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Paper 52
Date: October 14, 2020

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.

IPR2019-00975
Patent 9,838,807 B2

Before BARRY A. GROSSMAN, JAMES A. WORTH, and MICHAEL L. WOODS, *Administrative Patent Judges.*

WORTH, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision addressing an *inter partes* review challenging claims 1–12, 14, 16, 17, 25, 28, 33–35, 37–41, and 45–47 (the "challenged claims") of U.S. Patent No. 9,838,807 B2 (Ex. 1001, "the '807 patent"). We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has failed to demonstrate by a preponderance of the evidence that any of the challenged claims are unpatentable.

A. Procedural History

On April 15, 2019, Oticon Medical AB; Oticon Medical LLC; William Demant Holding A/S (collectively, "Oticon" or "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–12, 14, 16, 17, 25, 28, 33–35, 37–41, and 45–47 (the "challenged claims") of U.S. Patent No. 9,838,807 B2 (Ex. 1001, "the '807 patent"). On July 20, 2019, Cochlear Ltd. ("Cochlear" or "Patent Owner") filed a Preliminary Response (Paper 13, "Prelim. Resp.").

On October 16, 2019, we instituted an *inter partes* review of claims 1–12, 14, 16, 17, 25, 28, 33–35, 37–41, and 45–47 of the '807 patent. Paper 15 ("Dec. Inst."), 39.

Patent Owner filed a Response to the Petition. Paper 27 ("PO Resp.").[1] Petitioner filed a Reply. Paper 34 ("Pet. Reply"). Patent Owner filed a Surreply (Paper 42, "PO Surreply").[2]

Patent Owner also filed a Motion to Exclude certain evidence (Paper 43), to which Petitioner filed an Opposition (Paper 46).

An oral hearing was held on July 21, 2020, a transcript of which has been entered in the record. Paper 48 ("Tr.").

On September 17, 2020, we issued an Order (Paper 49) inviting supplemental briefing on claim construction, and in particular, on the construction of the preambles and "wherein" clauses of independent claims 1 and 8. *Id.* at 3.

On September 25, 2020, Petitioner filed a supplemental brief on claim construction. Paper 50 ("Pet. Supp. Br."). Also on September 25, 2020, Patent Owner filed a supplemental brief on claim construction. Paper 51 ("PO Supp. Br.").

B. Real Parties in Interest

Petitioner identifies Oticon Medical AB, Oticon Medical LLC, and William Demant Holding A/S as the real parties-in-interest. *See* Pet. 1. Patent Owner indicates that Cochlear Ltd. is the real party-in-interest. Paper 4, 2.

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[1] Pursuant to the protective order for this proceeding (*see* Paper 19, Appendix A; Paper 20, 3), Patent Owner filed unredacted and redacted versions of its Patent Owner Response (respectively, Papers 25 and 27). Unless otherwise indicated, this Decision refers to the pagination in the redacted version.

[2] Patent Owner filed unredacted and redacted versions of its Surreply (respectively, Papers 40 and 42). Unless otherwise indicated, this Decision refers to the pagination in the redacted version.

C. Related Matters

The parties note as related litigation in federal district court, *Cochlear Ltd. v. Oticon Medical AB et al.*, No. 3:18-cv-06684 (D.N.J., filed April 13, 2018). *See* Pet. 1; Paper 6, 2.

D. The '807 Patent (Ex. 1001)

The '807 patent is titled "Bone Anchor Fixture for a Medical Prosthesis" and relates to "hearing devices and, more particularly, to anchoring elements for bone anchored hearing devices." Ex. 1001, code (54), 1:19–20. The '807 patent discloses a need in the art for more effective osseointegration between an implant screw and the skull bone, to implant in patients having impaired bone quality and to allow loading of an implant at an earlier stage. *Id.* at 1:62–67.

In one embodiment, the '807 patent discloses a tapered anchoring fixture with an apical portion, a first threaded portion, and a second threaded portion, where the second threaded portion has an inner diameter greater than that of the first threaded portion. *Id.* at 2:16–28. The Specification discloses that "[t]his configuration provides compression in the radial direction on the skull bone to improve the initial stability of the anchoring fixture." *Id.* at 2:13–15.

In another embodiment, the '807 patent discloses a flange adjacent the second threaded portion, where the flange comprises a planar bottom portion adapted to rest on top of the skull when the fixture is implanted. *Id.* at 2:24–27. The '807 patent discloses that a person installing the fixture may drill a hole into the skull bone, where the hole has a diameter greater than the inner diameter of the first portion and less than the outer diameter of the second portion. *Id.* at 2:36–43.

Figure 2 of the '807 patent is reproduced below:

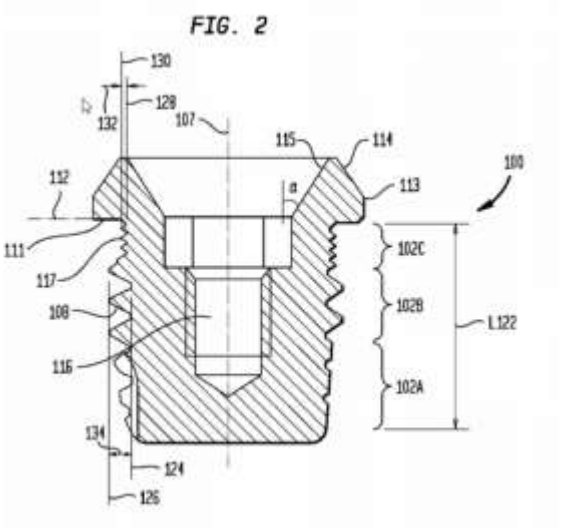


Figure 2 is a cross sectional view of one embodiment of the anchoring fixture. *See* Ex. 1001, 2:49–56. As shown in Figure 2, main body 102 comprises a distal tapered apical portion 102A and a straight, generally cylindrical body comprising two portions, a first portion 102B and a second portion 102C. *Id.* at 3:60–63.

E. Illustrative Claim

Claims 1 and 8 are the independent claims challenged in the Petition. Claim 1, reproduced below, is illustrative of the subject matter:

> 1. An anchoring fixture for anchoring a prosthesis to a skull bone comprising:
>
> a screw thread apparatus including a screw thread having a varying outer diameter;
>
> 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.

Ex. 1001, 5:56–6:3.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–12, 14, 16, 17, 25, 28, 33–35, 37–41, and 45–47 would have been unpatentable on the following grounds (Pet. 6):

Claim(s) Challenged	35 U.S.C. §	Reference/Basis
1–12, 14, 16, 25, 28, 33–35, 38, 39, 45, 46	§ 103	Westerkull '794[3], Choi[4]
17	§ 103	Westerkull '794, Choi, Håkansson[5]
37, 47	§ 103	Westerkull '794, Choi, Westerkull '222[6]
28, 40, 41	§ 103	Westerkull '794, Choi, Brånemark[7]

II. ANALYSIS

A. Legal Standards

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for

[3] US 7,116,794 B2, iss. Oct. 3, 2006 (Ex. 1003, "Westerkull '794").
[4] US 6,981,873 B2, iss. Jan. 3, 2006 (Ex. 1005, "Choi").
[5] WO 98/55049, pub. Dec. 10, 1998 (Ex. 1006, "Håkansson").
[6] US 7,074,222 B2, iss. July 11, 2006 (Ex. 1007, "Westerkull '222").
[7] WO 2006/065205 A1, pub. June 22, 2006 (Ex. 1008, "Brånemark").

another known in the field, the combination must do more than yield a predictable result." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 50–51 (1966)). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

Petitioner argues that a person of ordinary skill in the art 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, where additional education might substitute for some of the experience or substantial experience might substitute for some of the educational background. *See* Pet. 17 (citing Ex. 1002 ¶ 35).

Patent Owner argues that the subjects of audiology and otolaryngology are insufficient to give one the ordinary skills for the field of art of the '807 patent (citing Ex. 2037 ¶ 55), and that a person of ordinary skill would have included a person with a mechanical engineering degree and some experience with surgical procedures (citing *id.* ¶ 54). PO Resp. 14–15.

At the oral hearing, Petitioner acknowledged that the differences between the parties' assertions regarding the level of skill in the art would not be dispositive. Tr. 25:12–26:11. In view of the lack of material dispute on this issue, we adopt Patent Owner's asserted level of skill, which we find to be supported by the testimony of Dr. Rentschler. *See* Ex. 2037 ¶¶ 54–55;

see also Tr. 26:10–11 (Counsel for Petitioner: "We agree that the issues really here are highly mechanical.").

C. Claim Construction

We construe each claim "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." *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,340, 51,358 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

Petitioner requests construction of the following claim phrases and refrains from construing others: the preamble (claim 1); "circumferential groove" (claims 1 and 8); "means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone" (claim 35); "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" (claim 1); "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" (claim 8). Pet. 19–25. In its Response, Patent Owner requested construction of the following claim phrases: "a flange

configured to function as a stop . . . adapted to rest on top of bone" (claims 1 and 8); "circumferential groove" (claims 1 and 8); "means for exerting a compression onto the skull bone in a radial direction to stabilize the fixture in the skull bone" (claim 35). PO Resp. 15–17. In its Supplemental Briefing, Patent Owner also asserted constructions of the preambles and the "wherein" clauses of the independent claims. PO Supp. Br. 1–5.

