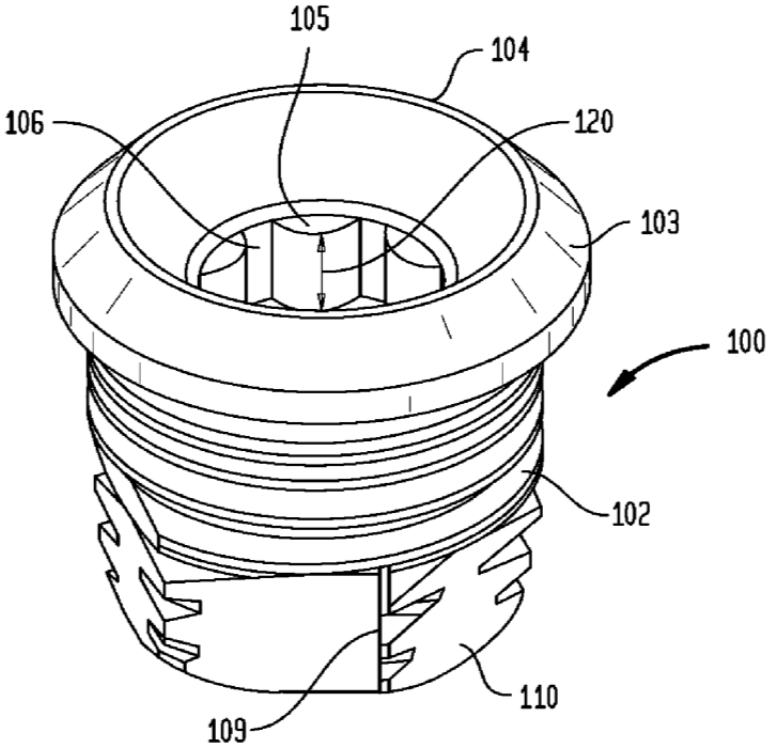
The '807 Patent relates to a screw-shaped anchoring fixture for anchoring a prosthesis in the skull bone. Ex. 1001, Abstract. Particularly, the anchoring fixture is configured to anchor elements for bone-anchored hearing devices. Ex. 1001, 1:19-21[1]. The anchoring fixture comprises a main body configured to be implanted in the bone, and a flange configured to function as a stop to prevent the main body from completely penetrating the bone. *Id.* at Abstract.

The '807 Patent includes two drawing Figures, which show one embodiment of the anchoring element. Fig. 1 (reproduced below) is representative of a

[1] Citations to patents are formatted Exhibit No., column:line-line or Exhibit No., column:line-column:line.

perspective view of the anchoring element, while Fig. 2 (reproduced below) is representative of a cross-sectional view of the anchoring element. *Id.* at 3:30-4:27.

FIG. 1



100 = anchoring fixture

102 = main body

103 = flange

104 = tool engaging socket

105 = internal grip section

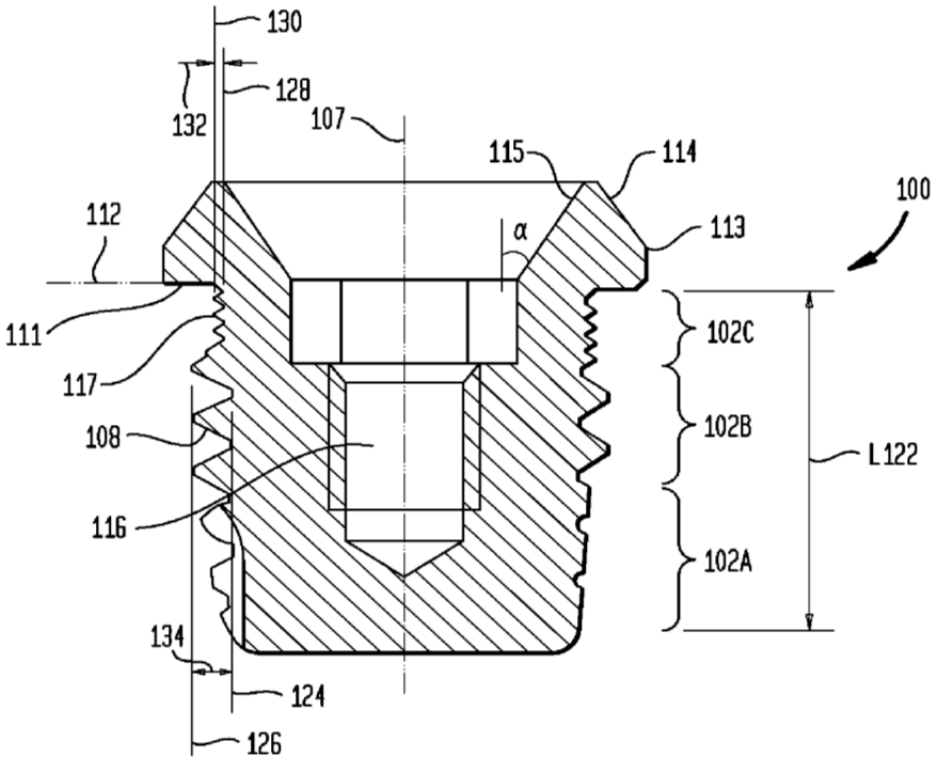
106 = lobe-shaped surfaces

107 = longitudinal axis

109 = self-tapping cutting edges

110 = clearance or relief surfaces

FIG. 2



100 = anchoring fixture

102 = main body

102A = distal tapered apical portion of main body

102B = first portion of main body

102C = second portion of main body

122 = length (L) of main body

103 = flange

108 = main screw thread

111 = planar bottom surface of flange

112 = outer bone surface

113 = cylindrical part of flange

114 = tapered top portion of flange

115 = tapered inner side wall of flange

116 = inner bottom bore

117 = circumferential grooves

124, 126 = inner and outer diameters of main screw thread

128, 130 = inner and outer diameters of circumferential grooves

132 = height of circumferential grooves

The main body 102 of the anchoring fixture 100 has a length 122 sufficient to securely anchor the fixture 100 into, without penetrating entirely through, the skull bone. *Id.* at 3:55-57. Therefore, the length 122 of the main body 102 of the fixture 100 may depend on the thickness of the skull bone at the implantation site, and in one embodiment, is no greater than approximately 5 mm. *Id.* at 3:57-60. The main body 102 comprises a distal tapered apical portion 102A, and a generally cylindrical body comprising a first portion 102B and a second portion 102C. *Id.* at

3:60-63. The first portion 102B comprises external threads that form the main screw thread 108 adjacent to the distal tapered apical portion 102A, while the second portion 102C is adjacent to the flange 103. *Id.* at 3:63-66. As shown in Figs. 1 and 2, the periphery of the distal tapered apical portion 102A may be provided, in alternating configuration, with self-tapping cutting edges 109 and clearance or relief surfaces 110. *Id.* at 4:8-11.

In the main body 102 of the fixture 101, circumferential grooves 117 are provided in the second portion 102C adjacent to the flange 103. *Id.* at Fig. 2. Each of the circumferential grooves 117 has an inner diameter 128 and an outer diameter 130. The inner diameter 128 of the circumferential grooves 117 exceeds the inner diameter 124 of the main screw thread 108. *Id.* at 4:46-52. Thus, when inserted into a hole created using a drill whose diameter is greater than the inner diameter 24 of the main thread 108, but less than the outer diameter 130 of the second portion 102C, the second portion 102C is able to compress the bone to some extent to impart initial stability when the fixture 100 is inserted into the drilled hole. *Id.* at 4:52-59. Since the wide diameter portion of the main body 102 of the fixture 100 is located next to the flange, the compressive action is more concentrated to the hard cortical part of the skull bone tissue. *Id.* at 4:59-62.

B. Prosecution History of the '807 Patent

The '807 Patent was filed on October 26, 2015 as U.S. Application No. 14/922,604 ("the '604 application") as a Continuation of U.S. Application No. 12/177,083 ("the '083 application"), filed July 21, 2008, and claimed domestic priority to U.S. Provisional Application Nos. 60/951,163 and 60/951,169, both filed July 20, 2007. Ex. 1009, 117-146.

A preliminary amendment was filed on October 26, 2015 in the '604 application, including amendments to the specification to provide cross-references to related applications. *Id.* at 147-149.

An Information Disclosure Statement (IDS) was filed on August 9, 2017. *Id.* at 65-82. This IDS cited, *inter alia*, the following prior art references pertaining to dental implants: U.S. Patent No. Des. 294,295 to P. Brånemark ("Brånemark'295") entitled "Dental Implant Screw," U.S. Patent Application Publication No. 2005/0287497 to R. Carter ("Carter") entitled "Internal Connection Dental Implant," U.S. Patent Application Publication No. 2006/0172257 to G. Niznick ("Niznick") entitled "Externally-Treaded Endosseous Dental Implants with Internal Abutment-Engaging and Fixture Mount-Engaging Surfaces," WO Publication No. 92/05745 to S. Hansson ("Hansson"), and WO Publication No. 99/23971 to L. Carlsson et al. ("Carlsson"). *Id.* at 67, 69, 71, and 72. The IDS also

cited WO Publication No. 2004/105650 to D. Pitulia ("Pitulia"). *Id.* at 72. Pitulia, provided herein as Exhibit 1011, expressly states,

> The fixtures which are used today for the **bone anchored hearing aid devices** are normally designed in such a way that a screw tap is required to form an internal thread in the hole drilled in the skull bone before the screw is inserted. **One example of such a fixture is illustrated in US Des. 294,295 [i.e., Brånemark'295]**.

Ex. 1011, 2:5-16 (emphases added).

The USPTO issued a Restriction Requirement on May 9, 2017. Ex. 1009, 100-104. Restriction was required between original claims 1-17 drawn to an anchoring fixture / varying thread, classified in 606/275, and original claims 18-26 drawing to an anchoring fixture / hearing prosthesis, classified in 381/326. *Id.* at 102.

In response to the Restriction Requirement, the applicant filed a response on August 9, 2017 and elected claims 1-17. Claims 2 and 19-26 were canceled, and new claims 27-43 were added. *Id.* at 83-98.

On October 13, 2017, the '605 applicant filed a Terminal Disclaimer against U.S. Patent No. 9,173,042 which issued, on October 27, 2015, from the '083 application. *Id.* at 58-64.

Thereafter, the Examiner issued a Notice of Allowability on October 25, 2017 including an Examiner's Amendment and statement of reasons for allowance. *Id.* at 24-39.

In the Examiner's Amendment, authorized by the '604 applicant's legal representative on October 13, 2017, the Examiner amended independent claim 1 to additionally recite,

> a flange configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when the anchoring fixture is implanted into the bone; and
>
> a circumferential groove located, with respect to a side of the flange, on the anchoring fixture on a threaded side of the anchoring fixture,
>
> wherein the anchoring fixture is configured for anchoring a hearing prosthesis component to the skull bone at a location behind an external ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea.

Id. at 27.

In the Examiner's Amendment, the Examiner also amended independent claim 10 to additionally recite similar language as set forth above. *Id.* at 28-29. The Examiner also offered the following statement of reasons for allowance, "The claims distinguish over closest prior art cited in attached 892." *Id.* at 38.

The Notice of Allowability further stated that "The restriction requirement is maintained. However, the elected invention was modified to be the second invention per restriction requirement." *Id.* at 27.

A Request for Expedited Issuance of Certificate of Correction was filed on July 17, 2018 for errors attributable to the USPTO. *Id.* at 2-14. In response, the USPTO issued a Certificate of Correction on August 14, 2018 amending claims 2, 7, 29, and 31. *Id.* at 1.

C. Prosecution History of the '083 Application

The '083 application, from which the '604 application was filed as a Continuation, issued as U.S. Patent No. 9,173,042 ("the '042 patent") on October 27, 2015. Ex. 1010, 1. The '083 application was filed, on July 21, 2008, along with an IDS citing, *inter alia*, the following references pertaining to dental implants: Brånemark'295, Hansson, and Carlsson. *Id.* at 436-437.

The USPTO issued a Restriction Requirement on June 13, 2011. *Id.* at 342-349. In response to the Restriction Requirement, the '083 applicant elected, without traverse, original claims 1-15, 17, 19, and 21-29. *Id.* at 329-336.

The USPTO issued a non-final Office Action on September 20, 2011. *Id.* at 305-321. Original claims 26-28 were rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,735,790 to B. Håkansson et al. ("Håkansson'790")

in view of Hansson. *Id.* at 318. In response to the Office Action, the '083 applicant filed a response on February 21, 2012, whereby claim 1 was amended to recite, "An anchoring fixture for anchoring a hearing prosthesis to a cranial section of a skull bone." *Id.* at 262-286. In discussion of the § 103 rejection of claims 26-28, the '083 applicant did **not** argue that Hansson was non-analogous art. *Id.* at 285.

Further, the USPTO presented subsequent Office Actions on April 19, 2012, June 25, 2014, and March 4, 2015 each of which maintained the § 103 rejection of claims 26-28 as being obvious in view of Hansson. *Id.* at 49-60, 102-111, 222-240. Further, in the Office Action dated June 25, 2014 and March 4, 2015, the Examiner also rejected claims 5-8 and 23-24 under 35 U.S.C. § 103 as being obvious over Håkansson'790 in view of U.S. Patent No. 6,953,463 to H. West, Jr. ("West"), and further in view of U.S. Patent No. 7,249,949 to R. Carter ("Carter'949") entitled "Internal Connection Dental Implant." *Id.* at 53, 106.

In response to the aforementioned Office Actions, the '083 applicant filed responses on October 19, 2012, June 17, 2013, and June 4, 2015, respectively, **without** arguing that either Hansson or Carter'949 were non-analogous art. *Id.* at 16-46, 64-76, 129-143. However, in the response filed June 4, 2015, the '083 applicant argued that two other § 103(a) references, West and U.S. Patent No.

6,030,162 to R. Huebner, neither of which disclosed a dental implant, were non-analogous art. *Id.* at 36-39, 43.

D. Person of Ordinary Skill in the Art

The level of ordinary skill in the art can be evidenced by relevant prior art. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *see also Ex parte Jellá,* No. 2008-1619 (BPAI Nov. 3, 2008). The relevant fields of art for the '807 Patent are mechanical or biomechanical engineering, otolaryngology, and audiology, with a focus on prosthetic implants that osseointegrate or otherwise anchor to bone and/or the design of such an implant. Ex. 1002, ¶ 34. The prior art discussed herein and in the Declaration of Dr. Hayes (Ex. 1002) demonstrates that a person of ordinary skill in the art ("POSA") would have an advanced degree in mechanical or biomechanical engineering, audiology, otolaryngology, or a related field along with two to three years' of experience in the field, such as experience with surgical implants or their design. *Id.* at ¶ 35. Additional education might substitute for some of the experience, and substantial experience might substitute for some of the educational background. *Id.*

V. CLAIM CONSTRUCTION - 37 C.F.R. § 42.100(B)

A. Legal Overview

In an IPR, claim terms shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 83 Fed. Reg. 51,340 (Oct. 11, 2018). Thus, in an IPR, the claim terms are interpreted according to the same claim construction standard that is applied in federal courts, which follow *Phillips v. AWH Corp*., 415 F.3d 1303 (Fed. Cir. 2005) (en banc) and its progeny. Accordingly, the claims are construed in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. *Phillips*, 415 F.3d at 1313. Where the construction of specific terms is not necessary to resolve the issues before the PTAB, the PTAB can refrain from construing those terms, "leaving that question to a later forum where the issue is determinative." *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013).