For purposes of this Decision, we construe the preambles, "circumferential groove," and the "wherein" clauses of claims 1 and 8, as follows.

1. *the preamble: "for anchoring a prosthesis to a skull bone" (claim 1)*

Petitioner argues that the claim phrase "for anchoring a prosthesis to a skull bone" is a statement of intended use. Pet. 19.

In the Decision on Institution, we set forth the preliminary construction of "for anchoring a prosthesis to a skull bone" to describe an intended use of the device, i.e., to anchor a prosthesis. Dec. Inst. 6.

In its supplemental brief, Petitioner argues that "Patent Owner's repeated failure to take any position regarding the preamble and 'wherein' clauses of independent claims 1 and 8 constituted a clear waiver on this issue." Pet. Supp. Br. 2 (citing *Unified Patents Inc. v. Nonend Inventions N.V.*, IPR2016-00174, Paper 28 at 3 (PTAB July 25, 2017) ("any argument for patentability not raised in the response will be deemed waived.")).

We make the following observations regarding Petitioner's waiver argument. First, the Board has an established practice of *sua sponte* inviting briefing on claim construction, including after the oral hearing, where a Board panel determines that it is necessary to clarify the claim construction. *See, e.g.*, *Next Caller Inc. v. TRUSTID, Inc.*, IPR2019-00039, Paper 62 (Nov. 22, 2019); *Apple Inc. v. Corephotonics Ltd.*, IPR2018-01140 (Oct. 29,

2019); *Samsung v. M & K Holdings*, IPR2018-00697 & -698, Paper 50 (June 12, 2019). Second, although we agree that Patent Owner would otherwise have waived arguments on this issue based on the Scheduling Order, which requires Patent Owner to make arguments in its Patent Owner Response (*see* Paper 16, 7), we determine that it is in the interest of justice for the Board to receive briefing on this issue based on its *sua sponte* request (Paper 49, 3), in order to clarify the proper claim construction before making a determination on the merits of patentability. Third, although Patent Owner may have waived the ability to contest specific proposed findings of fact made by Petitioner (*see* 37 C.F.R. § 42.23(a)), claim construction is ultimately a question of law based on underlying factual findings and § 42.23(a) does not mandate that we reach any particular conclusion on claim construction in this case or that we limit our factual findings to any proposed factual findings in the petition. *See Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–327 (2015) (claim construction is a question of law which may involve subsidiary findings of fact).

Nor does this issue fall into a category in which a tribunal would be prohibited from soliciting briefing *sua sponte*. For example, we are not seeking to waive a statutory requirement. *Cf. Baxter Intern., Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1334 (Fed. Cir. 1998) (statutory requirements may not be waived). Further, claim construction is not an affirmative defense that must be raised by a patent owner. *See* 37 C.F.R. § 42.120 (Patent owner response); c*f.* Fed. R. Civ. P. 8(c)(1) (affirmative defenses); 35 U.S.C. § 282(b) (defenses involving the validity or infringement of a patent); *Pei-Herng Hor v. Ching-Wu Chu*, 699 F.3d 1331, 1337–1338 (Fed. Cir. 2012) (estoppel is an affirmative defense). Here, the Petitioner raised as an issue in the Petition the meaning of the preamble of claim 1 and the "wherein"

clauses of claims 1 and 8. Pet. 19–20, 24–25. However, for claim construction, the tribunal "has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties." *See Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

We are well-aware that for an adjudication, like the one at issue here, the Administrative Procedure Act ("APA") requires the Board to "timely inform[ ]" the parties of "the matters of fact and law asserted." 5 U.S.C. § 554(b)(3); *see Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015). Section 554(b)(3) has been applied to mean that "an agency may not change theories in midstream without giving respondents reasonable notice of the change" and "the opportunity to present argument under the new theory." *Belden Inc. v. Berk-Tek*, 805 F. 3d at 1080 (quoting *Rodale Press, Inc. v. FTC*, 407 F.2d 1252, 1256–57 (D.C. Cir.1968)). We have followed the APA requirements. We, and the parties, have been consistent throughout this proceeding in stating that the claims are construed based on their ordinary and customary meaning. We requested input from the parties for claim construction issues not addressed specifically by the parties after institution. Each party submitted its views, which we considered. We state expressly in this Decision our determination of the ordinary and customary meaning of disputed terms, necessary to this Decision, based on the parties' arguments and evidence.[8]

[8] Even if we had maintained our preliminary claim construction from institution, we observe that our conclusion as to lack of motivation to modify the device of Westerkull '794 with the teachings of Choi would be unchanged. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (reasonable expectation of success, but not motivation to combine, is limited by the scope of the claims).

We now turn to the issue of whether the preamble of claim 1 is limiting. Petitioner argues that the preamble recites an intended use because the body of claim 1 recites the structural limitations but the preamble does not. Pet. Supp. Br. 3. Petitioner also argues that the preamble recites an intended use because, in another case between the same parties involving a different claim relating to the same subject matter, the court concluded that the preamble recited an intended use. *Id.* at 3 (citing *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020)). Patent Owner argues that the preamble is limiting because the phrase "the bone" has its antecedent basis in the phrase "a skull bone" in the preamble. PO Supp. Br. 3 (citing *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008)). We determine, as a matter of reading the words of the claim, that the antecedent basis for "the bone" is "a skull bone" in the preamble of claim 1. *See* Ex. 1001, 5:56–57. Accordingly, we determine that the preamble is limiting. *See Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 436 F.3d 1366 (Fed. Cir. 2006) ("anode gel" was understood to be the antecedent basis for "said zinc anode").[9] In other words, it is a requirement that the prosthesis is structured so that it is appropriate for being anchored into the skull bone. *See Catalina*

[9] Patent Owner also argues that the cases relied on in the Petition to argue that the preamble is not limiting stand for the opposite proposition because, in those cases, the preambles were limiting because they introduced or defined terms later used in the claims. PO Supp. Br. 4 n.1 (citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305–06 (Fed. Cir. 1999); *Rowe v. Dror*, 112 F.3d 473, 478-79 (Fed. Cir. 1997)). We agree with Patent Owner that the statement of law in the Petition, i.e., that a preamble may recite an intended use when the body of the claim recites all structural elements (*see* Pet. 19), is not dispositive of this case because the body of the claim refers back to the preamble.

Marketing International, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) ("dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention.").

2. the preamble: "bone fixture configured to anchor to bone" (claim 8)

For similar reasons as for the preamble of claim 1, we determine that the preamble of claim 8 is limiting, i.e., because it provides antecedent basis for "the bone" in the body of the claim. However, the preamble of claim 8 only refers to "bone" and not to "a skull bone" and therefore does not itself impose a limitation of a "skull bone." *Compare* Ex. 1001, 6:22, *with id.* at 5:56–57.

3. "circumferential groove" (claims 1 and 8)

Petitioner argues that the claim phrase "circumferential groove" means "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." Pet. 20. Petitioner also asserts that a person of ordinary skill would understand that a circumferential groove is provided to "exert a compressive radial force on the skull bone to improve stability of the anchoring fixture." *Id.* (citing Ex. 1013, 3; Ex. 1002 ¶ 36).

The District Court construed "circumferential groove" to mean "a narrow channel extending around the cylindrical periphery of the main body of the implant." Ex. 3001, 33.[10]

[10] The District Court's Markman Order did not construe any of the other terms that we construe herein. *See* Ex. 3001.

In the Decision on Institution, consistent with the District Court, we set forth the preliminary construction of "circumferential groove" to mean "a narrow channel extending around the cylindrical periphery of the main body of the implant." Dec. Inst. 7. We also invited the parties to brief whether a periphery, would refer to the widest portion of the device that is inserted into the skull, i.e., below the flange, or rather to any outer portion. *Id.* at 7–8.

Patent Owner agrees with this construction. PO Resp. 16.

After considering all evidence and arguments anew, we determine that it is proper to maintain our construction of "for anchoring a prosthesis to a skull bone" to mean "a narrow channel extending around the cylindrical periphery of the main body of the implant" as consistent with the plain and ordinary meaning of the terms. This construction is also consistent with the usage in the Specification. *See* Ex. 1001, 3:9–15, 4:50–52, 4:63–5:2.[11]

In response to our question inviting further briefing, Petitioner submits that "periphery" refers to the widest portion of the fixture inserted into the skull and distinct from the flange. *See* Pet. Reply 2. Patent Owner does not comment on the question. *See* PO Resp. 15–17. For purposes of this Decision, we determine that it is not necessary to further construe the term "periphery." *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999) (claims are construed only to the extent necessary to resolve a dispute).

4. *"wherein the anchoring fixture is configured for anchoring a hearing prosthesis component to the skull bone at a location behind an external*

[11] Claim 1 recites both "a screw thread" and "a circumferential groove." *See* Ex. 1001, 5:57–65. We note, as relevant to our discussion of the prior art, that the parties are also in agreement that Choi's threads can be a groove. *See* Tr. 9:11–22, 32:9–15. Accordingly, there is agreement that a groove can be a type of thread, distinct from the other recited "screw thread."

ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea" (claim 1); "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" (claim 8) (collectively, the "wherein" clauses)

Petitioner argues that the "wherein" clauses are statements of intended use. *See* Pet. 24–25.

In the Decision on Institution, we set forth the preliminary construction that the "wherein" clauses describe an intended use of the implant fixture, i.e., to anchor a hearing aid prosthesis in a particular place. Dec. Inst. 9.

In its supplemental briefing, Petitioner concedes that the Specification of the '807 patent states that "the length of main body 102 may therefore depend on the thickness of the skull bone at the implantation site" (citing Ex. 1001, 3:57–59), but argues that this would not be a proper basis to read structural requirements into the "wherein" clauses as this is merely an embodiment. Pet. Supp. Br. 4–5 (citing *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)). Patent Owner argues that, as in the case of *Griffin v. Bertina*, the wherein clauses repeat an aspect of the invention stated in the preamble and therefore gives "life and meaning" to the claims. PO Supp. Br. 4–5 (citing 285 F.3d 1029, 1033 (Fed. Cir. 2002)). Patent Owner also argues that the "wherein" clauses are limiting because it was added by the Examiner, following an interview with the Examiner, to make the claim allowable. *Id.* at 5 (citing Ex. 1009, 28–29). We agree with Patent Owner that the "wherein" clauses repeat aspects of the preambles, which indicates that the "wherein" clause is limiting. We also determine that the location of the hearing aid implant, i.e., anchored into

the skull bone, is necessary to give life and meaning to the claims, i.e., "so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea." *See* Ex. 1001, 6:1–3, 6:35–37. Without the preambles and the wherein clauses, the claims would just be directed to a type of screw with certain types of threads and grooves and a flange. *See Griffin v. Bertina*, 285 F.3d at 1033 (aspect of invention was repeated in the body of the count in the wherein clause and was necessary to give life and meaning to the manipulative steps).

Patent Owner is also correct that the Notice of Allowability in the prosecution history refers to an Examiner's amendment, which includes the addition of the "wherein" clauses. *See* Ex. 1009, 28–29.[12] The reference to the Examiner's amendment in the Notice of Allowability indicates that allowance was based in part on the "wherein" clauses. The prosecution history is also consistent with the Summary section of the '807 patent, which describes four out of four embodiments therein as a fixture or a method for anchoring a prosthesis to a skull bone. *See Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358–62 (Fed. Cir. 2004) (preamble limiting where the preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history); *cf. Hoffer v. Microsoft*, 405 F.3d 1326 (Fed. Cir. 2005) ("whereby" clause held to be

[12] In our Decision on Institution, we also provided a preliminary construction for a limitation in dependent claim 35. Dec. Inst. 8. However, our analysis in this Final Decision for the dependent claims here is based on our conclusion that Petitioner has not met its burden for showing the unpatentability of the independent claims, and in particular has not shown that a person of ordinary skill would have combined the references as argued.

limiting where it was consistent with the summary of the invention and where there was a prosecution history disclaimer).

As Petitioner points out, another part of the Specification is also consistent with the understanding that the location of the anchoring device in the skull bone may limit the structure of the device, e.g., at least the length of the device. *See* Ex. 1001, 3:57–59.

For these reasons, we conclude that the "wherein" clauses are more than an intended use, and that the hearing aid implant of claims 1 and 8 must be structured such that it can appropriately be anchored in the skull bone. For both claims 1 and 8, this imposes a requirement of being anchored in the skull bone.

We do not reach the construction of any other claim terms. *See Vivid Techs., Inc.*, 200 F.3d at 803.

D. Obviousness of Claims 1–12, 14, 16, 25, 28, 33–35, 38, 39, 45, and 46 over Westerkull '794 (Ex. 1003) and Choi (Ex. 1005)

In its Petition, Petitioner sets forth its contentions as to how the limitations of claims 1–12, 14, 16, 25, 28, 33–35, 38, 39, 45, and 46 are disclosed in, or obvious over, the combination of Westerkull '794 and Choi. Pet. 26–62. Petitioner relies on the declaration of Wilson Hayes, Ph.D. Ex. 1002. Patent Owner opposes. PO Resp. 17–68. Patent Owner relies on the declaration of Mark E. Rentschler, Ph.D. Ex. 2037. We address these contentions below.

1. Overview of Westerkull '794

Westerkull '794 is titled "Hearing-Aid Anchoring Element" and "relates to an anchoring fixture for anchoring a direct bone-conduction hearing-aid to the skull bone." Ex. 1003, code (54), 1:5–7.

Westerkull ’794 describes problems with then-existing fixtures. In particular, the diameter of the drilled hole was close to the inner diameter of the thread, such that copious bone shivers were generated. *See id.* at 2:11–19. To accommodate the bone shivers, large shiver cavities were required. *Id.* at 2:19–21. However, it was difficult to have shiver spaces of sufficient depth without interfering with the inner hole of the fixture for the connection of the abutment connection screw. *Id.* at 2:17–25. In addition, the smooth machined titanium surface did not present optimal properties for osseointegration. *Id.* at 2:27–32.

Poor osseointegration led to clinical problems. Fixtures that lacked proper osseointegration at the beginning required additional procedures, and certain fixtures that osseointegrated became loose due to the mechanical load and also required additional procedures. *Id.* at 2:39–49.

As a solution to the above-identified problems in the art, Westerkull ’794 discloses a thread pitch in the range of 0.5 to 0.8 mm, which it states to be optimal for osseointegrated fixtures from a biomechanical point of view. *Id.* at 3:7–9. Westerkull ’794 further discloses a thread depth that is at least 10% and not greater than 20% of the maximum diameter of the thread fixture in order to improve grip in bone and also to improve removal forces if such forces are applied to screw out the fixture from the bone. *Id.* at 3:10–26.

Westerkull ’794 further discloses that the fixture has at least one cutting edge and each cutting edge has an adjacent cavity where bone shivers may be collected. *See id.* at 4:9–19. Westerkull ’794 discloses that the total volume of the cavities may be greater than 50% of the cut off bone volume when the fixture has been screwed into a hole in the bone where the

hole has a diameter that is 10% greater than the inner diameter of the thread in order to collect bone shivers. *Id.* at 4:32–38.

Westerkull '794 discloses a preferred embodiment with a titanium oxide layer with a thickness of at least 100 nm on the surface of the threaded portion in order to improve osseointegration. *Id.* at 4:66–5:5. Westerkull '794 discloses that the titanium oxide may include or be covered by other chemical or biological substances to further improve osseointegration. *Id.* at 5:15–18.

Westerkull '794 discloses a preferred embodiment with at least one groove extending at least one turn on the side of the flange facing the threaded portion, which acts as a microthread in contact with the bone to hinder bone resorption under the flange. *Id.* at 5:26–32.

Figure 2 of Westerkull '794 is reproduced below:

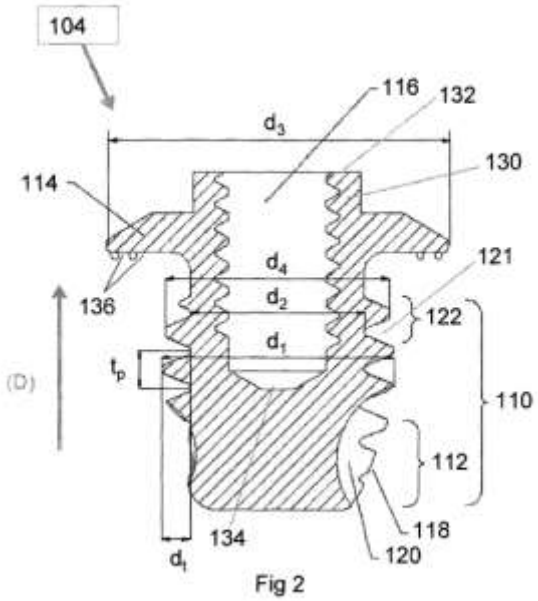


Fig 2

Figure 2 depicts a cross-sectional view of the fixture of Westerkull '794. *Id.* at 5:41–42.

Westerkull '794 discloses an overall diameter of 3.5–5 mm and thread pitch of 0.5–0.8mm. *Id.* at 1:65–2:2. Westerkull '794 also discloses that the appropriate length of the fixture is determined by the skull bone thickness that is between 3–5 mm. *Id.* at 1:61–63.

Westerkull '794 discloses that in a preferred embodiment there is a relieving portion at its distal end that "reduces the friction between the fixture and the bone at the distal part of the threaded portion and therefore contributes to a lower insertion torque when inserting the fixture in the bone." Ex. 1003, 4:53–65. Westerkull '794 discloses that the distal direction is represented by the arrow (D). *Id.* at 6:17–18. The relieving portion 122 has outer diameter d_4 that, preferably, is smaller than the maximum outer diameter d_1 of threaded portion 110. *Id.* at 6:18–20.