Any claim terms not included in this section do not need to be construed beyond their plain and ordinary meaning. In addition, Petitioner's constructions are offered solely for the purposes of this proceeding and are not admissions as to the scope of definiteness of any claim term in any other proceeding.

B. Claim Terms Needing Construction

1. Preamble - "for anchoring a prosthesis to a skull bone"

The preamble of claim 1 recites "for anchoring a prosthesis to a skull bone." Under the proper claim construction standard, this preamble language should be given no patentable weight.

When the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed limitations, the preamble is not considered a limitation and is of no significance to claim construction. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.,*182 F.3d 1298, 1305 (Fed. Cir. 1999); *see also Rowe v. Dror,* 112 F.3d 473, 478 (Fed. Cir. 1997). Here, independent claim 1 recites three components of the anchoring fixture: (1) "a screw thread apparatus;" (2) "a flange;" and (3) "a circumferential groove located, with respect to a side of the flange, on the anchoring fixture on a threaded side of the anchoring fixture." Under the correct claim construction standard, the preamble phrase "for anchoring a prosthesis to a skull bone" is merely an intended use, and does not provide any distinct definition for structural limitations of the apparatus as recited in the body of the claim. Thus,

this preamble language should be given no patentable weight under the correct claim construction standard.

2. "circumferential groove"

The Patent Owner has asserted that a POSA would have understood the term "circumferential groove" to mean "a long narrow channel around part or all of a circular periphery of the implant." Ex. 1012, p. 2

Petitioner has asserted that a POSA would have understood the term "circumferential groove" in the '807 Patent to mean "a channel, distinct from the screw thread and distinct from the flange, extending around the cylindrical portion of the main body of the anchor, having an inner diameter and an outer diameter." A POSA would further understand that the "circumferential groove" is provided to "exert a compressive radial force on the skull bone to improve stability of the anchoring fixture." Ex. 1013, p. 3; Ex. 1002, ¶ 36.

A POSA would understand that a groove is a channel. Webster's New International Dictionary Unabridged (2d ed.) defines *groove* as "A furrow, channel, or long hollow, such as may be formed by cutting, molding, grinding, the wearing force of flowing water, or constant travel; a worn path; a rut." Ex. 1014. Webster's New World Dictionary Third College Edition defines *groove* as "any channel or rut cut or worn in a surface." Ex. 1015. A POSA would further understand, both from

these definitions and from the ordinary background knowledge of the field, that a channel must exist in relation to some surface through which it passes, and, as such, the groove must be characterized not only by its lowest point (i.e., inner diameter) but also its highest points (i.e., outer diameter). Ex. 1002, ¶ 38.

The specification of the '807 Patent states that '[p]referably, the second portion has at least one groove extending around the periphery of the cylindrical portion." Ex. 1001, 3:9-11; Ex. 1002, ¶ 37. The '807 Patent does not describe this groove as being on any other surface than the cylindrical portion of the main body, further informing the understanding of a POSA that the term "circumferential groove" means a channel, extending around the cylindrical portion of the main body of the anchor, having an inner diameter and an outer diameter. Ex. 1001, 5:15-16; Ex. 1002, ¶ 37-42. In addition, because claims 1 and 8 specifically require a screw thread, a flange, and a circumferential groove, a POSA would understand that these are separate structures, and so the circumferential groove is necessarily distinct from the screw thread and distinct from the flange. Ex. 1001, Fig. 2, claims 1 and 8; Ex. 1002, ¶¶ 39-41.

Finally, a POSA would appreciate from the '807 patent that the claimed "circumferential groove" is configured to exert a radial compressive force on the bone to improve stability of the anchoring fixture in the bone upon implantation.

Ex. 1001, 4:65-5:5, 5:18-22; Ex. 1002, ¶¶ 43-44. Indeed, the grooves described in the patent exert a compressive radial force on the skull bone to improve stability of the anchoring fixture. Ex. 1002, ¶ 45.

Under either Patent Owner's or Petitioner's construction, a circumferential groove is taught by the prior art as set forth in the grounds below.

3. "means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone" (claim 35)

The Patent Owner has asserted that a POSA would have understood the term "means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone" to be interpreted as requiring "a wider portion adjacent to the flange than at the distal end and equivalents." Ex. 1012, p. 4.

Petitioner recognizes that claim elements of the '807 Patent reciting "means," or some similar generic placeholder, may be subject to interpretation under pre-AIA 35 U.S.C. § 112, ¶ 6. Petitioner does not concede that the '807 Patent discloses adequate structure for performing the functions associated with any claimed "means" and accordingly reserves the right to argue in other forums, such as in district court, that the lack of such adequate structure renders such claimed

"means" language as indefinite. Solely for the purpose of aiding the Board's consideration of the '807 Patent claims, Petitioner submits the following.

To the extent it can be construed at all, the term "means for exerting a compression onto the skull bone in a radial direction" should be construed according to the structures, if any, in the '807 Patent figures and description for performing the claimed function. Ex. 1002, ¶¶ 66-69.

A POSA would identify second portion 102C, adjacent to flange 103 having an inner diameter 128 which exceeds the inner diameter 124 of the main threads 108 of the first portion 102B, as the structure identified in the '807 Patent for performing this function. Ex. 1001, Fig. 2; Ex. 1002, ¶¶ 66, 69. The descriptions in the '807 Patent of radial compression each describe an anchor that has a portion with a wider diameter than the main screw thread. Ex. 1002, ¶ 69. For example, the patent specification states, "the wider second portion of the fixture, i.e., the portion next to the flange, provides a certain compression to the bone, specifically the cortical bone, in the radial direction of the hole." Ex. 1001, 3:25-29. Similarly, the patent describes using circumferential grooves with an inner diameter wider than the inner diameter of the main screw thread to also provide compression on the surrounding bone. *Id.* at 4:57-5:6. Thus, a POSA would understand that the claimed structure that performs the function "exerting a

compression onto the skull bone in a radial direction" is the second portion 102C including the circumferential grooves and equivalents thereof. Ex. 1002, ¶ 69.

Under either Patent Owner's or Petitioner's construction, means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone is taught by the prior art as set forth in the grounds below.

4. Intended use limitations

Claim language pertaining to the manner in which the claimed anchoring/bone fixture is intended to be used, or pertaining to what a patient may physically experience while fitted with the claimed anchoring/bone fixture, does not differentiate the claimed apparatus from any prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 U.S.P.Q.2d 1647 (BPAI Feb. 26, 1987). An apparatus claim should cover what a device is, not what it does. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.,* 909 F.2d 1464, 1469 (Fed. Cir. 1990).

The language of claim 1 stating "wherein the anchoring fixture is configured for anchoring a hearing prosthesis component to the skull bone at a location behind an external ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea" and the language of claim 8 stating "wherein the bone fixture is configured to anchor a hearing aid prosthesis to a skull bone at a location behind

an external ear of a recipient so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea" merely refers to manner in which the claimed implant is intended to be employed.

5. Additional Terms

Petitioner and Patent Owner have also proposed respective constructions for the terms "screw thread," "threaded tapered portion," "wherein a maximum width of the bone fixture is about the same as a height of the bone fixture," and "a flange configured to function as a stop . . . adapted to rest on top of the bone" in Civil Action No. 3:18-cv-06884. Ex. 1012, pp. 2-4; Ex. 1013, pp. 3-6. *See also* Ex. 1002, ¶¶ 46-75. Because the claims are invalid based on the various grounds outlined below regardless of the proposed construction, Petitioner requests that the PTAB refrain from construing these terms, "leaving that question to a later forum where the issue is determinative." *Leo Pharm. Prods.* at 1353.

VI. GROUND 1: CLAIMS 1-12, 14, 16, 25, 28, 33-35, 38, 39, 45 AND 46 ARE UNPATENTABLE AS BEING OBVIOUS UNDER PRE-AIA 35 U.S.C. § 103(A) OVER WESTERKULL'794 (EX. 1003) IN VIEW OF CHOI (EX. 1005)

A. Westerkull'794 and Choi teach all claim features of Claims 1-12, 14, 16, 25, 28, 33-35, 38, 39, 45 and 46

1. Teachings of Westerkull'794 (Ex. 1003)

Westerkull'794 discloses an anchoring fixture 104 for anchoring a prosthesis to a skull bone. Ex. 1003, Abstract; 1:5-7; Ex. 1002, ¶ 76. In particular, Westerkull'794 "relates an anchoring fixture for anchoring a direct bone-conduction hearing-aid to the skull bone." Ex. 1003, 1:5-7; Ex. 1002, ¶ 76. Westerkull'794 further discloses that direct bone conduction hearing aids have a vibrating transducer that transmits vibrations directly to a fixture anchored to the bone, i.e., the skin only minimally influences the transmission of the vibrations from the vibrator to the fixture in the bone. Ex. 1003, 1:13-17; Ex. 1002, ¶ 76.

The anchoring fixture 104 in Westerkull'794 includes a screw thread portion 110 with a screw thread 121 having a varying outer diameter. Ex. 1003, Fig. 2, 5:60-61, 6:15-20; Ex. 1002, ¶ 77. The anchoring fixture 104 also includes a flange 114 configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when the anchoring fixture 104 is implanted into the bone. Ex. 1003, Fig. 2, 5:65-67; Ex. 1002, ¶ 77. The anchoring fixture 104 is configured for

anchoring a bone-conducting hearing aid to the skull bone, such hearing aid having a vibrating transducer that transmits vibration directly to the fixture anchored in the bone. Ex. 1003, 1:5-7, 1:13-15; Ex. 1002, ¶ 77. A POSA would understand that the term "bone conduction hearing aid," refers to a hearing aid having a surgically implanted fixture placed in the bone behind the ear, designed to transfer sounds by bone vibration directly to the cochlea. Ex. 1002, ¶¶ 77, 117. Further, Westerkull'794 describes that the appropriate length of the fixture is determined by the thickness of the skull bone which is "usually between 3-5 mm." Ex. 1003, 1:61-63. A POSA would understand that the thickness of the skull bone in the area behind the ear is in the range of 3-5 mm. Ex. 1002, ¶ 77.

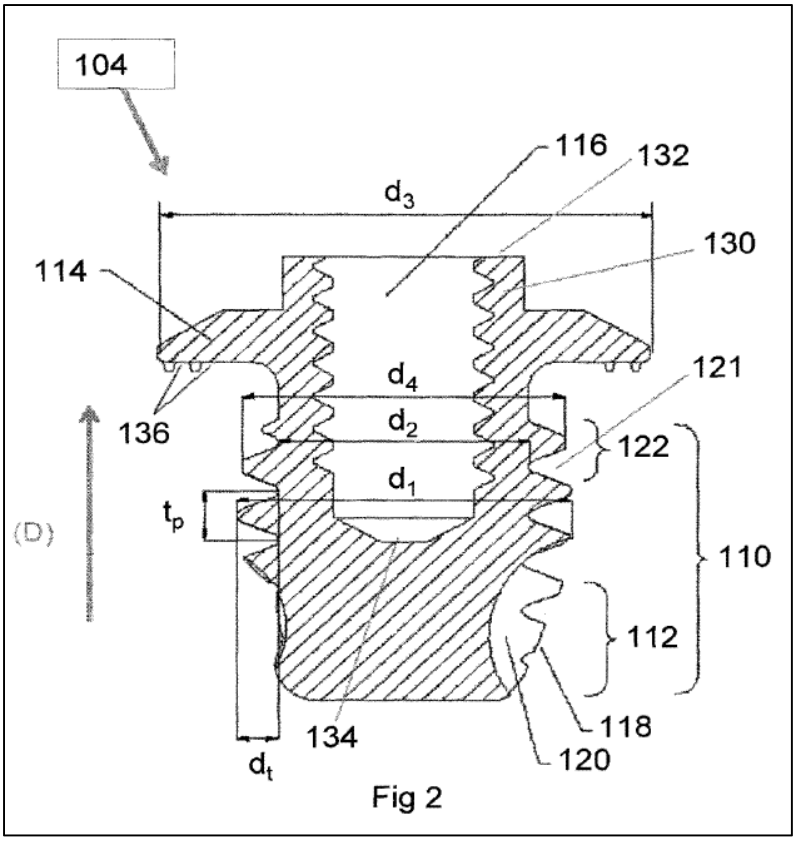


Fig 2

The anchoring fixture 104 is tapered over at least a portion of a longitudinal length (conical outer portion 112) of the anchoring fixture 104, highlighted in red in the figure below. Ex. 1003, Fig. 2, 5:62-64; Ex. 1002, ¶ 78.