2. Overview of Choi

Choi is titled "Dental Implant and Head for a Compaction Drill" and relates particularly to a dental implant that can immediately brace artificial dental structures, and also can accomplish enhanced bonding between a bone tissue and the implant. Ex. 1005, code (54), 1:6–13. Choi also relates to a head for a compaction drill specially designed for the implant. *Id.* at 1:13–15.

Choi describes an aesthetic problem with dental implants that required only one surgery, i.e., there was a metal portion of the implant exposed above the gum line. *Id.* at 1:26–28. Choi also describes other problems in the art of dental implants, i.e., limited surface area and stress distribution around the screw. *Id.* at 3:38–40.

Figure 6 of Choi is depicted below:

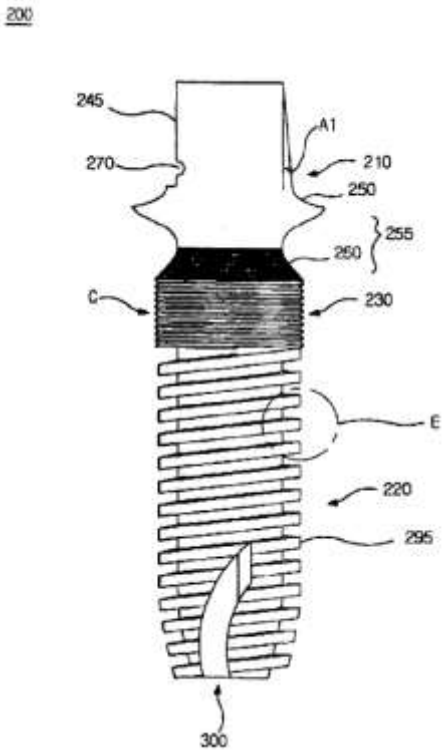


Figure 6 of Choi depicts an enlarged side view for illustrating a perspective view for showing a preferred embodiment of Choi's dental implant. *Id.* at 6:38–42.

Choi discloses a dental implant with fixture portion 220, settling portion 230, and abutment portion 210. *Id.* at 7:7–12. Figure 9 (not shown) is an enlarged side view of Figure 6. *Id.* at 6:48. In the embodiment of Figures 6 and 9, Choi discloses a number of minute screwed grooves 290 formed on the surface of the settling portion 230. *Id.* at 9:1–2. The screwed grooves 290 have the pitch (D_2) of about 0.15 to about 0.25 mm, preferably about 0.20 mm and the thread angle (A_3) of about 80 to about 120°. *Id.* at 9:3–5. The settling portion 230, like a wise crystal module, can disperse the stress on the implant 200 into the cortex-bone of the jawbone and minimize osteolysis so as to increase the bond with the bone. *Id.* at 9:5–8; *see also id.* at 9:8–16.

Choi discloses that in general its implant 200 has the length of about 18.0 mm and the diameter of about 4.0 mm when implant 200 is implanted in the jaw bone. *Id.* at 7:23–25. In this case, portion 210 has the length of about 6 mm, settling portion 230 has the length of about 2 mm and fixture portion 220 has the length of about 10 mm, respectively. *Id.* at 7:25–28. Also, the diameter of abutment portion 210 is about 5 mm, the diameter of the upper portion of settling portion 230 is about 4.2 mm, and the diameter of fixture portion 220 is about 4.0 mm, respectively. *Id.* at 7:29–32. Choi discloses that these sizes may vary. *Id.* at 7:32–35.

In one embodiment, Choi discloses that at least one thread on the fixture portion has a depth of about 300 to about 500 μm and a pitch of about 700 to about 900 μm. *Id.* at 5:5–7. By comparison, Choi discloses an embodiment with a pitch of 0.15 to 0.25 μm for screwed grooves on the settling portion. *See id.* at 4:67–5:3.

3. Analysis of Independent Claim 1

a) preamble: "An anchoring fixture for anchoring a prosthesis to a skull bone comprising"; "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"

Petitioner asserts, *inter alia*, that the preamble and the wherein clause are not entitled to patentable weight because they recite intended uses. *See* Pet. 19, 24–25. Patent Owner does not separately dispute that Westerkull '794 discloses these recitations. *See* PO Resp. 17–65.

Petitioner asserts that Westerkull '794 discloses an anchoring fixture 104 for anchoring a prosthesis to a skull bone. Pet. 47, 49 (citing Ex. 1003, Abstract, 1:5–7; Ex. 1002 ¶¶ 76, 95–96, 139–140). We determine that Westerkull '794 discloses these limitations. In particular, Westerkull '794

discloses an anchoring fixture for anchoring a direct bone-conduction hearing-aid to the skull bone. Ex. 1003, 1:5–7. Petitioner, relying on Dr. Hayes's Declaration, asserts that a person of ordinary skill in the art would understand that a "bone conduction hearing aid" would be anchored to the skull bone at a location behind the ear. Pet. 49 (citing Ex. 1003, 1:13–17; Ex. 1002 ¶ 117). Dr. Hayes points, *inter alia*, to Wazen[13], which depicts bone-anchored hearing aids in the post-auricular area. Ex. 1002 ¶ 117 (citing, e.g., Ex. 1023, Figs. 1a–1b). We determine that Wazen supports Dr. Hayes's opinion that a bone conduction hearing aid would have been positioned behind the ear. *See* Ex. 1023, Figs. 1a–1b (depicting placement) and captions thereto.

b) "a screw thread apparatus including a screw thread having a varying outer diameter"

Petitioner asserts that Westerkull '794 discloses anchoring fixture 104 that includes screw thread portion 110 with screw thread 121 having a varying outer diameter. Pet. 47 (citing Ex. 1003, Fig. 2, 5:60–61, 6:15–20; Ex. 1002 ¶¶ 77–78, 97–98, 141). Patent Owner does not separately dispute this limitation. *See* PO Resp. 17–65. We determine that Westerkull '794 discloses the limitation. In particular, Westerkull '794 discloses that threaded portion 110 has relieving portion 122 at the distal end and positioned below flange 114 but above outer end 112. Ex. 1003, 6:15–17. Westerkull '794 discloses relieving portion 122 has an outer diameter d_4 that, preferably, is smaller than the maximum outer diameter d_1 of threaded portion 110. *Id.* at 6:18–20.

[13] Jack J. Wazen et al., *Long-Term Results With the Titanium Bone-Anchored Hearing Aid: The U.S. Experience*, 19 THE AMERICAN JOURNAL OF OTOLOGY 737–741 (1998) (Ex. 1023, "Wazen").

c) "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"

Petitioner asserts that Westerkull '794 discloses that anchoring fixture also includes flange 114 configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when anchoring fixture 104 is implanted into the bone. Pet. 47–48 (citing 1003, 5:65–67, Fig. 2; Ex. 1002 ¶¶ 77, 80, 84, 99–100, 145–146).

Patent Owner argues, *inter alia*, that Petitioner's expert dismissed his previous reliance on Figure 1 of Westerkull '794 and argues that Westerkull '794 (in Figure 2) depicts micro thread 136[14] that would not cut into bone and would prevent flange 110 from resting on bone. *See* PO Resp. 66–68. Patent Owner argues that Dr. Rentschler's opinion that flange 110 would contact the skull depends in part on the curvature of the skull and does not take into account the rigidity of the skull. *Id.* at 68 (discussing Ex. 2037 ¶ 128). Petitioner replies that Westerkull '794's item 136 is a micro groove that would not prevent the flange from contacting the skull bone given the overall dimensions. Pet. Reply 19. We determine that even if micro thread 136 prevented direct contact between flange 110 and the skull bone, flange 110 would still be understood to "rest" on the skull bone because indirect contact would still satisfy the claim limitation. *See, e.g., Linear Technology Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049 (Fed. Cir. 2009) ("We agree with Linear that the Commission improperly narrowed this claim limitation

[14] Despite the similar nomenclature, we note that Choi's microthreads are different than Westerkull '794's micro threads inasmuch as Choi's microthreads are located on the shaft of the implant that is inserted into the jaw bone and Westerkull '794's micro threads 136 are located on the underside of Westerkull '794's flange (rather than on the shaft).

to exclude indirectly monitoring current through the measurement of voltage. The claim limitation does not state directly monitoring current."). The '807 patent discloses that "flange 103 prevents the fixture 100 from completely penetrating through the skull bone" (*see* Ex. 1001, 4:19–21). Westerkull '794's flange operates in a similar manner.

Accordingly, we determine that Westerkull '794 discloses the "adapted" limitation.

d) "a circumferential groove located, with respect to a side of the flange, on the anchoring fixture on a threaded side of the anchoring fixture"

Petitioner asserts that, to the extent that Westerkull '794 may be interpreted as not having the claimed circumferential groove, Choi discloses 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. Pet. 48 (citing Ex. 1005, Abstract, 9:1–16, Figs. 5, 6, 9; Ex. 1002 ¶¶ 90–93, 101, 109–111, 150–152, 174–176, 184, 208, 232). We determine that Choi discloses a number of minute screwed grooves 290 formed on the surface of settling portion 230. Ex. 1005, 9:1–2.