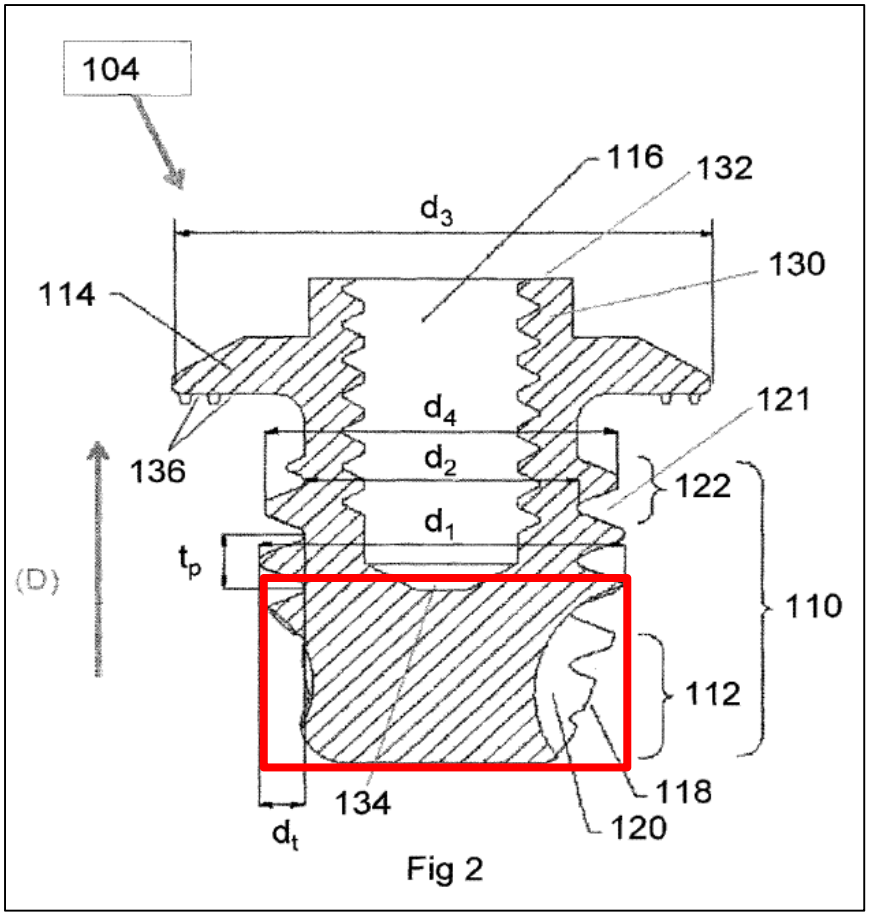


Fig 2

The anchoring fixture 104 is formed of a material capable of integrating into surrounding bone tissue. Ex. 1002, ¶ 79. In particular, Westerkull'794 discloses that the fixture is made of titanium, and also includes a titanium oxide layer having a thickness of 100 nm to provide improved osseointegration properties. Ex. 1003, 1:24-26, 4:66-5:5; Ex. 1002, ¶ 79.

Further, Westerkull'794 teaches that the flange operates to prevent the fixture from being pushed through the skull bone. Ex. 1003, 1:24-26; Ex. 1002, ¶ 80. Thus, a surface of the flange 114 is expected to come into contact with the

bone. Ex. 1002, ¶ 80. Westerkull'794 teaches that the side of the flange 114 facing the threaded portion has a micro thread that comes in contact with the bone. Ex. 1003, 5:26-30; Ex. 1002, ¶ 80.

Westerkull'794 teaches that the surface of the threaded portion 110 is provided with a thicker titanium oxide layer, that of 100 nm. Ex. 1003, 4:66-5:5; Ex. 1002, ¶ 81. This allows the surface of the threaded portion 110 has an increased average surface roughness S_α of 1 μm ≤ S_α ≤ 3 μm, which contributes to an improved strength of the osseointegration of the fixture in the bone. Ex. 1003, 5:19-25; Ex. 1002, ¶ 81.

Further, in regard to successful osseointegration, Westerkull'794 teaches the importance of initial stability in the fixture, stating that

> For the osseointegration process to be successful it is also important that the fixture is stable in the bone during the first 3 months when the osseointegration is established. The initial stability of the fixture in the bone is therefore also important for a successful treatment.

Ex. 1003, 1:44-49; Ex. 1002, ¶ 82.

The anchoring fixture 104 of Westerkull'794 includes an axial extension 130 (highlighted in red below) that provides a hexagonal interface that is capable of receiving torque from a wrench. Ex. 1003, Fig. 4, 6:1-3; Ex. 1002, ¶ 83. Because

the axial extension 130 is in the shape of a hexagonal nut, it is capable of being turned by a wrench. Ex. 1002, ¶ 83.

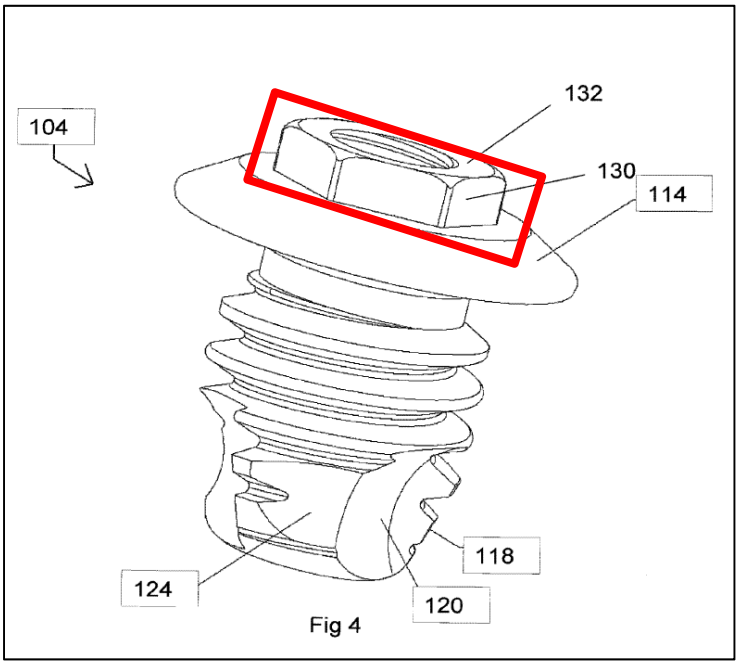


Fig 4

The flange 114 of the anchoring fixture 104 includes a cylindrical portion (shown in red highlighting below). Ex. 1003, Fig. 2, 5:65-68; Ex. 1002, ¶ 84. In a preferred embodiment, the flange 114 also includes at least one groove extending at least one turn on the side of the flange facing the threaded portion, such arrangement acting as a micro thread in contact with the bone. Ex. 1003, 5:26-30; Ex. 1002, ¶ 84. The purpose of the groove on the flange is described as follows,

> Since bone resorbtion [sic] starts in the periphery of the flange, this arrangement hinders the bone resorbtion [sic] under the flange. The thread is hindering the bone resorbtion [sic] from going further down along the threaded portion in contra distal direction.

Ex. 1003, 5:30-34; Ex. 1002, ¶ 84.

Therefore, Westerkull'794 addresses potential bone resorption or bone loss along the fixture. Ex. 1002, ¶ 84.

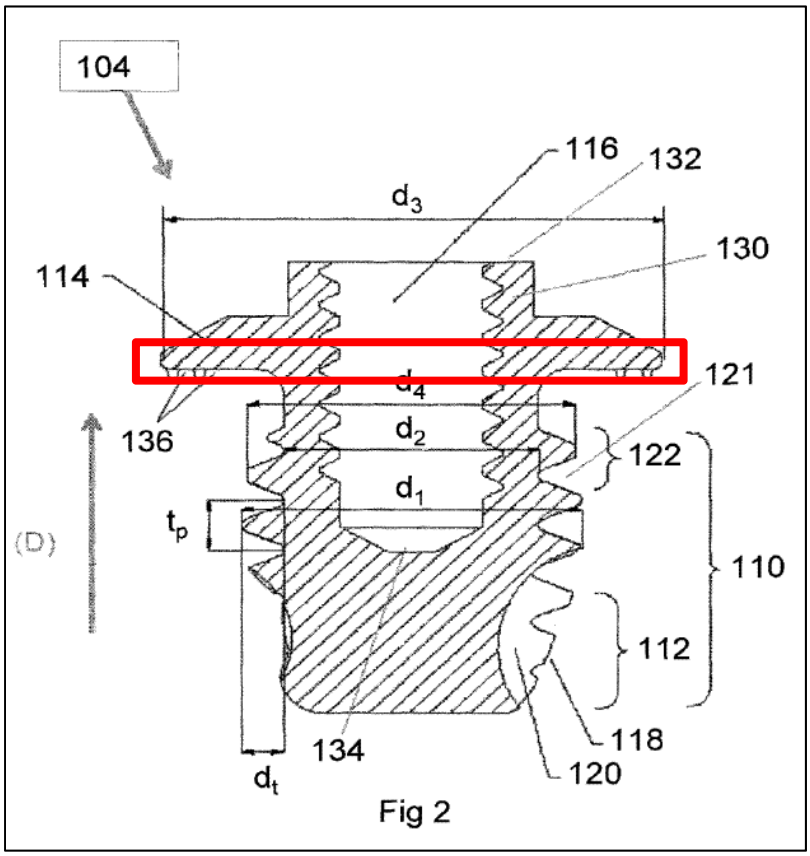


Fig 2

In addition, at the junction between the flange 114 and the threaded portion 110, the threaded portion flares out to have a tapered shape (highlighted in red below). Ex. 1003, Fig. 2; Ex. 1002, ¶ 85.

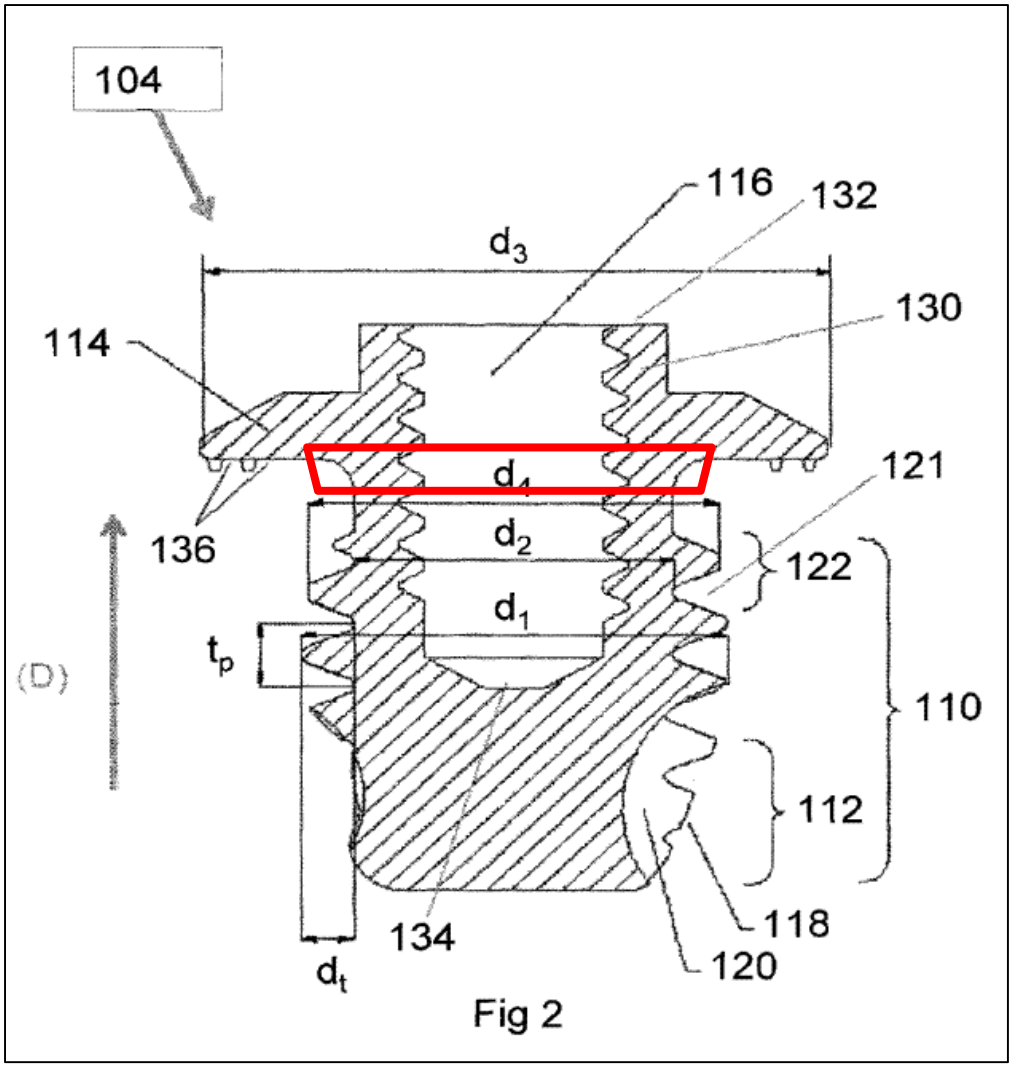


Fig 2

The anchoring fixture 104 includes a self-tapping apparatus 118 where at least a portion of the screw thread apparatus (threaded portion 110) is part of the self-tapping apparatus 118. Ex. 1003, Figs. 2 and 3, Abstract, 6:8-12, 6:25-28; Ex. 1002, ¶ 86. In particular, at least a portion of the screw thread apparatus 110 includes cutting edges 118_{abc} of the self-tapping apparatus and relief areas 124_{abc} behind the cutting edges 118_{abc}. Ex. 1003, Figs. 2 and 3, 6:22-24; Ex. 1002, ¶ 86.

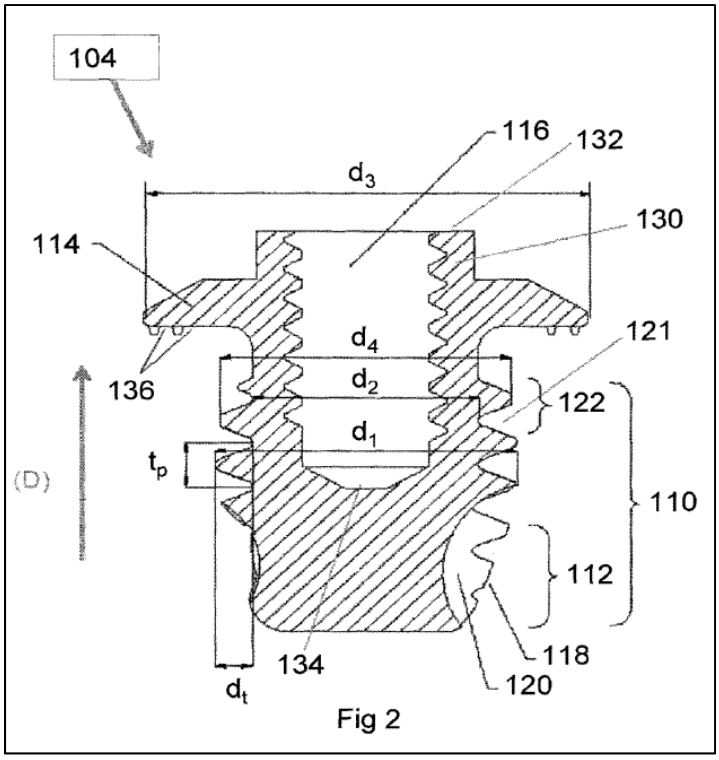
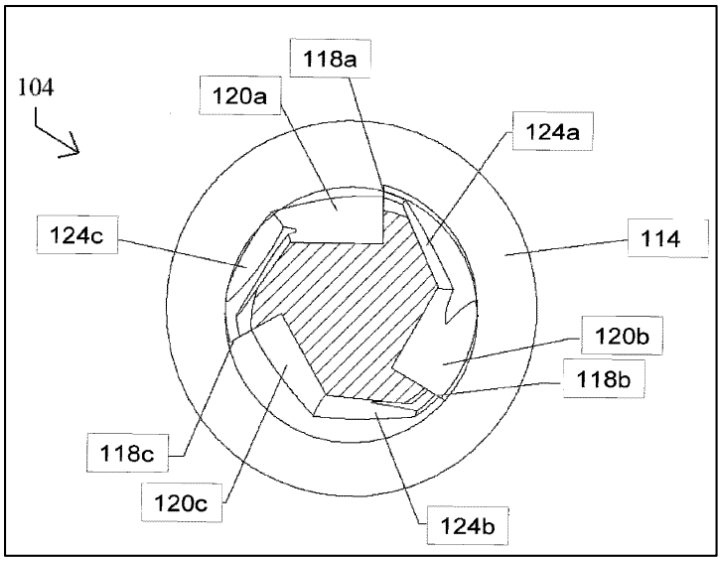


Fig 2



The anchoring fixture 104 includes an inner bore including an internal screw thread as evidenced by the axial threaded inner hole 116, highlighted in red in the figure below. Ex 1003, Fig. 2, 6:1-3; Ex. 1002, ¶ 87.

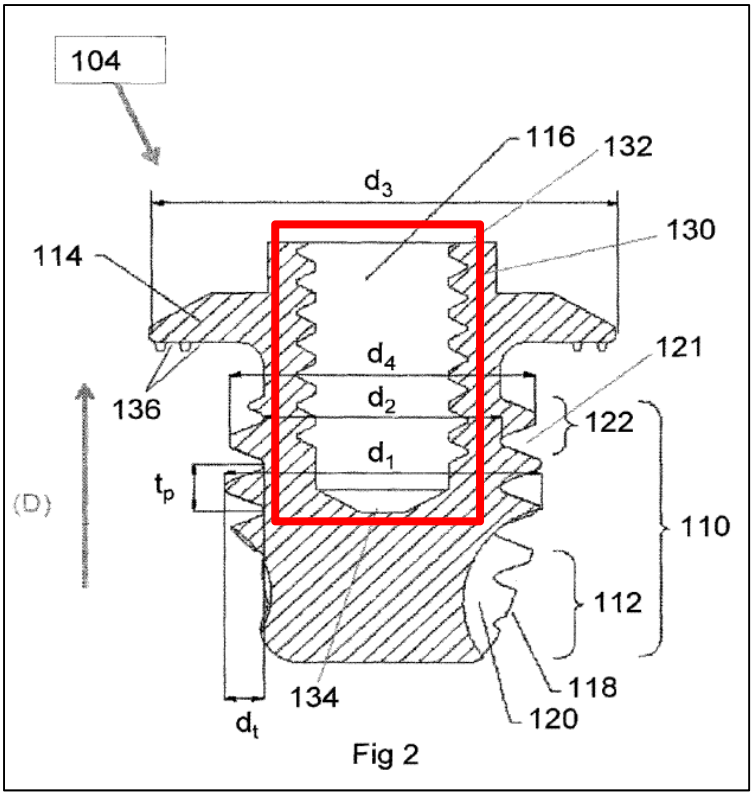


Fig 2

The screw thread 110 includes an inner diameter d_2 that remains about constant over about at least two turns of the screw thread 121 (highlighted in blue in the figure below). Ex. 1003, Fig. 2, 5:60-61; Ex. 1002, ¶ 88. Notably, at a lower most portion of the conical outer portion 112 of the screw thread (highlighted in red below), the diameter of that lower most portion is less than at the junction between the flange 114 and the threaded portion 110 (also highlighted in red below). Ex. 1003, Fig. 2; Ex. 1002, ¶ 88.

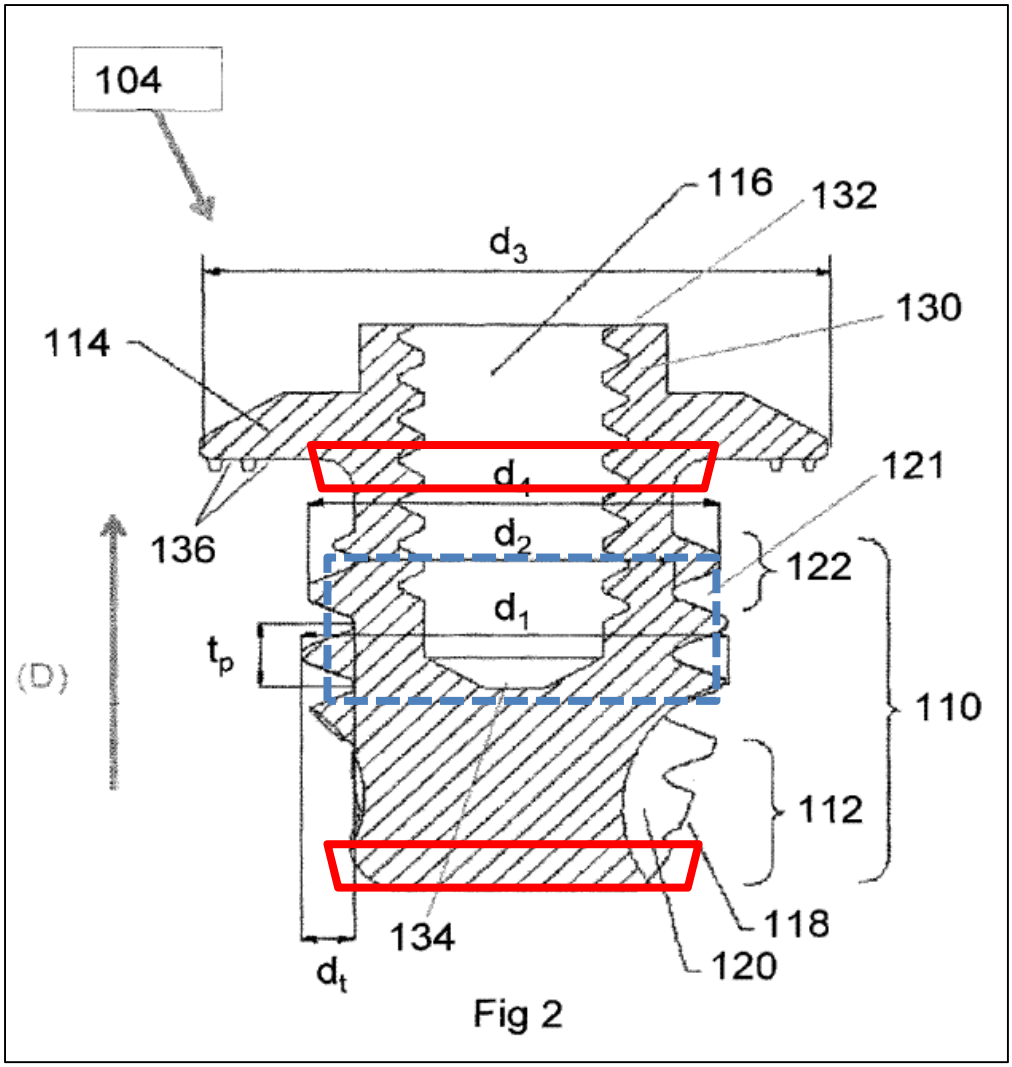


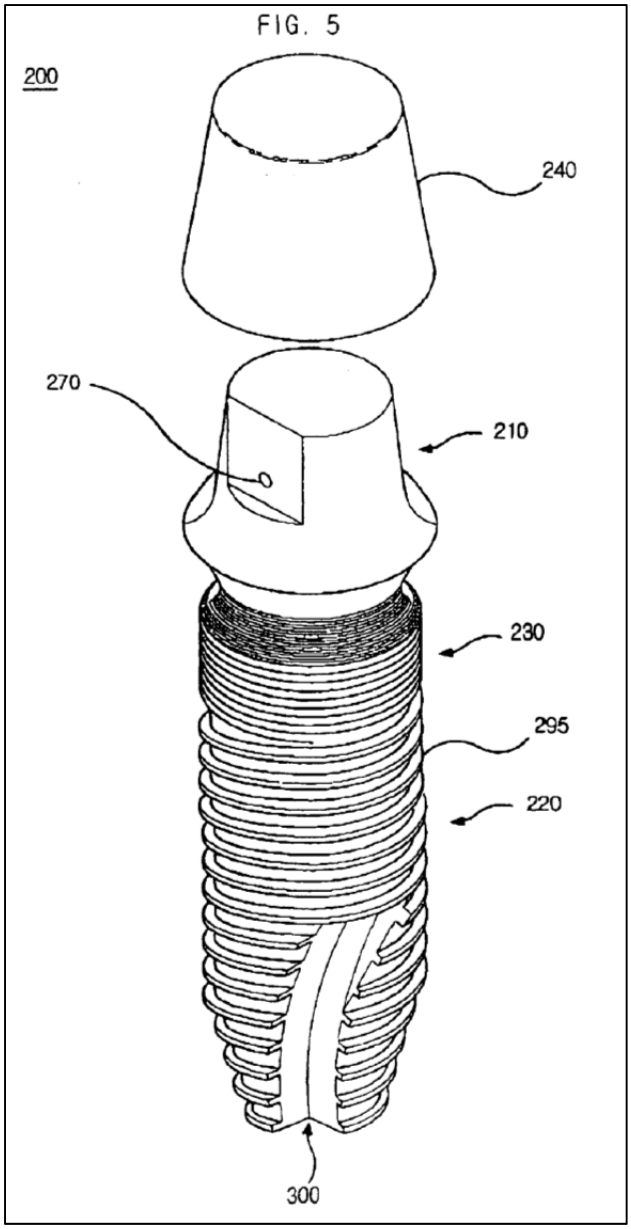
Fig 2

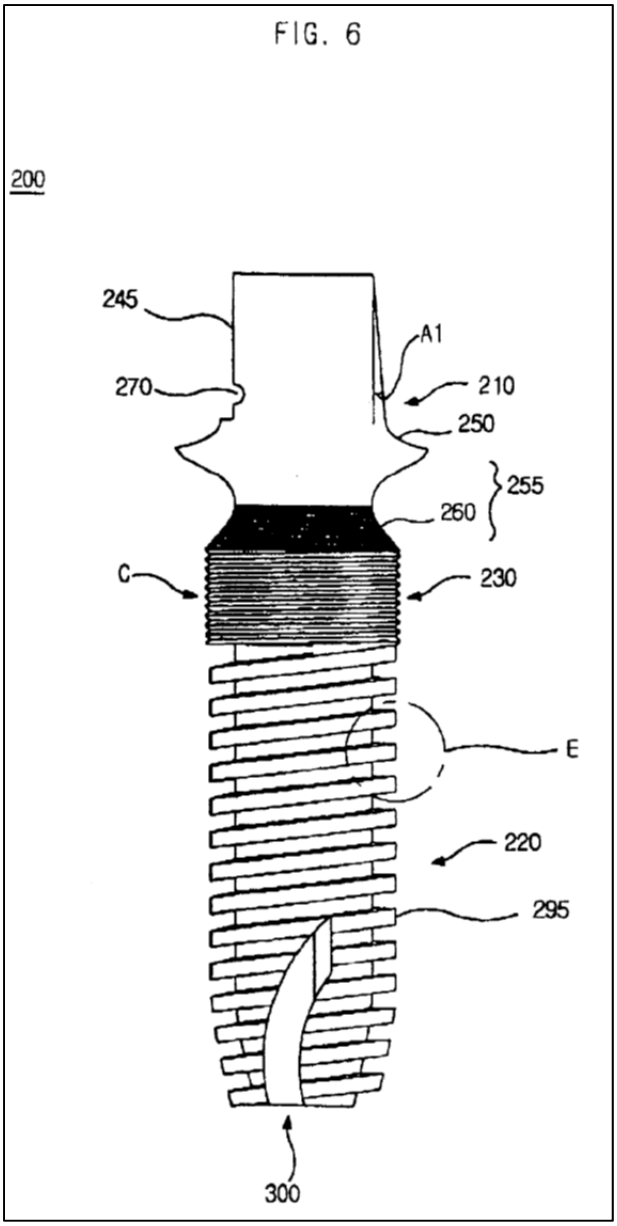
Westerkull'794 discloses that a diameter of the fixture is in the range of 3.5-5 mm. Ex. 1003, 1:63-66; Ex. 1002, ¶ 89. In addition, Westerkull'794 discloses that thickness of the skull bone is usually between 3-5 mm and the thickness determines the appropriate length of the fixture. Ex. 1003, 1:61-63; Ex. 1002, ¶ 89. As such, the length from a bottom of the flange 114 to a distal end of the anchoring fixture 104, which would include the threads 110, is no greater than 5

mm. Ex. 1002, ¶ 89. Because the diameter of the flange 114 is between 3-5 mm and the length from the bottom of the flange 114 to the distal end of the anchoring fixture 104 is no greater than 5 mm, Westerkull'794 discloses that the maximum diameter of the flange 114 can be greater than the length from the bottom of the flange 114 to the distal end of the anchoring fixture 104. *Id.*

2. Teachings of Choi (Ex. 1005)

Choi discloses a dental implant 200 whose structure is designed to achieve, among other things, superior bonding between the fixture of the implant and the bone tissue and the prevention of osteolysis. Ex. 1005, 3:66-4:5; Ex. 1002, ¶ 90. The implant 200 includes an upper abutment portion 210, a lower fixture portion 220, and a settling portion 230 formed between the abutment portion 210 and the fixture portion 220. Ex. 1005, Figs. 5-6, Abstract, 7:7-11; Ex. 1002, ¶ 91. Threads 295 are formed on the surface of the fixture portion 220. Ex. 1005, Figs. 5-6, 9:24-30; Ex. 1002, ¶ 90. Cutting means 300 (including multiple cutting edges 305, 310, 315) are also formed on the lower tip of the fixture portion 220. Ex. 1005, Figs. 5, 11, 12, 9:36-47; Ex. 1002, ¶ 90.