Petitioner contends that a person of ordinary skill would have modified Westerkull '794's implant by adding Choi's grooves on the threaded side of the flange because Choi discloses that its grooves improve stability of the fixture, dispersing stress on the implant to the cortex bone, preventing bone loss, and improving bonding of the fixture with bone. Pet. 45–46 (citing, e.g., Ex. 1002 ¶¶ 90, 92, 110, 113, 151, 154, 205, 208–209).

Patent Owner argues that Petitioner does not establish that a person of ordinary skill would have been motivated to combine the references to arrive at the claimed invention and does not provide evidence of a reasonable expectation of success. PO Resp. 33–58. More specifically, Patent Owner

argues that (1) Petitioner's expert failed to consider important design considerations and failed to analyze the differences between the jaw bone and the skull in the proposed combination (PO Resp. 33–35); (2) Petitioner failed to address materially different mechanical differences between the claimed skull bone implant and prior art implants (*id.* at 35–38, 42–43); (3) Petitioner's expert failed to articulate how a person of ordinary skill would have modified the prior art to meet the claim limitations (*id.* at 38–42, 59–63); (4) Petitioner's expert failed to articulate why a person of ordinary skill would have modified the prior art and provided conclusory explanations (*id.* at 43–45, 47–51); (5) Petitioner failed to prove a reasonable expectation of success for combining Westerkull '794 and Choi to arrive at the claimed skull bone implant and failed to analyze the expectation of success of modifying Choi's teachings given the constraints of the skull bone (*id.* at 45–47); (6) Petitioner's proposed combination would negate the alleged benefit of Westerkull '794's implant design, i.e., that relieving portion 122 reduces friction between the fixture and the bone and contributes to lower insertion torque (*id.* at 51–53); and (7) Petitioner's proposed combination is illogical because it adds redundant structure to Westerkull '794 because (a) Choi's settling portion and Westerkull '794's flange are both intended to restrain the implant from sinking and the references both recognize that a flange can cause bone loss (*id.* at 52–54, 55–57); (b) Choi's settling portion and Westerkull '794's groove structure both minimize osteolysis (*id.* at 54–55); and (c) Choi's settling portion and Westerkull '794's flared region are both intended to disperse stress from the implant into the cortex bone (*id.* at 58–59).

Petitioner argues that Patent Owner's concern with adding Choi's minute grooves to Westerkull '794's implant, where the minute groove

region of Choi is larger than the space available on Westerkull '794's implant, is merely one of bodily incorporation and that obviousness does not require incorporating the precise number of minute grooves of Choi's settling portion 230 into the fixture of Westerkull '794's implant. Pet. Reply 13–14 and n.7. Petitioner also argues that each minute groove satisfies the claimed "circumferential groove." *Id.* at 14 n.7.

Although Patent Owner does not bear the burden of proof, we are persuaded by Patent Owner that Petitioner's proposed combination of Westerkull '794 and Choi is based on hindsight and that Petitioner has not established that a person of ordinary skill would have modified Westerkull '794's implant to add a minute groove region with circumferential grooves, as taught by Choi. In particular, we agree with Patent Owner that Petitioner and Petitioner's expert have not adequately accounted for, in their argument and analysis, the differences between the jaw bone in which Choi's implant is inserted and the skull bone in which Westerkull '794's device is inserted and the extent to which those differences would have impacted design considerations in the proposed, modified prior art.

We analyze the issues of analogous art, rationale to combine, and reasonable expectation of success as follows.

(1) Analogous Art

Petitioner first argues that a person of ordinary skill would have been fully aware of developments that occurred in the dental anchoring art and would have been willing to consider such developments in making improvements to bone-implant hearing aids. Pet. 44 (citing Ex. 1023; Ex. 1024; Ex. 1002 ¶ 103). Petitioner also argues that the teachings of Choi would have been 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 stability of the fixture upon implantation, promoting osseointegration, and preventing bone loss. Pet. 44 (citing Ex. 1025; Ex. 1026; Ex. 1002 ¶¶ 79–82, 90, 92, 104–108, 113, 154).[15] Petitioner argues that Choi discloses 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. Pet. 39.

In our Decision on Institution, in a section analyzing whether to institute through the lens of 35 U.S.C. § 325(d), we made a preliminary finding that Choi deals with similar problems, as the '807 patent, of implanting a fixture in bone (Dec. Inst. 18–19) and that it appears that persons of skill in the art of hearing aid implants were cognizant of both types of implants into bone. *Id.* at 19–20 (citing Ex. 1007, 1:62–65).

Patent Owner responds that "a [person of ordinary skill in the art (POSITA's)] mere awareness of art does not make it obvious to combine it with art in another field" and that "[s]imply alleging that two prior art references are directed to the same general field of art and the same general problem, without more, is not sufficient to show a motivation to combine."

[15] The legal issue for purposes of analogous art is whether Choi would have been addressing the same problem to be solved by the '807 patent, not whether Choi would have been addressing the same problem to be solved by Westerkull '794. This argument is therefore legally deficient. *See In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) ("Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved."). Nevertheless, for completeness of discussion, we consider Petitioner's arguments regarding Choi.

PO Resp. 46 (citing *Securus Techs., Inc. v. Glob. Tel*Link Corp.*, 701 F. App'x 971, 977 (Fed. Cir. 2017) (internal citations omitted)). Patent Owner also refers to the portion of Westerkull '222 (Ex. 1007) relied on the Decision on Institution and points out that Westerkull '222 also states that "[h]owever, these types of fixtures which are used in the jaw-bone cannot be used for anchorage in the skull bone, which bone is much thinner than the jaw-bone." PO Resp. 49 (citing Ex. 1007, 1:58–67).

After reviewing the arguments and evidence based on a full trial record, and particularly in view of Ex. 1007, 1:58–67,[16] we determine that Choi was analogous art inasmuch as a person of ordinary skill in the art of hearing aid implants would have been aware of dental implants and because Choi pertains to a similar problem as the '807 patent. Nevertheless, even if Choi is analogous art, we recognize that that does not necessarily mean that a person of ordinary skill would have been motivated to modify Westerkull '794 with the teachings of Choi. *E.g., Securus*, 701 F. App'x at 977.

(2) Rationale to Combine

For the reasons that follow, we determine that Petitioner's proposed combination is based on improper hindsight and that Petitioner has not persuasively proven its stated rationale for modifying the skull bone implant of Westerkull '794 with the minute groove region of Choi's dental implant,

[16] Westerkull '222 discussed certain then-prior art self-tapping dental implants before stating: "However, these types of fixtures which are used in the jaw-bone cannot be used for anchorage in the skull bone, which bone is much thinner than the jaw-bone. The dental implants (fixtures) are too long and they have very deep, longitudinal bone cavities for collecting and retaining all the cut-off bone chips material." Ex. 1007, 1:62–67. Westerkull '222 then proceeds to disclose its invention of a self-tapping screw that overcame its identified challenges. *Id.* at 2:1–17.

i.e., that a person of ordinary skill would have expected predictable results when applying Choi's teachings to Westerkull '794's device. *See* Pet. 46.

(a) Differences Between the Jaw Bone and the Skull Bone

Patent Owner argues that the jaw bone has substantially different parameters from the skull bone in terms of, among other things, overall depth, thickness of the outer cortical layer, thickness of trabecular bone, and porosity (of trabecular bone). PO Resp. 37 (citing Ex. 2037 ¶¶ 94–95). In particular, Dr. Rentschler provides the following data in the table shown below:

Bone Characteristics	Skull Bone	Jaw Bone
Shape	near flat	cylindrical ridge shape
Depth	4.9 – 5.6 mm	13.4 – 24.9 mm
Thickness of outer cortical layer	2.0 – 2.2 mm	0.1 – 1.3 mm
Thickness of inner cortical layer	1.0 – 2.0 mm	N/A
Thickness of trabecular bone	0.5 – 3.0 mm	3.9 – 6.8 mm
Porosity of trabecular bone	56.8% – 69.0%	72.6% – 87.4%
Forces on implant under normal use	0.2 N (e.g., weight of sound processor)	117 – 368 N (e.g., chewing)

Ex. 2037 ¶ 94 (citing Ex. 1022, Abs., Fig. 9; Ex. 2046, Table 9; Ex. 2047, Table 1; Ex. 2049, Table 3; Ex. 2050, 3). The above-depicted table identifies several bone characteristics (e.g., shape, depth, forces on implant in use) and the relevant differences of such characteristics between the skull and jaw bones. We find that Dr. Rentschler's averments are adequately supported by the cited documentary evidence, with the exception of the weight of a sound processor (0.2 N or about 20g), which appears to be based on his estimate. *See* Ex. 2037 ¶ 94; Ex. 1022, Abs., Fig. 9; Ex. 2046, Table 9; Ex. 2047, Table 1; Ex. 2049, Table 3; Ex. 2050, 3. Petitioner does not

challenge these data.[17] Accordingly, we find that a jaw bone implant is ordinarily subjected to more force during chewing than a skull bone hearing aid implant would be subjected to by virtue of the weight of the implant, and that the overall thickness of the jaw bone is greater than the overall thickness of the skull bone. We also find that a jaw bone implant has greater porosity of the trabecular bone than the skull bone.