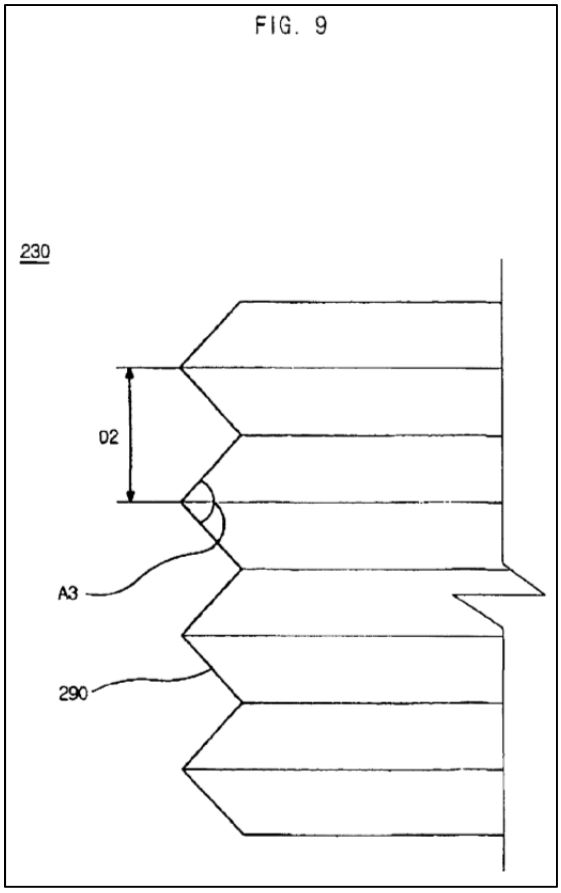




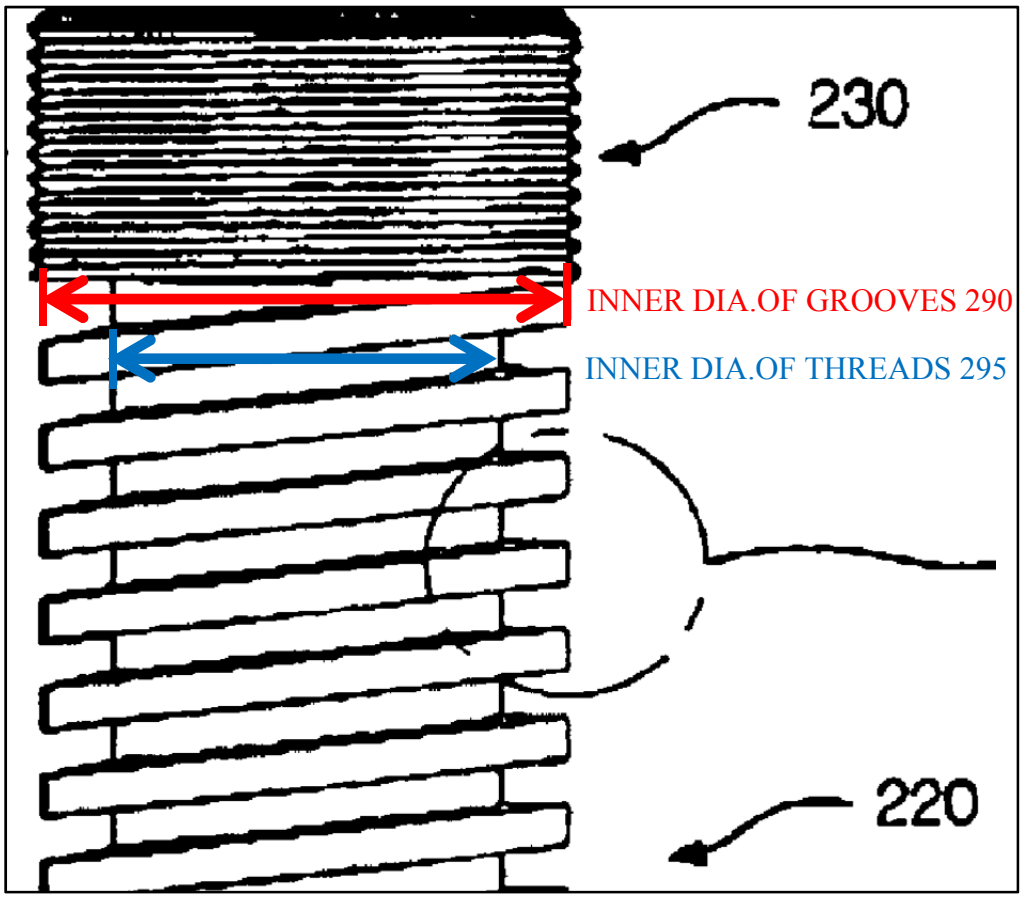
In Choi, the settling portion 230 gradually decreases in diameter in the downward direction. Ex. 1005, 8:60-62; Ex. 1002, ¶ 91. According to this gradual decrease, the upper portion of the settling portion 230 (adjacent to the curved shoulder 255) has a diameter of about 4.2 mm, while the lower portion of the

settling portion 230 has a diameter of about 4.0 mm. Ex. 1005, 8:62-65; Ex. 1002, ¶ 91. Adjacent to the lower portion of the settling portion 230, the fixture portion 220 also has a diameter of about 4.0 mm. Ex. 1005, 7:30-33; Ex. 1002, ¶ 91. However, the diameter of the fixture portion has a sharply reduced diameter of about 2.0 mm at the lower end. Ex. 1005, 9:20-24; Ex. 1002, ¶ 91. Choi teaches that the implant 200 is implanted into the jawbone from the fixture portion to the upper portion of the settling portion 230, which attaches to the cortex bone of the jawbone. Ex. 1005, 5:50-51, 8:62-63, 9:18-20; Ex. 1002, ¶ 91.

As shown in Figure 9 (reproduced below), a number of minute screwed grooves 290 are formed on the surface of the settling portion. Ex. 1005, 9:1-2; Ex. 1002, ¶ 92. These screwed grooves 290 have a pitch between about 0.15 to about 0.25 mm and a thread angle of about 80 to about 120 degrees. Ex. 1005, Figs. 6, 9; 9:2-5; Ex. 1002, ¶ 92. According to Choi, the minute screwed grooves 290 disperse the stress on the implant 200 to the cortex bone and minimize osteolysis, thus improving the bond with the cortex bone of the jawbone. Ex. 1005, 9:5-16; Ex. 1002, ¶ 92.



As clearly shown in the cross-sectional view of Figure 6, partially reproduced below, the inner diameter of the minute screwed grooves 290 of the settling portion 230, highlighted in red below, is greater than the inner diameter for all turns of the thread. Ex. 1005, Fig. 6; Ex. 1002, ¶ 93.



B. *KSR* Rationale to Combine

For obviousness analysis, prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)). To the extent that the Patent Owner may attempt to argue that dental implants are not in the same field of endeavor, Petitioner notes that the Supreme Court held "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a

different one." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). In other words, the art must be (1) within the inventors field of endeavor or (2) reasonably pertinent to the problem the invention attempts to solve. *In re Clay*, 966 F.2d 656 (Fed. Cir. 1992).

Finally, "it is proper to take into account not only specific teachings of the reference, but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968).

The combination of Westerkull'794 and Choi discloses each element of independent claims 1 and 8 of the '807 Patent. Ex. 1002, ¶¶ 94-118, 138-59.

With respect to claims 1 and 8, Westerkull'794 discloses an anchoring fixture (i.e., bone fixture) 104 for anchoring a prosthesis to a skull bone. Ex. 1003, Abstract, 1:5-7; Ex. 1002, ¶¶ 76, 95-96, 139-140. This anchoring fixture 104 includes a screw thread portion 110 with a screw thread 121 having a varying outer diameter, at least part of the threaded portion 110 being tapered (conical outer portion 112). Ex. 1003, Fig. 2, 5:60-64, 6:15-20; Ex. 1002, ¶¶ 77-78, 97-98, 141. The anchoring fixture 104 of Westerkull'794 includes a flange 114 configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when the anchoring fixture 104 is implanted into the bone. Ex. 1003, Fig. 2, 5:65-67; Ex. 1002, ¶¶ 77, 80, 84, 99-100, 145-146. Further, the anchoring fixture 104 is

configured for anchoring a hearing prosthesis component to the skull bone at a location behind an external ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea. Ex. 1003, Abstract; 1:5-7, 1:11-17, 3:14-17; Ex. 1002, ¶¶ 76-77, 117-118, 158-159.

Moreover, with respect to claim 8, Westerkull'974 discloses that the maximum width of the fixture 104 is about the same as the height of the fixture. Ex. 1002, ¶¶ 141-144. Westerkull'974 teaches that the diameter of the fixture is in the range of 3.5-5 mm. Ex. 1003, 1:63-66; Ex. 1002, ¶¶ 89, 142, 193, 196, 198, 226. In addition, Westerkull'794 discloses that thickness of the skull bone is usually between 3-5 mm, and that the thickness determines the appropriate length of the fixture. Ex. 1003, 1:61-63; Ex. 1002, ¶¶ 77, 89, 142, 194-196, 199, 227-229. Westerkull'794 further teaches that a design consideration is "to prevent the fixture from being pushed into the skull," and thus the length of the fixture should not exceed the thickness of the skull bone. Ex. 1003, 5:66-67; Ex. 1002, ¶¶ 77, 89, 142, 194, 199, 227-229. The POSA would therefore understand that the teachings of Westerkull'794 covers an embodiment where both the maximum diameter of the fixture 104 and the maximum length of the fixture 104 are about 5 mm, i.e., about the same. Ex. 1002, ¶¶ 141-144, 191-196, 224-229.

To the extent Patent Owner may allege that Westerkull'794 lacks a circumferential groove located on a threaded side of the anchoring fixture, with respect to an upper portion of the fixture, Choi makes up for this deficiency. *Id.* at ¶¶ 90, 109-110, 113, 150-154, 176-178, 213-217, 231-234.

Choi is in the same field of endeavor as Westerkull'794 as they are both directed to anchoring fixtures that are inserted into bone. *Id.* at ¶¶ 76, 90, 102-107, 148. That is, at the time of the '807 Patent's filing, the POSA would have been fully aware of developments that have occurred in the dental anchoring art and would have been willing to consider such developments in making improvement to bone-implant hearing aids. Ex. 1023; Ex. 1024; Ex. 1002, ¶ 103.

Moreover, the teachings of Choi would be reasonably pertinent to the problem being solved in Westerkull'794 as both Choi and Westerkull'794 address mechanical and biological aspects of stability in their respective fixtures including improving the initial stability of the fixture upon implantation, promoting osseointegration, and preventing bone loss. Ex. 1025; Ex. 1026; Ex. 1002, ¶¶ 79-82, 90, 92, 104-108, 113, 154. Specifically, Choi discloses a circumferential groove region above the threaded fixture portion of an implant, which includes a number of minute screwed grooves for dispersing stress transferred through the implant into the cortex bone, preventing osteolysis and improving bonding of the

implant with bone. Ex. 1005, 9:1-16; Ex. 1002, ¶¶ 90-93, 101, 109-111, 150-152, 174-176, 184, 208, 232. Westerkull'794 is likewise concerned with promoting osseointegration (e.g., by providing a surface treatment of titanium) and preventing bone resorption along the threaded portion (e.g., by providing a micro thread on the flange surface contacting bone). Ex. 1003, 5:1-5, 5:15-18, 5:26-34; Ex. 1002, ¶¶ 79, 81-82, 84, 108, 123, 149, 188, 263.

Further, to the extent Patent Owner may allege that Westerkull'794 does not satisfy the "circumferential groove" features of claims 1 and 8, a POSA would have found it obvious to modify the Westerkull'794 anchoring fixture by providing a circumferential groove region as taught by Choi. Ex. 1002, ¶¶ 101-116, 147-157, 176-177. A POSA would understand, in view of Choi's disclosure, various advantages of providing a circumferential groove region. Such advantages include improving stability of the fixture, dispersing stress on the implant to the cortex bone, preventing bone loss, and improving bonding of the fixture with bone. *Id.* at ¶¶ 90, 92, 110, 113, 151, 154, 205, 208-209. Further, because Choi discloses an anchor arrangement where the circumferential groove region is located on a threaded side of the implant, with respect to an upper portion of the implant, a POSA would have found it obvious to position the circumferential groove region on a threaded side anchoring fixture of Westerkull'794 with respect to the flange.

Ex. 1005, Figs. 5-6, 7:7-11; Ex. 1002, ¶¶ 90, 109-110, 113, 150-154, 176-178, 213-217, 231-234. Making the aforementioned modifications to Westerkull'794 would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions. Ex. 1002, ¶¶ 101-116, 147-157, 174-177, 213-216, 230-233. Such an obvious modification would also satisfy a demand for improving known bone anchors to attain predictable and beneficial results. *See KSR*, 550 U.S. at 416 (2007); Ex. 1002, ¶¶ 101-114, 147-155.

Choi describes a number of minute screwed grooves 290 in the circumferential groove region formed as channels, distinct from the screw thread 295 and extending around the cylindrical portion of the main body of the anchor. Ex. 1005, Fig. 6; 9:1-2, 9:22-35; Ex. 1002, ¶¶ 92-93, 109-111, 150-152. The screwed grooves 290 have an outer and an inner diameter. Ex. 1005, Fig. 9; Ex. 1002, ¶¶ 92-93, 110, 151, 184, 205, 208, 221-222. In Choi, both the outer and inner diameters of the screwed grooves 290 in the upper portion of the circumferential groove region exceed the respective outer and inner diameters of the screw thread 295 in the fixture portion 220, thereby being configured to exert a compressive radial force on the skull bone and thus improve stability of the anchoring fixture. Ex. 1005, Fig. 6, Abstract; Ex. 1002, ¶¶ 93, 110, 151, 184, 205, 208, 221-222. Furthermore, to the extent that Patent Owner argues a broader

construction of "circumferential groove," each of Choi's screwed grooves 290 is a long narrow channel around part or all of a circular periphery of the implant. Ex. 1005, Fig. 6; Ex. 1002, ¶¶ 111, 152.

A POSA would have had a reasonable expectation of success in configuring the anchoring fixture of Westerkull'794 in view of Choi. Ex. 1002, ¶¶ 115, 156.

For ease in review, the following claims chart further details how the obvious modification of Westerkull'794 in view of Choi satisfies all features recited in independent claims 1 and 8 of the '807 Patent.

Independent Claims 1 and 8 of the '807 Patent	**Exemplary Citations in Westerkull'794 (Ex. 1003) and Choi (Ex. 1005)**
Claim 1. "An anchoring fixture for anchoring a prosthesis to a skull bone comprising:"	Note the proposed claim construction above regarding "for anchoring a prosthesis to a skull" (preamble, no patentable weight) (Section V.(B.)(4.). Should the board conclude otherwise, the prior art still discloses this feature below. *Westerkull'794* discloses an anchoring fixture 104 for anchoring a prosthesis to a skull bone. Ex. 1003, Abstract; 1:5-7; Ex. 1002, ¶¶ 76, 95-96, 139-140.
"a screw thread apparatus including a screw thread having a varying outer diameter;"	*Westerkull'974* discloses the anchoring fixture 104 includes a screw thread portion 110 with a screw thread 121 having a varying outer diameter. Ex. 1003, Fig. 2, 5:60-61, 6:15-20; Ex. 1002, ¶¶ 77-78, 97-98, 141.
"a flange configured to function as a stop for the anchoring fixture	The anchoring fixture 104 of *Westerkull'974* also includes a flange 114

Independent Claims 1 and 8 of the '807 Patent	**Exemplary Citations in Westerkull'794 (Ex. 1003) and Choi (Ex. 1005)**
adapted to rest on top of the bone when the anchoring fixture is implanted into the bone; and"	configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when the anchoring fixture 104 is implanted into the bone. Ex. 1003, Fig. 2, 5:65-67; Ex. 1002, ¶¶ 77, 80, 84, 99-100, 145-146.
"a circumferential groove located, with respect to a side of the flange, on the anchoring fixture on a threaded side of the anchoring fixture,"	To the extent that *Westerkull'974* may be interpreted as not having the claimed circumferential groove, *Choi* discloses a dental implant 200 including a number of circumferential grooves 290 located on a threaded side of the implant with respect to an upper portion of the implant. Ex. 1005, Figs. 5, 6, 9, Abstract, 9:1-16; Ex. 1002, ¶¶ 90-93, 101, 109-111, 150-152, 174-176, 184, 208, 232. The obvious location for the circumferential groove region taught by *Choi*, in relation to the anchoring fixture 104 of *Westerkull'794*, would be on a threaded side of the fixture 104 with respect to the flange 114. Section VI.(B.); Ex. 1002, ¶¶ 90, 109-110, 113, 150-154, 176-178, 215-217, 231-234.
"wherein the anchoring fixture is configured for anchoring a hearing prosthesis component to the skull bone at a location behind an external ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea."	Note the proposed claim construction above regarding "the anchoring fixture is configured for anchoring a hearing prosthesis component to the skull bone at a location behind an external ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea" (intended use) (Section V.(B.)(4.)). Should the board conclude otherwise, the prior art still discloses this feature below.

Independent Claims 1 and 8 of the '807 Patent	**Exemplary Citations in Westerkull'794 (Ex. 1003) and Choi (Ex. 1005)**
	Westerkull'794 discloses "an anchoring fixture for anchoring a direct bone-conduction hearing-aid to the skull bone." Ex. 1003, 1:5-7; Ex. 1002, ¶ 76. *Westerkull'794* further describes that direct bone conduction hearing aids have a vibrating transducer that transmits vibrations directly to a fixture anchored in the bone, i.e., the skin only minimally influences the transmission of the vibrations from the vibrator to the fixture in the bone. Ex. 1003, 1:13-17; Ex. 1002, ¶ 76. A POSA would understand that a "bone conduction hearing aid" would be anchored to the skull bone at a location behind the ear. Ex. 1002, ¶ 117. A POSA would also understand that a "bone conduction hearing aid" transfers sounds by bone vibration directly to the cochlea. Ex. 1003, 1:13-17, Ex. 1002, ¶ 117.
Claim 8. "A bone fixture configured to anchor to bone, comprising:"	*Westerkull'974* discloses a bone fixture 104 configured to anchor to bone. Ex. 1003, Abstract, 1:5-7; Ex. 1002, ¶¶ 76, 95-96, 139-140.
"a threaded tapered portion, wherein a maximum width of the bone fixture is about the same as a height of the bone fixture;"	*Westerkull'974* discloses the bone fixture 104 includes a screw thread portion 110 including a tapered portion, i.e., conical outer portion. Ex. 1003, Fig. 2; 5:60-64; Ex. 1002, ¶¶ 78, 97, 141. *Westerkull'974* discloses that a diameter of the fixture is in the range of 3.5-5 mm. Ex. 1003, 1:63-66; Ex. 1002, ¶¶ 77, 89, 142, 194-196, 199, 227-279. In addition, *Westerkull'794* discloses that thickness of

Independent Claims 1 and 8 of the '807 Patent	**Exemplary Citations in Westerkull'794 (Ex. 1003) and Choi (Ex. 1005)**
	the skull bone is usually between 3-5 mm and the thickness determines the appropriate length of the fixture. Ex. 1003, 1:61-63; Ex. 1002, ¶¶ 77, 89, 142, 194, 199, 227-229. Therefore, a POSA would understand that the bone fixture 104 of Westerkull'974 could have a maximum width that is about the same as a height of the bone fixture. Ex. 1002, ¶¶ 141-144, 191-196; 224-249.
"a flange configured to function as a stop for the bone fixture adapted to rest on top of the bone when the bone fixture is implanted into the bone; and"	The anchoring fixture 104 of *Westerkull'974* also includes a flange 114 configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when the anchoring fixture 104 is implanted into the bone. Ex. 1003, Fig. 2, 5:65-67; Ex. 1002, ¶¶ 77, 80, 84, 99-100, 145-146.
"a circumferential groove located, with respect to a side of the flange, on the bone fixture on a threaded side of the bone fixture,"	To the extent that *Westerkull'974* may be interpreted as not having the claimed circumferential groove, *Choi* discloses a dental implant 200 including a number of circumferential grooves 290 located on a threaded side of the implant with respect to an upper portion of the implant. Ex. 1005, Figs. 5, 6, 9, Abstract; 9:1-16; Ex. 1002, ¶¶ 90-93, 101, 109-111, 150-152, 174-176, 184, 208, 232. The obvious location for the circumferential groove region taught by *Choi*, in relation to the anchoring fixture 104 of *Westerkull'794*, would be on a threaded side of the fixture 104 with respect to the flange 114. Section VI.(B.); Ex. 1002, ¶¶ 90, 109-110, 113, 150-154, 176-178, 215-517, 231-234.

Independent Claims 1 and 8 of the '807 Patent	**Exemplary Citations in Westerkull'794 (Ex. 1003) and Choi (Ex. 1005)**
"wherein the bone fixture is configured to anchor a hearing aid prosthesis to a skull bone at a location behind an external ear of a recipient so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea."	Note the proposed claim construction above regarding "wherein the bone fixture is configured to anchor a hearing aid prosthesis to a skull bone at a location behind an external ear of a recipient so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea" (intended use) (Section V.(B.)(4.)). Should the board conclude otherwise, the prior art still discloses this feature below. *Westerkull'794* discloses "an anchoring fixture for anchoring a direct bone-conduction hearing-aid to the skull bone." Ex. 1003, 1:5-7; Ex. 1002, ¶ 76. *Westerkull'794* further describes that direct bone conduction hearing aids have a vibrating transducer that transmits vibrations directly to a fixture anchored in the bone, i.e., the skin only minimally influences the transmission of the vibrations from the vibrator to the fixture in the bone. Ex. 1003, 1:13-17; Ex. 1002, ¶ 76. A POSA would understand that a "bone conduction hearing aid" would be anchored to the skull bone at a location behind the ear. Ex. 1002, ¶ 117. A POSA would also understand that a "bone conduction hearing aid" transfers sounds by bone vibration directly to the cochlea. Ex. 1003, 1:13-17; Ex. 1002, ¶ 117.

C. Dependent Claims 2-7, 9-12, 14, 16, 25, 28, 33-35, 38, 39, 45 and 46

The obvious combination of Westerkull'794 and Choi also clearly satisfies all the features in various dependent claims of the '807 Patent as follows.

With respect to claim 2, a POSA would understand that the anchoring fixture 104 of Westerkull'794 is tapered over at least a portion of a longitudinal length (e.g., conical outer portion 112) of the anchoring fixture 104. Ex. 1003, Fig. 2, 5:60-64; Ex. 1002, ¶¶ 78, 97, 119-121, 141, 161-162.

With respect to claim 3, a POSA would understand that the anchoring fixture 104 of Westerkull'794 is formed of a material capable of integrating into surrounding bone tissue. Ex. 1002, ¶¶ 79, 81, 108, 122-124, 149, 188, 263. Westerkull'794 discloses that the fixture is made of titanium, and includes a titanium oxide layer having a thickness of 100 nm to provide improved osseointegration properties. Ex. 1003, 1:24-27, 4:66-5:5; Ex. 1002, ¶¶ 79, 81, 108, 123, 149, 188.

With respect to claim 4, a POSA would understand that the anchoring fixture 104 of Westerkull'794 includes an axial extension 130 providing a hexagonal interface capable of receiving torque from a wrench. Ex. 1003, Fig. 4, 6:1-3; Ex. 1002, ¶¶ 83, 125-127, 167. A POSA would understand that, since the axial

extension 130 is in the shape of a hexagonal nut, it is capable of being turned by a wrench. Ex. 1002, ¶¶ 83, 125-127, 167.

With respect to claim 5, a POSA would understand that the flange 114 of the anchoring fixture 104 of Westerkull'794 includes a cylindrical portion. Ex. 1003, Fig. 2, 5:65-68; Ex. 1002, ¶¶ 84, 128-130.

With respect to claims 6 and 7, a POSA would understand that the anchoring fixture 104 of Westerkull'794 includes a self-tapping apparatus 118, wherein at least a portion of the screw thread apparatus (threaded portion 110) is part of the self-tapping apparatus 118. Ex. 1003, Figs. 2-4, Abstract, 6:8-12, 6:25-28; Ex. 1002, ¶¶ 86, 131-134, 136-137, 170-173. A POSA would understand that at least a portion of this screw thread apparatus 110 includes cutting edges 118_{abc} of the self-tapping apparatus. Ex. 1003, Figs. 2-3, 6:8-10; Ex. 1002, ¶¶ 86, 132-137, 170-173.

With respect to claim 9, a POSA would understand that the threaded tapered portion (conical outer portion 112) of the anchoring fixture 104 of Westerkull'794 tapers toward a longitudinal axis of the anchoring fixture 104 with a distance toward a distal end. Ex. 1003, Fig. 2, 5:62-64; Ex. 1002, ¶¶ 78, 97, 141, 160-162.

With respect to claim 10, a POSA would understand that the anchoring fixture 104 of Westerkull'794 includes an inner bore including an internal screw

thread as evidenced by the axial threaded inner hole 116. Ex 1003, Fig. 2, 6:1-3; Ex. 1002, ¶¶ 87, 163-165.

With respect to claim 11, a POSA would understand that the anchoring fixture 104 of Westerkull'794 includes an axial extension 130 capable of interfacing with a wrench so that torque can be transferred from the wrench to the bone fixture, such axial extension being in the form of a hex. Ex. 1003, Fig. 4, 6:1-3; Ex. 1002, ¶¶ 83, 125-127, 166-168.

With respect to claim 12, a POSA would understand that the anchoring fixture 104 of Westerkull'794 includes a self-tapping apparatus 118, wherein a thread of the tapered portion (conical outer portion 112) includes first discontinuities forming respective cutting edges 118_{abc} of the self-tapping apparatus 118 and second discontinuities forming relief areas 124_{abc} wherein the relief areas 124_{abc} and the cutting edges 118_{abc} are provided in an alternating configuration around the body of the anchoring fixture 104. Ex. 1003, Figs. 2-3, 6:22-24; Ex. 1002, ¶¶ 86, 132-134, 136-137, 169-173.

With respect to claim 14, to the extent Patent Owner may allege that the anchoring fixture 104 of Westerkull'794 lacks a circumferential groove between the flange 114 and all of the threads of the threaded portion 110, Choi makes up for this deficiency. Ex. 1002, ¶¶ 90, 109-110, 113, 150-154, 175-178, 213-217, 231-

234. Choi discloses a circumferential groove region comprised of a number of circumferential grooves (screwed grooves 290) between an upper portion of the implant and all the threads 295 of a fixture portion 220. Ex. 1005, Figs. 5-6, 7:29-32, 9:18-27; Ex. 1002, ¶¶ 90-93, 109-111, 150-152, 176, 184, 208, 232. Therefore, a POSA would understand that having modified Westerkull'794 to include a circumferential groove region as taught by Choi, the modified anchoring fixture would provide a circumferential groove between the flange and all the threads of the fixture. Ex. 1002, ¶¶ 113, 150-151, 154, 176-178, 215-217, 231-234.

With respect to claim 16, a POSA would understand that the screw thread 121 of the anchoring fixture 104 of Westerkull'794 includes an inner diameter d_2 that remains about constant over about at least two turns of the screw thread 121. Ex. 1003, Fig. 2; Ex. 1002, ¶¶ 179-181.

With respect to claim 25, Westerkull'794 discloses that the threaded portion 110 has a conical outer portion 112 including at least three turns of tapered threads 121. Ex. 1003, Fig. 2, 5:62-64; Ex. 1002, ¶¶ 78, 182-183. To the extent Patent Owner may allege that the anchoring fixture 104 of Westerkull'794 lacks a circumferential groove having an inner diameter that exceeds an inner diameter of at least three turns of tapered threads, Choi makes up for this deficiency. Ex. 1002, ¶¶ 93, 110, 151, 183-184. Choi discloses a circumferential groove region with a

number of circumferential grooves (screwed grooves 290) which have an inner diameter that clearly exceeds the inner diameter of all the threads 295 of the fixture portion 220. Ex. 1005, Fig. 6; Ex. 1002, ¶¶ 93, 110, 151, 184. Therefore, a POSA would understand that having modified Westerkull'794, which shows at least three turns of a tapered thread in Fig. 2, to include a circumferential groove region as taught by Choi, the modified anchoring fixture would provide a circumferential groove that has an outer diameter that exceeds an inner diameter of at least three turns of the tapered thread. Ex. 1002, ¶¶ 183-186.

With respect to claim 28, as explained in section VI.(A.)(1.), Westerkull'794 teaches that the surface of the flange 114 facing the threaded portion 110 is in contact with the bone, but a thicker titanium oxide layer is applied on the surface of the threaded portion 110 to improve bonding to the bone. Ex. 1003, 4:66-5:30; Ex. 1002, ¶¶ 80, 81, 84, 187-189. As such, Westerkull'794 describes that a portion of a surface of the fixture (the surface of the threaded portion) has a modified increased surface roughness relative to another portion of the surface that contacts bone (the surface of the flange facing the threaded portion). Ex. 1002, ¶¶ 80, 81, 84, 188-190.

With respect to claim 33, Westerkull'794 discloses that a diameter of the anchoring fixture 104 is in the range of 3.5-5 mm. Ex. 1003, 1:63-66; Ex. 1002, ¶¶

89, 142, 193, 196, 198, 226. In addition, Westerkull'794 further teaches that thickness of the skull bone is usually between 3-5 mm, and the thickness determines the appropriate length of the fixture. Ex. 1003, 1:61-63; Ex. 1002, ¶¶ 77, 89, 142, 194-195, 199, 227-228. In addition, Westerkull'794 teaches that a design consideration is "to prevent the fixture from being pushed into the skull" (Ex. 1003, 5:66-67), thus indicating that the "appropriate length" of the fixture does not exceed the thickness of the skull bone. Ex. 1002, ¶¶ 80, 99, 142, 155, 195, 228. Therefore a POSA would understand that the maximum diameter of the threaded portion 110 of Westerkull'794 is between 3.5 and 5 mm, and a length from a bottom of the flange to a distal end of the fixture 104 is no greater than 5 mm, the threaded portion 110 and distal end being on the same side of the flange 114. Ex. 1002, ¶¶ 193-196, 227-229.