Dr. Rentschler also opines that "[p]enetration of the inner cortical bone may cause serious consequences such as infection and damage to brain tissue. Worse yet, cracking or slight penetration of this inner cortical bone layer may go undetected, until much later after an infection has already taken place. Such limitations and risks are not present for the jaw bone, because the jaw bone is substantially deeper than the skull bone and does not protect delicate brain tissue." Ex. 2037 ¶ 95. Petitioner does not disagree with Dr. Rentschler's opinion in this regard, and we accept these undisputed assertions as factual findings.

Accordingly, we determine that a person of ordinary skill would have had to take into account the differences between the jaw bone and skull bone in determining whether and how to modify Westerkull '794's hearing aid implant with the minute groove region of Choi's dental implant. The differences are relevant, as discussed in more detail below in the following section, because Choi discloses not only a longer implant but also a

[17] Dr. Hayes in his Reply Declaration does opine that Dr. Rentschler testified that the dental arts are analogous to skull bone implants. Ex. 1028 ¶ 19. Dr. Hayes also opines that Dr. Rentschler's surface area calculations, for adding the settling or grooved region of Choi to Westerkull '794's device, are problematic for accuracy and for relevance for estimations of what the increase in surface torque would be to insert the modified device of Westerkull '794. *See id.* ¶¶ 28–29.

microgroove region with grooves of a different pitch than the main screw threads, such that the modified device of Westerkull '794 would have a minute groove region with a different pitch than the main threads of Westerkull '794's self-tapping screw. The parties also debate whether the modified device would have a greater insertion torque. PO Resp. 42–52; Pet. Reply 15–17.

(b) Whether Petitioner's Rationale for Modifying Westerkull '794 is Supported

Petitioner argues that "[a person of ordinary skill (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." Pet. 45 (citing Ex. 1002 ¶¶ 90, 92, 110, 113, 151, 154, 205, 208–209). Petitioner further argues that "[m]aking 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." Pet. 46 (citing Ex. 1002 ¶¶ 101–116, 147–157, 174–177, 213–216, 230–233). Petitioner further argues that "[s]uch an obvious modification would also satisfy a demand for improving known bone anchors to attain predictable and beneficial results." *Id.* (citing *KSR.*, 550 U.S. at 416; citing Ex. 1002 ¶¶ 101–114, 147–155).

In support of its argument, Petitioner cites the Hayes Declaration at paragraphs 101–116, 147–157, 174–177, 213–216, 230–233. Of these paragraphs, only paragraphs 101–116 refer to claim 1; the other paragraphs refer to other claims and are generally redundant as to the reasons to modify Westerkull '794's implant with the grooves of Choi.

Paragraphs 101–103 and 108–113 provide Dr. Hayes's opinion that Choi would remedy any deficiency in Westerkull or otherwise relate to the issue of analogous art. Ex. 1002 ¶¶ 101–103, 108–113. Dr. Hayes does opine that "[i]t was also understood that the size and the shape of the screw may differ based on the location and the load on the screw." *Id.* ¶ 103 (citing Ex. 1024[18], 86). We find this to be an acknowledgement that there are factors that might require a screw to be different depending on the location and does not necessarily support the proposition that the skull bone would have been predicted to behave in the same manner as the jaw bone. To the extent Petitioner argues that a person of ordinary skill would have modified a jaw bone implant to work in the setting of the skull bone, Petitioner does not provide specific information as to how to accomplish this modification and this argument does not necessarily support the argued rationale to combine the teachings of Westerkull '794 and Choi, i.e., that the modification could be accomplished with predictable results. *See* Pet. 61.

Paragraphs 104–107 relate to Dr. Hayes's opinion that "a POSA would look to teachings from dental anchor devices to modify bone anchors for hearing aids to improve bone anchors with predictable results." *See* Ex. 1002 ¶ 104. Paragraph 104 of the Hayes Declaration states:

> A study from around 1981 concerning an osseointegrated titanium screw found that "a stable long-term anchorage of titanium implants may be achieved in the temporal bone." Ex. 1025, 308. This result was expected by the authors because "[t]he histologic appearance of the bone tissue in the os temporale does not significantly differ from the bone tissue in other parts of the body where titanium implants have been used. The technique used at installation of the implants is well

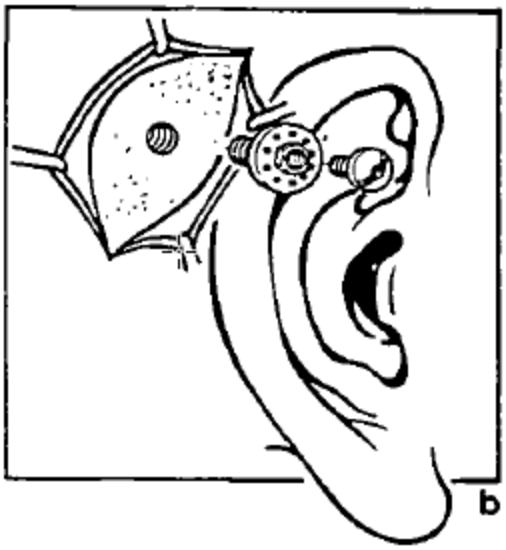
[18] Marshall Chasin, *Current Trends in Implantable Hearing Aids*, 2 Trends in Amplification 84 (1997) (Ex. 1024, "Chasin").

> established and has been used successfully for many years." Ex. 1025[19], 308. Therefore, it is my opinion that a POSA would look to teachings from dental anchor devices to modify bone anchors for hearing aids to improve such bone anchors with predictable results.

Id. In other words, Dr. Hayes bases his opinion that there would be predictable results on Tjellström's statement that the bone tissue in the temporal bone has a similar "histologic appearance" as other bone in which the implant has been used. However, Dr. Hayes does not address the difference in thickness of the skull bone and the jaw bone nor does Dr. Hayes address the differences in forces to which the skull bone and the jaw bone are subjected, as pointed out by Patent Owner. *See* Ex. 2037 ¶ 94.

Further, Tjellström does not disclose a screw with two different types of threads, i.e., threads and microgrooves, as disclosed in Choi. Tjellström's method was to prepare a hole in the bone behind the ear and "[t]he hole was then threaded, using a specially constructed tap, and the titanium screw—the fixture—was inserted." Ex. 1025, 306. Step (b) of Figure 2 of Tjellström is reproduced below:

[19] Anders Tjellström et al., *Osseointegrated Titanium Implants in the Temporal Bone*, 2(4) The American Journal of Otology 304 (1981) (Ex. 1025, "Tjellström").



In the illustrated step (b) of Tjellström Figure 2, i.e., after creating an incision, "[a] threaded hole is carefully prepared in the exposed bone tissue. The dimensions of the hole correspond exactly to the titanium fixture." Ex. 1025, 307. We also observe that Tjellström uses a "specially constructed tap"; whereas, Westerkull '794, which is the primary reference to be modified, would have been considered to be self-tapping. *See* Ex. 1002 ¶ 132 (discussing cutting edges 118 of Westerkull '794). Thus, Tjellström does not address certain features of the proposed combination, i.e., the self-tapping screw of Westerkull '794, and the use of threads of different pitches, as taught by Choi.

Dr. Hayes also relies on a study by Rasmusson of different types of dental implants, i.e., with different types of threads. *See* Ex. 1002 ¶¶ 105–107 (discussing Ex. 1026[20]). However, Rasmusson does not comment on

[20] Lars Rasmusson et al., *Effects of Implant Design and Surface Bone Regeneration and Implant Stability: An Experimental Study in the Dog Mandible*, 3(1) Clinical Implant Dentistry and Related Research 2 (2001) (Ex. 1026, "Rasmusson").

whether the skull bone would have been expected to behave in a similar manner to the jaw bone.

Paragraphs 115 and 116 of the Hayes Declaration appear to restate the opinion that a person of ordinary skill would have expected no change in the respective functions with predictable results without providing additional support. *See id.* ¶¶ 115–116. We have reviewed the other portions of the Hayes Declaration relied on by Petitioner in support of a motivation to combine, i.e., Ex. 1002 ¶¶ 147–157, 174–177, 213–216, 230–233, and find that those paragraphs discuss Westerkull '794 and Choi but do not provide additional persuasive evidence that applying the teachings of Choi's jaw bone implant to Westerkull '794's skull bone implant would have yielded predictable results with no change in function for the skull bone.

Petitioner also argues that a person of ordinary skill would have had a reason to modify Westerkull '794's implant in view of Choi's disclosure of advantages of providing a circumferential groove region, including "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." Pet. 45 (citing Ex. 1002 ¶¶ 90, 92, 110, 113, 151, 154, 205, 208–209); Pet. Reply 15 (citing Ex. 1028 ¶ 31; Ex. 1002, ¶¶ 113-114, 149, 151, 154-155). Although these benefits of Choi may provide general motivation to use Choi's circumferential grooves in a dental implant, we determine that Petitioner has not shown specific motivation to add circumferential grooves to a skull bone implant (such as that of Westerkull '794), particularly in view of the countervailing evidence relied on by Patent Owner that the skull bone and jaw bone have material differences impacting the design of implants suitable for the particular bone.