With respect to claim 34, because the diameter of the flange 114 in Westerkull'794 is clearly the part of the fixture 104 with the widest diameter (Ex. 1003, Figs. 2 and 4; Ex. 1002, ¶ 197-198), and the diameter of the fixture is between 3-5 mm (Ex. 1003, 1:63-66; Ex. 1002, ¶¶ 89, 142, 193, 196, 198, 226), a POSA would understand that the flange 114 in Westerkull'794 has a diameter up to 5 mm. Ex. 1002, ¶¶ 89, 142, 193, 196, 198-199, 226. Further, in Westerkull'794, the length from the bottom of the flange 114 to the distal end of the anchoring

fixture 104 is less than 5 mm, given that the length should not exceed the thickness of the skull which is between 3.5 and 5 mm. Ex. 1003, 1:61-63, 5:66-67; Ex. 1002, ¶¶ 89, 142, 195, 199. Thus, a POSA would understand that Westerkull'794 teaches that a maximum diameter of the flange 114 in Westerkull'794 is greater than the length from the bottom of the flange 114 to the distal end of the anchoring fixture 104. Ex. 1002, ¶¶ 198-201.

With respect to claim 35, under a proper construction of the "means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone" discussed above, the inner diameter of the minute screwed grooves 290 in Choi's circumferential groove region exceeds the inner diameter of the thread 295 of the lower fixture portion 220. Ex. 1005, Fig. 6, 7:7-10, 9:1-2, 9:24-25; Ex. 1002, ¶¶ 66-69, 203. As such, the obvious modification of Westerkull'794 of positioning a circumferential groove region between the flange and the threaded portion would provide a second portion of the fixture adjacent to the flange having an inner diameter that exceeds the inner diameter of the main threads of the first portion. Ex. 1002, ¶¶ 205-206.

Further, to the extent that Patent Owner argues that the "means" of claim 35 should be construed as a wider portion adjacent to the flange than at the distal end and equivalents, the diameter of the upper portion of Choi's circumferential groove

region is larger than the diameter of its lower portion and the diameter of the threaded fixture portion 220. Ex. 1005, 7:29-32, 8:60-67; Ex. 1002, ¶¶ 207-208. Therefore, a POSA would understand that having modified Westerkull'794 to include a circumferential groove region as taught by Choi, the modified anchor would provide an additional means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone. Ex. 1002, ¶¶ 202-212.

Moreover, Westerkull'794 itself discloses a flared region of the threaded portion 110 adjacent to the flange 114 that has a greater diameter than the inner diameter d_2 of the threaded portion 110. Ex. 1003, Fig. 2; Ex. 1002, ¶¶ 85, 210. As such, Westerkull'794 discloses a wider portion adjacent to the flange than at the distal end, which is capable of exerting a compression onto the skull bone. Ex. 1002, ¶¶ 210-211.

With respect to claim 38, to the extent that it can reasonably be alleged that the anchoring fixture 104 of Westerkull'794 lacks a circumferential groove between the flange 114 and all of the threads of the threaded portion 110, Choi makes up for this deficiency. Ex. 1002, ¶¶ 90, 109-110, 113, 150-154, 176-178, 213-217, 231-214. Choi discloses a circumferential groove region comprised of a number of circumferential grooves (screwed grooves 290) between an upper portion of the implant and all the threads 295 of a fixture portion 220. Ex. 1005,

Figs. 5-6, 7:29-32, 9:18-27; Ex. 1002, ¶¶ 90-93, 109-111, 150-152, 176, 184, 208, 232. Therefore, a POSA would understand that having modified Westerkull'794 to include a circumferential groove region as taught by Choi, the modified anchoring fixture would provide a circumferential groove between the flange and all the threads of the fixture. Ex. 1002, ¶¶ 113, 150-151, 154, 176-178, 215-217, 231-234.

With respect to claim 39, even if this claim is not interpreted as merely being an intended use limitation, the upper portion of Choi's circumferential groove region has a larger diameter than that of the lower portion thereof and that of the threaded fixture portion 220. Ex. 1005, 7:30-32, 8:60-66; Ex. 1002, ¶¶ 91, 93, 110, 151, 184, 205, 208, 222. Therefore, a POSA would understand that, having modified Westerkull'794 to incorporate a circumferential region as taught by Choi, on a threaded side of the anchor with respect to the flange, the modified anchor would certainly be configured to apply more radially compressive force on surrounding bone during implantation at a first location of the bone fixture below the flange relative to a second location of the bone fixture, wherein the second location is at a distal end of the bone fixture, the screw thread apparatus being on the same side of the flange as the distal end. Ex. 1002, ¶¶ 206, 209, 218-223.

Moreover, as explained in section VI(A.)(1.), in Westerkull'794, the junction of flange 114 and the threaded portion 110 has a larger diameter than the lowermost portion of the conical portion 112. Ex. 1003, Fig. 2; Ex. 1002, ¶¶ 85, 210, 219. Therefore, the anchor 104 in Westerkull'794 is capable of providing more radially compressive force on surrounding bone during implantation at the junction of the flange 114 and the threaded portion 110 of the anchor below the flange 114, compared to the lowermost portion of the conical portion 112 of the anchor 104. Ex. 1002, ¶¶ 211, 219-220.

With respect to claim 45, Westerkull'794 discloses that a diameter of the anchoring fixture 104 is in the range of 3.5-5 mm. Ex. 1003, 1:63-66; Ex. 1003, 1:63-66; Ex. 1002, ¶¶ 89, 142, 193, 196, 198, 225-226. In addition, Westerkull'794 further teaches that thickness of the skull bone is usually between 3-5 mm and the thickness determines the appropriate length of the fixture. Ex. 1003, 1:61-63; Ex. 1002, ¶¶ 77, 89, 142, 194-195, 199, 227-228. In addition, Westerkull'794 teaches that a design consideration is "to prevent the fixture from being pushed into the skull" (Ex. 1003, 5:66-67), thus indicating that the "appropriate length" of the fixture does not exceed the thickness of the skull bone. Ex. 1002, ¶¶ 80, 99, 142, 155, 195, 228. Therefore a POSA would understand that the maximum diameter of the threaded portion 110 of Westerkull'794 is between 3.5 and 5 mm, and a length

from a bottom of the flange to a distal end of the fixture 104 is no greater than 5 mm, the threaded portion 110 and distal end being on the same side of the flange 114. Ex. 1002, ¶¶ 194-196, 224, 226-229.

With respect to claim 46, to the extent that it can reasonably be alleged that Westerkull'794 lacks a circumferential groove from which the threaded portion 110 extends to a distal end of the anchoring fixture 104, Choi makes up for this deficiency. Ex. 1002, ¶¶ 231-234. Choi discloses a circumferential groove region including a number of circumferential grooves (screwed grooves 290) formed between an upper portion of the implant and a threaded fixture portion 220. Ex. 1005, Figs. 5-6, 7:9-11, 9:1-2; Ex. 1002, ¶¶ 90-93, 109-111, 150-152, 176, 184, 208, 232. Choi further shows the threads 295 of the fixture portion 220 extending from the circumferential groove region to the distal end of the implant. Ex. 1005, Figs. 5-6; Ex. 1002, ¶¶ 90, 176, 215, 232. Therefore, a POSA would understand that having modified Westerkull'794 to include a circumferential groove region as taught by Choi, the threaded portion of the modified anchoring fixture would extend from a circumferential groove to a distal end of the fixture. Ex. 1002, ¶¶ 231-234.

VII. GROUND 2: CLAIM 17 IS UNPATENTABLE UNDER PRE-AIA 35 U.S.C. § 103(A) AS BEING OBVIOUS OVER WESTERKULL'794 (EX. 1003) IN VIEW OF CHOI (EX. 1005) AND HÅKANSSON (EX. 1006).

A. Westerkull'794, Choi, and Håkansson teach all claim features of Claim 17

Claim 17 depends directly from independent claim 1. Claim 17 recites "The anchoring fixture of claim 1, wherein[] a cross-section of the fixture lying on and parallel to a longitudinal axis of the anchoring fixture has, on one side, with respect to location from a proximal end to a distal end of the fixture, starting at a location of maximum screw thread radius on the one side, six turns inclusive of the turn having the maximum screw thread radius."

The obvious combination of Westerkull'794 and Choi satisfies all features of claim 1. Ex. 1002, ¶¶ 95-118. Further, as shown in Fig. 2 (reproduced below), Westerkull'794 discloses an anchoring fixture with a cross-section of the fixture lying on and parallel to a longitudinal axis of the anchoring fixture having, on one side, with respect to a location from a proximal end to a distal end of the fixture, starting at a location of maximum screw thread radius (i.e., underneath the relieving portion 122), multiple turns inclusive of the turn having the maximum screw thread radius (d1). *Id.* at ¶¶ 77-78, 97, 141, 235-238.

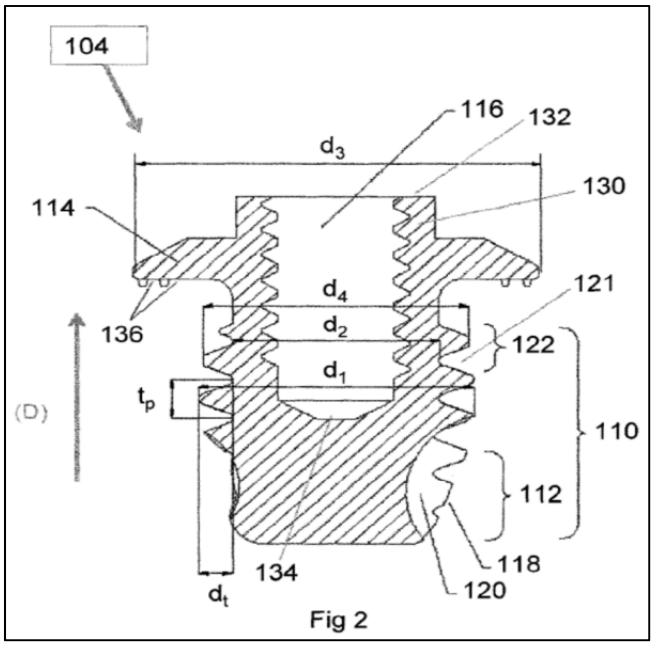


Fig 2

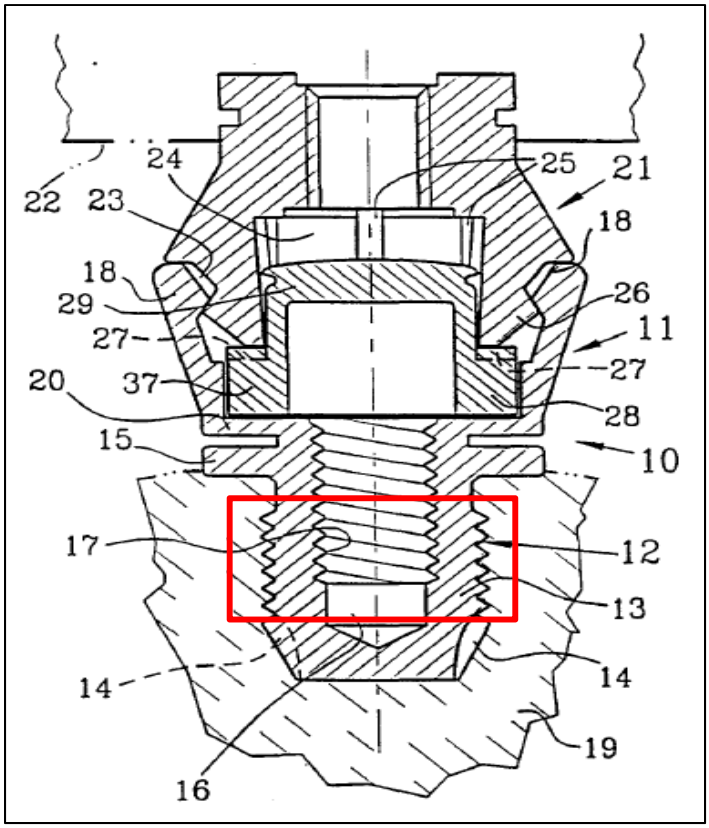
Patent Owner may argue, however, that the Westerkull'794-Choi combination discloses a cross-section of the fixture having less than six turns starting at a location of maximum screw thread radius, and thus not satisfy the additional limitations of dependent claim 17. As detailed below, an obvious modification of the Westerkull'794-Choi combination, in view of Håkansson, satisfies all the claim features of claim 17. *Id.* at ¶¶ 237, 239-45.

1. Teachings of Håkansson (Ex. 1006)

Håkansson relates to a "skull bone anchored implants for transfer of signals from a hearing aid connected to the implant." Ex. 1006, 1; Ex. 1002, ¶ 240. An objective of Håkansson is to create such an implant, which further has "the ability

to take up a certain external force without the implant coming loose." Ex. 1006, 2; Ex. 1002, ¶ 240.

Håkansson discloses an implant 10 including a flange fixture 12 consisting of a screw 13 and a flange 15. Ex. 1006, Fig. 1; 3; Ex. 1002, ¶ 241. Håkansson describes that the screw 13 is intended to be screwed into a bore in the bone tissue 19, e.g., skull bone, with the screw being tightened so deeply that the flange 15 will rest against the bone tissue. Ex. 1006, 4; Ex. 1002, ¶ 241. As shown in Fig. 1, reproduced below (with red highlighting added), the screw 13 includes a screw thread parallel to a longitudinal axis of the fixture 12 having six turns (as highlighted), starting at the location of maximum screw thread radius. Ex. 1006, Fig. 1; Ex. 1002, ¶ 241.



B. *KSR* Rationale to Combine

To the extent not disclosed by Westerkull'794 and Choi, a POSA would have found it obvious to modify the anchoring fixture of the Westerkull'794-Choi combination (Section VI. above) to include, in a cross-section of the fixture lying on and parallel to a longitudinal axis of the fixture, on one side, with respect to a location from a proximal end to a distal end of the fixture, starting at a location of maximum screw radius on the one side, six turns inclusive of the turn having the maximum screw thread radius, as recited in claim 17 of the '807 Patent. Ex. 1002, ¶¶ 239-245.

To the extent Patent Owner may argue that the cross-section of the fixture in the Westerkull'794-Choi combination does not include, on one side, six turns starting at the location of the maximum screw thread radius, Håkansson teaches this feature. Ex. 1006, Fig. 1; Ex. 1002, ¶¶ 241, 242.