Petitioner argues that "even it modifying an element may involve trade-offs, 'a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine. Upon weighing the advantages and alleged disadvantage, a person of ordinary skill would have been motivated to modify Westerkull'794 to incorporate Choi's teachings of miniature grooves region." Pet. Reply 16 (citing *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006)); Ex. 1028 ¶ 31; Ex. 1002 ¶¶ 113–114, 149, 151, 154–155). However, we agree with Patent Owner that Petitioner is essentially providing a generic recitation of the law without providing adequate evidentiary support for how a person of ordinary skill would weigh any advantages or disadvantages. *See* PO Surreply 22–23.[21]

Petitioner's expert, Dr. Hayes, states as follows in the Reply Declaration: "Therefore, to the extent that combining Westerkull'794 with the teaching of Choi provides an increase in insertion torque, it is my opinion that a POSA would accept such an increase in insertion torque to achieve the greater stability and increased osseointegration taught by Choi." Ex. 1028 ¶ 31 (citing Ex. 1002 ¶¶ 113–114, 149, 151, 154–155). The Hayes Reply Declaration is relying on portions of the Hayes Declaration that re-state the benefits of Choi, i.e., dispersing stress, providing radial

[21]At the oral hearing, counsel for Patent Owner stated that "I don't believe that Petitioner addressed in his Petition or the accompanying declaration whether the grooves would be damaging to the bone, so that's kind of a -- I agree that that's a problem, but it's a problem that wasn't addressed in the record that we have here, so I don't know that I can comment further on that." Tr. 40:10–14.

compression, and promoting osseointegration (*see* 1002 ¶¶ 113–114, 149, 151, 154–155), without comparing the advantages and benefits.

Paragraph 31 of the Hayes Reply Declaration does follow several preceding paragraphs (Ex. 1028 ¶¶ 25–30), which criticize Dr. Rentschler's basis for stating that the minute grooves of Choi would "significantly" increase the insertion torque for Westerkull '794. *See* Ex. 1028 ¶ 25. Dr. Hayes opines that the relieving portion of Westerkull '794 (which decreases the insertion torque) is only a preferred embodiment of Westerkull that "may" be present and is not required (citing Ex. 1003, 4:58–62); that Dr. Rentschler has not attempted to quantify how much greater the insertion torque would be by the inclusion of the minute grooves taught by Choi; that Dr. Rentschler has in certain instances relied on approximate measurements taken from patent drawings not drawn to scale and has not provided guidance to the mathematical relationships that he used to relate geometric figures to surface area so that his calculations cannot be verified; and that Dr. Rentschler has not attempted to calculate the relevant surface areas for the Westerkull '794 implant that has been modified based on the teachings of a minute groove region of Choi. Ex. 1028 ¶¶ 26–30.

Dr. Hayes's opinion, i.e., that the advantages of modifying Westerkull '794 with Choi outweigh the disadvantages, thus appears to be based on the opinion that Patent Owner and Dr. Rentschler have not shown that the disadvantages would be significant. Petitioner's logic appears to reverse the burden of proof, which rests with Petitioner, i.e., to prove that the disadvantages of adding a second set of threads with a different pitch to an implant for thinner bone would not be significant. *See* 35 U.S.C. § 316(e); *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) ("In an *inter partes* review, the burden of persuasion is on

the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee."). Further, Petitioner's stated rationale for combining is that, in satisfaction of *KSR*, a person of ordinary skill would have been able to apply the teachings of Choi to Westerkull '794 with predictable results. As above, Petitioner has not provided persuasive evidence to show predictable results.

Even if, arguendo, Petitioner had shifted a burden of production to Patent Owner by pointing to Choi's stated advantages for dental implants, we conclude that Patent Owner would have shifted the burden of production back to Petitioner by showing that the jaw bone has substantially different parameters from the skull bone in terms of, among other things, overall depth, thickness of the outer cortical layer, thickness of trabecular bone, and porosity and that the jaw bone implant is ordinarily subjected to 117–368 N of force on the implant under normal use whereas the skull bone implant is typically subjected to 0.2 N of force under normal use. Ex. 2037 ¶¶ 94–95; Ex. 1022, 2046–2050; *see also* Ex. 1007:1:58–67 (skull "bone is much thinner than jaw-bone") (*cited in* PO Resp. 49).

Further, although Dr. Hayes points to a lack of detail in Dr. Rentschler's calculations regarding the insertion torque required for implantation of the modified device, Dr. Hayes appears to be in general agreement with Dr. Rentschler regarding the basic physics. For example, Dr. Hayes has stated that a person of ordinary skill would understand that Choi creates an "interference fit providing radial contact pressure between the implant the surrounding bone" (Ex. 1002 ¶ 110) and, in the context of describing the '807 patent, Dr. Hayes has explained that in mechanical engineering, an interference fit has a "radial compressive force [that] creates high friction between the two materials and thereby allows such interfaces to

resist large forces and torques that would tend to separate two cylindrical parts by either pulling or twisting" (Ex. 1002 ¶ 43). *See* Ex. 2037 ¶ 122. In other words, Dr. Hayes own testimony would support the understanding that Choi's minute groove region creates a radially compressive force that creates resistance under certain enumerated conditions. We conclude that the burden of proving whether or not a person of ordinary skill would have found such additional forces to be insignificant for the skull bone rests with Petitioner. Nor has Petitioner provided a competing set of mathematical calculations.[22, 23]

Nor is this a situation where there are simply advantages and disadvantages for including a *feature* of a device because here there is a question about whether the device would have been suitable for implantation in the skull bone in the first instance. As observed by Patent Owner,

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[22] Further, although it is not in and of itself a teaching away, nor on its own dispositive, we agree with Patent Owner that Westerkull '794 does in fact disclose that in a preferred embodiment there is a relieving portion at its distal end that "reduces the friction between the fixture and the bone at the distal part of the threaded portion and therefore contributes to a lower insertion torque when inserting the fixture in the bone." Ex. 1003, 4:53–65. Petitioner's proposed modification would have added resistance instead of relieving friction.

[23] In the Decision on Institution, we set forth the preliminary analysis that a person of ordinary skill could have extended the at-least-one-turn thread under the flange of Westerkull '794 to create a micro groove. *See* Dec. Inst. 30. However, at the oral hearing, counsel for Petitioner stated that this was not the Petition's proposed way of modifying Westerkull '794. *See* Tr. 11:9–14. In other words, it is Petitioner's theory of the case that a person of ordinary skill would have had to replace the relieving portion of Westerkull '794 with the minute groove region of Choi. Therefore, under *SAS*, we evaluate only Petitioner's proposed modification. *See SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (explaining that "the petitioner is master of its complaint").

Petitioner's expert witness admitted that he "wouldn't dream of just taking a dental implant and shoving it someplace else -- in the body. We -- we want to know both these general characteristics -- behaviors of these interfaces as well as the loading environment and what real estate you have to work with." Ex. 2036, 25:23–25; *see* PO Resp. 34.

Further, Petitioner has not shown that merely shortening the minute groove region from Choi's device would have been sufficient to implant a minute groove region in the thinner skull bone given the forces that would have been involved because Petitioner has not shown that a person of ordinary skill would have sought to increase the resistance of Westerkull '794's device by adding a second set of threads (a groove region) with a different pitch than the primary pitch of Westerkull '794's self-tapping screw. Petitioner's stated rationale for modifying the device of Westerkull '794 with Choi's teachings is that there would be predictable results, but Petitioner has not provided support for the conclusion that there would be predictable results when applying a dental implant teaching for a skull bone implant.

We conclude that Petitioner's proposed modification of Westerkull '794's hearing aid implant with a feature of a dental implant is based on an improper hindsight reconstruction of the invention of the '807 patent. Notwithstanding Choi's disclosure of its advantages for a dental implant, Petitioner has not shown that a person of ordinary skill would have specifically sought to modify the hearing aid implant of Westerkull '794 for its implantation in the skull bone. Having found that Petitioner has not established an adequate rationale for combining the teachings of Westerkull '794 and Choi, we need not reach Patent Owner's other arguments in this regard and we need not reach Patent Owner's arguments on objective indicia

of nonobviousness. *See, e.g.*, *Hamilton Beach Brands, Inc. v. f'real Foods, LLC*, 908 F.3d 1328, 1343 (Fed. Cir. 2018) (holding, in affirming Board decision determining that petitioner had not shown unpatentability, that "objective indicia of nonobviousness" "need not [be] addressed").

(3) Reasonable Expectation of Success

Petitioner asserts that "[a] POSA would have had a reasonable expectation of success in configuring the anchoring fixture of Westerkull '794 in view of Choi." Pet. 47 (citing Ex. 1002 ¶¶ 115, 156). Petitioner argues that obviousness does not require absolute predictability but only a reasonable expectation of success (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)); that Patent Owner is improperly arguing an issue of bodily incorporation; and that Patent Owner is improperly arguing the cost of the implant. Pet. Reply 12–15.