Westerkull'794 recognizes a problem with anchoring fixtures is that "the lack of optimized key design parameters may lead to the need for patients coming in for surgical procedures, which could have been avoided if the fixture design would have been more favorable from a biomechanical and biological point of view." Ex. 1003, 2:56-61. Ex. 1002, ¶ 243. Further, Håkansson describes an objective of its implant is to have the "ability to take up a certain external force without the implant coming loose," i.e., to improve stability. Ex. 1006, 2; Ex. 1002, ¶ 240. A POSA would understand that stability is a biomechanical aspect. Ex. 1002, ¶ 244. To a POSA, the number of screw threads is a result-effective variable that is a factor in determining the stability of the fixture. *Id.* A POSA would have therefore found it obvious to modify the anchoring fixture of the Westerkull'794-Choi combination (Section VI. above) to include six turns of screw threads in the threaded portion underneath the relieving portion 122. *Id.* at ¶¶ 239-245. Through routine optimization, providing six screw turns would have been an obvious variation of the Westerkull'794-Choi combination for a POSA to try. *Id.*

at ¶ 245. This modification would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, to yield predictable results. *Id.* Thus, a POSA would found it obvious to modify the Westerkull'794-Choi combination to have six screw turns on one side of a cross-section of the fixture, starting at the location of maximum screw thread radius and inclusive of turn having maximum screw thread radius. *Id.* at ¶¶ 239-245.

A POSA would have had a reasonable expectation of success in configuring the anchoring fixture of Westerkull'794-Choi in view of Håkansson. *Id.* at ¶ 245.

VIII. GROUND 3: CLAIMS 37 AND 47 ARE UNPATENTABLE UNDER PRE-AIA 35 U.S.C. § 103(A) AS BEING OBVIOUS OVER WESTERKULL'794 (EX. 1003) IN VIEW OF CHOI (EX. 1005) AND WESTERKULL'222 (EX. 1007).

A. Westerkull'794, Choi, and Westerkull'222 teach all claim features of Claims 37 and 47

Claim 37 depends from claim 1. Claim 37 recites, "The anchoring fixture of claim 1, wherein[] the flange has a maximum diameter that exceeds a peak diameter of the thread by approximately 10-20%."

Claim 47 depends from claim 8. Claim 47 recites "The bone fixture of claim 8, wherein[] the flange has a maximum diameter that exceeds a peak diameter of a thread of the threaded taper portion by approximately 10-20%."

The obvious combination of Westerkull'794 and Choi discloses all features of claims 1 and 8. Ex. 1002, ¶¶ 95-118, 138-157. To the extent Patent Owner may argue that this combination does not satisfy the additional features recited in dependent claims 37 and 47, Westerkull'222 discloses these features. *Id.* at ¶¶ 250-252.

1. Teachings of Westerkull'222 (Ex. 1007)

Westerkull'222 "relates to a screw-shaped anchoring element (fixture) for permanent anchorage of hearing aid devices or extraoral prostheses in the form of ear and orbital prostheses in the skull bone." Ex. 1007, 1:6-9; Ex. 1002, ¶ 250. Figure 3 of Westerkull'222 (reproduced below) shows a side view of one embodiment of the invention. Ex. 1007, 2:30-31; Ex. 1002, ¶ 251. According to Westerkull'222, the fixture includes a main body 8 comprising external threads, which is intended to be installed in the skull bone. Ex. 1007, Fig. 3, 2:40-42, 3:36-38; Ex. 1002, ¶ 251. Westerkull'222 teaches that the main body 8 in Figure 3 is slightly tapered. Ex. 1007, 3:26-29; Ex. 1002, ¶ 251. Also, the fixture in Westerkull'222 includes a flange 7 to function as a stop when the fixture is installed in the skull bone. Ex. 1007, 2:40-44; Ex. 1002, ¶ 252. Westerkull'222 discloses that "[t]he flange has a diameter which exceeds the peak diameter of the threads [of the main body 8] with 10-20%." Ex. 1007, 3:12-14; Ex. 1002, ¶ 252.

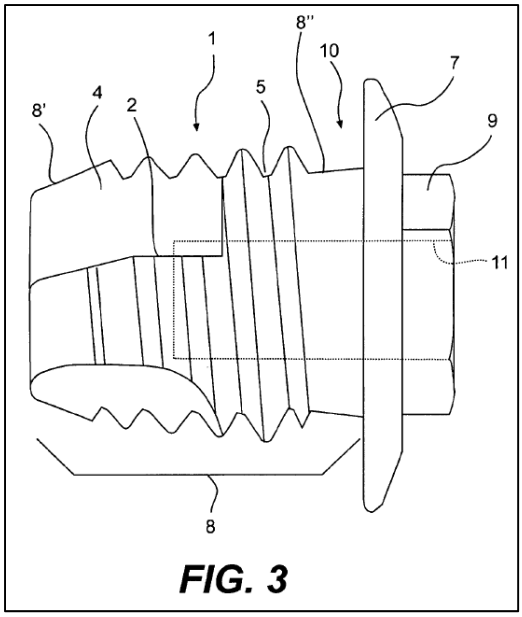


FIG. 3

B. *KSR* Rationale to Combine

To the extent not disclosed in Westerkull'794 and Choi, a POSA would have found it obvious to modify the anchoring fixture of the Westerkull'794-Choi combination (Section VI. above) so that the flange has a maximum diameter that exceeds a peak diameter of a thread of the threaded taper portion by approximately 10-20%, as recited in claims 37 and 47. Ex. 1002, ¶¶ 246-253.

Westerkull'222 describes that its flange 7 "has a diameter which exceeds the peak diameter of the threads with 10-20%." Ex. 1007, 3:12-14; Ex. 1002, ¶ 252. Westerkull'222 teaches that such a flange 7 is sufficient "to provide a stop for the anchoring element when the anchoring element is screwed down into the comparatively thin skull bone." Ex. 1007, Abstract; Ex. 1002, ¶ 252. As explained by Dr. Hayes, a POSA would have recognized that it is desirable to design the

flange with sufficient diameter to function as a stop for the anchoring fixture. Ex. 1002, ¶ 253. Thus, it would have been obvious to a POSA to modify the anchoring fixture of the Westerkull'794-Choi so that the flange has a diameter exceeding the peak diameter of the screw thread by approximately 10-20%, as taught in Westerkull'222. *Id.* at ¶¶ 246-53. Doing so would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, to attain predictable results. *Id.* at ¶ 253. A POSA would have had a reasonable expectation of success in configuring the anchoring fixture of Westerkull'794-Choi in view of Westerkull'222. *Id.* at ¶ 253.

IX. GROUND 4: CLAIMS 28, 40, AND 41 IS UNPATENTABLE UNDER PRE-AIA 35 U.S.C. § 103(A) AS BEING OBVIOUS OVER WESTERKULL'794 (EX. 1003) IN VIEW OF CHOI (EX. 1005) AND BRÅNEMARK (EX. 1008).

A. Westerkull'794, Choi, and Brånemark teach all claim features of Claims 28, 40 and 41

Claims 28 and 40 depend from claim 1. Claim 28 recites "The anchoring fixture of claim 1, wherein[] a portion of a surface of the fixture that contacts bone has a modified increased surface roughness relative to another portion of the surface of the fixture that contacts bone." Claim 40 recites "The anchoring fixture of claim 1, wherein[] a surface of a first portion of the bone fixture below the

flange has a surface roughness that is greater than that of a second portion, the second portion including the circumferential groove."

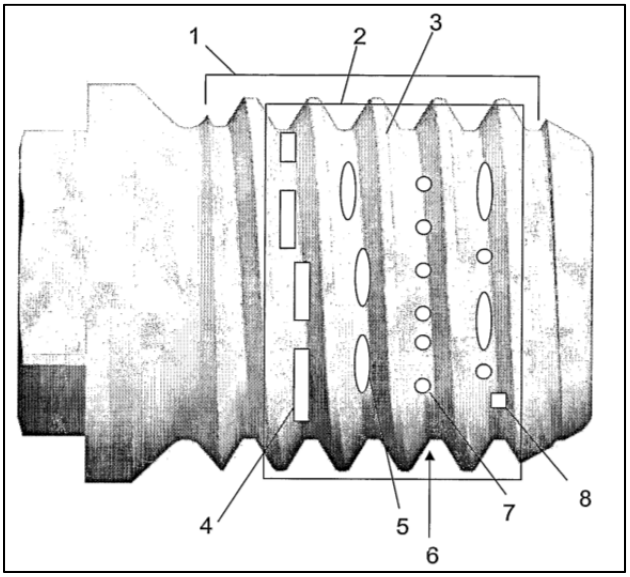
Claim 41 depends on claim 8. Claim 41 recites "The bone fixture of claim 8, wherein[] a surface of a first portion of the bone fixture below the flange is a modified surface that increases surface roughness, the first portion being separate from a second portion that includes the circumferential groove, wherein the roughness of the first portion is greater than that of the second portion."

The obvious combination of Westerkull'794 and Choi discloses all claim features in claims 1 and 8. Ex. 1002, ¶¶ 95-118, 138-157. However, to the extent Patent Owner may argue that this combination does not satisfy additional features recited in dependent claims 28, 40 and/or 41, Brånemark discloses these features. *Id.* at ¶¶ 254-262.

1. <u>Teachings of Brånemark (Ex. 1008)</u>

Brånemark relates to implants "comprising means for attachment to living biological tissue of a human being." Ex. 1008, 1:3-4; Ex. 1002, ¶ 259. As shown in Fig. 1 (reproduced below), Brånemark describes a threaded skull implant with a single threaded section of constant pitch. Ex. 1008, Fig. 1, 8:18-21, 9:11-12; Ex. 1002, ¶ 259.

Brånemark also discloses the use of surface roughening to enhance interaction with biological tissue. Ex. 1008, 6:14-19, 6:23-32; Ex. 1002, ¶¶ 260-262. Brånemark teaches that the biocompatibility and the stability of an anchor can be improved by adding deposits of hydroxyapatite to delimited areas of the anchor that are in direct contact with the bone. Ex. 1008, 7:10-16, 8:29-9:1; Ex. 1002, ¶¶ 261. Brånemark further discloses that titanium and hydroxyapatite "have different properties with regard to" biocompatibility. Ex. 1008, 8:26-29; Ex. 1002, ¶ 262. A POSA would understand that hydroxyapatite would have a modified increased surface roughness relative to titanium. Ex. 1002, ¶ 262.



B. *KSR* Rationale to Combine

A POSA would have found it obvious to modify the anchoring fixture of the Westerkull'794-Choi combination (Section VI. above) by adding hydroxyapatite to

certain areas of the anchoring fixture that are in direct contact with the bone, as disclosed by Brånemark. Ex. 1008, 7:10-16, 8:29-9:1; Ex. 1002, ¶¶ 246-253. Such modification would increase the surface roughness of the portions to which the hydroxyapatite is added, relative to the other portions. Ex. 1002, ¶¶ 261-262. Westerkull'794 expressly contemplates such a modification could be advantageous, stating that "The titanium oxide on the fixture surface may well include or be covered by other chemical or biological surface to even further improve the osseointegration." Ex. 1003, 5:15-18; Ex. 1002, ¶ 263. Therefore, the aforementioned modification to the Westerkull'794-Choi combination would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, to attain predictable results. Ex. 1002, ¶ 264.

A POSA would have recognized Brånemark as just one example of a well-known feature - the use of two different materials on the outer surface of the implant. *Id.* at ¶ 263. Further, a known advantage of adding hydroxyapatite to the bone anchoring fixture includes improving biocompatibility of the anchoring fixture. Ex. 1008, 7:10-16; Ex. 1002, ¶¶ 261-263.

A POSA would have had a reasonable expectation of success in configuring the anchoring fixture of Westerkull'794-Choi in view of Brånemark. Ex. 1002, ¶ 264.

X. CONCLUSION

Petitioner has demonstrated a reasonable likelihood that Petitioner will prevail in demonstrating that the challenged are unpatentable as being obvious over the art discussed above. 35 U.S.C. § 314(a). Petitioner requests that the PTAB institute an *inter partes* review proceeding and cancel the challenged claims.

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Respectfully submitted,

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Appendix – List of Exhibits

APPENDIX – LIST OF EXHIBITS

Ex. No.	Description
1001	U.S. Patent No. 9,838,807 (L. Jinton et al.)
1002	Expert Declaration by Dr. Wilson Hayes
1003	U.S. Patent No. 7,116,794 (P. Westerkull)
1004	U.S. 2006/0093175 (P. Westerkull)
1005	U.S. Patent No. 6,981,873 (Y. Choi et al.)
1006	WO 98/55049 (B. Håkansson)
1007	U.S. Patent No. 7,074,222 (P. Westerkull)
1008	WO 2006/065205 (R. Brånemark et al.)
1009	Prosecution history of U.S. Patent No. 9,838,807
1010	Prosecution history of U.S. Patent No. 9,173,042
1011	WO 2004/105650 (D. Pitulia)
1012	Patent Owner's Preliminary Claim Construction
1013	Oticon Medical's Preliminary Claim Construction
1014	Webster's New International Dictionary Unabridged (2d ed.) (groove)
1015	Webster's New World Dictionary Third College Edition (groove)
1016	Webster's New International Dictionary Unabridged (2d ed.) (screw thread)
1017	Webster's New World Dictionary Third College Edition (screw)
1018	Webster's New World Dictionary Third College Edition (screw thread)
1019	Webster's New World Dictionary Third College Edition (thread)
1020	Webster's New International Dictionary Unabridged (2d ed.) (flange)
1021	Webster's New World Dictionary Third College Edition (flange)
1022	E.M. Lillie et al., "Evaluation of Skull Cortical Thickness Changes With Age and Sex From Computed Tomography Scans," *Journal of Bone and Mineral Research*, Vol. 31(2), pp. 299-307 (February 2016)
1023	J.J. Wazen et al., "Long-Term Results With the Titanium Bone-Anchored Hearing Aid: The U.S. Experience," *The American Journal of Otology*, Vol. 19, pp. 737-741 (1998)
1024	M. Chasin et al., "Current Trends in Implantable Hearing Aids," *Trends in Amplification*, Vol. 2, No. 3, pp. 84-107 (1997)
1025	A. Tjellström et al., "Osseointegrated Titanium Implants in the Temporal Bone," *The American Journal of Otology*, Vol. 2, No. 4, pp. 304-310 (1998)

Ex. No.	Description
1026	L. Rasmusson et al., "Effects of Implant Design and Surface on Bone Regeneration and Implant Stability: An Experimental Study in the Dog Mandible," *Clinical Implant Dentistry and Related Research*, Vol. 3, No. 1, pp.2-8 (2001)

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), Petitioner hereby certifies, in reliance on the word count of the word-processing system (Microsoft Office Word 2010) used to prepare this Petition, that the number of words in this paper is 13,979, which is 14,000 words or less as required by 37 C.F.R. § 42.24(a)(1)(i). This word count excludes the table of contents, table of authorities, certificate of word count, certificate of service, and exhibit list.

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing IPR Petition and all Exhibits listed in the Appendix of the IPR Petition were served on April 15, 2019, via Federal Express to the correspondence address for the '807 Patent as follows:

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