Patent Owner argues that Petitioner's expert declaration includes generic, conclusory, and "boilerplate" statements of reasonable expectation of success without any explanation, support, or specifics. PO Resp. 44–45, 47. Patent Owner argues that utilizing a hearing implant requires consideration of a variety of factors such as load conditions, biological environment, mechanical properties, and appropriate modifications. *Id.* at 47. Patent Owner argues that "The Petition did not make a showing of reasonable expectation of success because Dr. Hayes did not analyze the proposed combination of Westerkull '794 and Choi from the perspective of designing an implant that would work." *Id.* (citing Ex. 2036 at 101:17–102:11). Patent Owner also argues that there would have been added machining or design costs, that there would have been undue

experimentation (citing *In re Wands*)[24], and that a person of ordinary skill would have encountered significant difficulty. *Id.* at 41–43.

Patent Owner analogizes this case to *Spine Sols., Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1311 (Fed. Cir. 2010), *abrogated on other grounds by Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016). *Id.* at 50. Patent Owner states that in *Spine Sols*, the court found that a person of ordinary skill would not have viewed a single keel as being stable enough for a disc replacement device. *Id.* Patent Owner argues that here Petitioner's expert stated that he did not consider the differences between the jaw bone and the skull bone and therefore could not have rendered the necessary opinion. *Id.*

For similar reasons as described in more detail in the section on rationale to combine, *supra*, we agree with Patent Owner that Petitioner's analysis of reasonable expectation of success is conclusory. The problem that would have been facing a person of ordinary skill is not merely that Choi's settling region was longer than Westerkull '794's implant and that Choi's implant would have been longer than the depth of skull bone, and thereby penetrated into the skull. Rather, a person of ordinary skill would also have been facing the problem that the environment of the skull bone in which Westerkull '794 is implanted differs from that of the jawbone in which Choi is implanted, and we conclude that Petitioner has not demonstrated that a person of ordinary skill faced with this problem would have modified Westerkull '794's device in the manner proposed, using

[24] We note that undue experimentation is the terminology for the legal analysis of enablement rather than reasonable expectation of success. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Choi's microgrooves, with a reasonable expectation of successfully arriving at the claimed subject matter.

e) Summary of Claim 1

On this trial record Petitioner has not established by a preponderance of the evidence that claim 1 is unpatentable over Westerkull '794 and Choi.

4. Analysis of Dependent Claims 2–7, 16, 25, 28, 33–35, and 38

Claims 2–7, 16, 25, 28, 33–35, and 38 depend from claim 1. Because we find that Petitioner has not established that claim 1 is unpatentable, we find that Petitioner has not established that claims 2–7, 16, 25, 28, 33–35, and 38 are unpatentable for the same reason.

5. Analysis of Independent Claim 8

Independent claim 8 contains several similar limitations and requirements as independent claim 1, and independent claim 8 additionally recites "a threaded tapered portion, wherein a maximum width of the bone fixture is about the same as a height of the bone fixture." Ex. 1001, 6:24–26.

On review of the evidence, we determine that Petitioner has not met its burden of showing that independent claim 8 would have been unpatentable over Westerkull '794 and Choi, for the same reason as for independent claim 1. In particular, Petitioner has not established that a person of ordinary skill would have modified Westerkull '794's device with the minute groove region of Choi's dental implant for implantation into the skull bone.

6. Analysis of Dependent Claims 9–12, 14, 39, 45, and 46

Claims 9–12, 14, 39, 45, and 46 depend from claim 8. Because we find that Petitioner has not established that claim 8 is unpatentable, we find that Petitioner has not established that claims 9–12, 14, 39, 45, and 46 are unpatentable for the same reason.

E. Obviousness of Claim 17 Over Westerkull '794, Choi, and Håkansson (Ex. 1006)

Petitioner contends that claim 17 is unpatentable as obvious over Westerkull '794, Choi, and Håkansson. Pet. 63–68. Patent Owner opposes. PO Resp. 68–71.

1. Håkansson

Håkansson is titled "A Device for Anchoring and Energy Transfer at Implants" and relates to a device at implants for anchoring in bone tissue and supporting of a prosthesis or transfer of electrical and/or mechanical energy from a transmitter or the like to the implant via a coupling device, which incorporates a first and a second coupling part. Ex. 1006, code (54), 1:7–10. Håkansson describes a problem in the prior art with two-piece implants, i.e., high manufacturing costs and the requirement for high tolerances for the internal fitting of the parts, in particular for signal transferring applications. *Id.* at 2:8–12. Håkansson, *inter alia*, discloses a device where a coupling part and flange fixture are made integral so that the operation can be carried out in one stage and the device can be used to the full extent after a healing period of a few weeks. *Id.* at 5:1–5.

Figure 1 of Håkansson is reproduced below:

FIG. 1

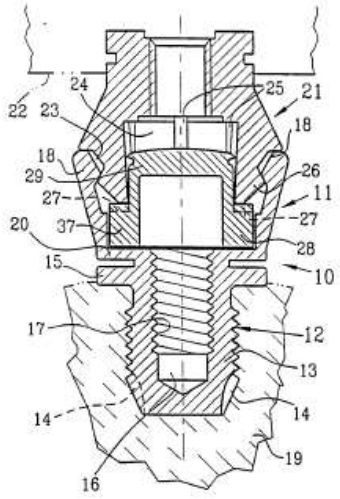

Figure 1 of Håkansson shows a longitudinal section through an embodiment of an implant with added apparatus coupling part. Ex. 1006, 3:8–9.

2. Analysis of Claim 17

Claim 17 depends from claim 1 and further recites:

> 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.

Ex. 1001, 7:22–29.

Petitioner does not rely on Håkansson to remedy the deficiency in the combination of Westerkull ’794 and Choi, which we have addressed above. Accordingly, we determine that Petitioner has not established that claim 17 would have been obvious over Westerkull ’794, Choi, and Håkansson.

F. Obviousness of Claims 37 and 47 over Westerkull '794, Choi, and Westerkull '222 (Ex. 1007)

Petitioner contends that claims 37 and 47 are unpatentable as obvious over Westerkull '794, Choi, and Westerkull '222. Pet. 68–71. Patent Owner opposes. PO Resp. 45.

1. Westerkull '222

Westerkull '222 is titled "Anchoring Element" and 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, which is thinner than the jaw bone. Ex. 1007, code (54), 1:5–8. Westerkull '222 describes that dental implants are too long for the skull bone and cannot be installed without the use of screw taps. *Id.* at 1:58–67. Westerkull '222, *inter alia*, discloses a self-tapping screw for anchoring in comparatively thin skull bone. *Id.* at 2:5–8.

2. Analysis of Claims 37 and 47

Claims 37 and 47 depend respectively from claims 1 and 8 and further recite "wherein: the flange has a maximum diameter that exceeds a peak diameter of the thread by approximately 10-20%." Ex. 1001, 9:41–43, 10:42–44.

Petitioner does not rely on Westerkull '222 to remedy the deficiency in the combination of Westerkull '794 and Choi discussed above. Accordingly, we determine that Petitioner has not established that claims 37 and 47 would have been obvious over Westerkull '794, Choi, and Westerkull '222.

G. Obviousness of Claims 28, 40, and 41 over Westerkull '794, Choi, and Brånemark (Ex. 1008)

Petitioner contends that claims 28, 40, and 41 are unpatentable as obvious over Westerkull '794, Choi, and Brånemark. Pet. 71–75. Patent Owner opposes. PO Resp. 71.

1. Brånemark

Brånemark is titled "An Implant and an Implant Member" and relates to an implant comprising means for attachment to living biological tissue of a human being or an animal, the implant having an outer surface comprising a first part and a second part which have different properties with regard to the biocompatibility of each part with biological tissue, and to a method for producing such an implant, and to a masking unit used in said method. Ex. 1008, code (54), 1:3–8. Brånemark describes that the use of titanium and titanium alloys was limited to tissue of good quality. *Id.* at 1:25–29. Brånemark, *inter alia*, discloses an implant comprising a surface portion of a ground surface and one or more several delimited regions making up a second part. *Id.* at 2:28–30. Brånemark discloses that the heterogeneous structure of the surface provides the possibility to tailor the interaction of an implant with different specific biological systems. *Id.* at 3:6–8.

2. Analysis of Claims 28, 40, and 41

Claims 28 and 40 depend from claim 1 and claim 41 depends from claim 8. Each contains further recitations relating to surface roughness.

Petitioner does not rely on Brånemark to remedy the deficiency in the combination of Westerkull '794 and Choi discussed above. Accordingly, we determine that Petitioner has not established that claims 28, 40, and 41 would have been obvious over Westerkull '794, Choi, and Brånemark.

III. PATENT OWNER'S MOTION TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence ("FRE"). *See* 37 C.F.R. §§ 42.20(c), 42.62(a).

Patent Owner moves to exclude a number of exhibits for various reasons. First, Patent Owner asserts that Exhibit 1028, the Hayes Reply Declaration, should be excluded in its entirety as an improper attempt to circumvent the word count set forth in 37 C.F.R. § 42.24(b). Paper 43. However, aside from providing the word count for the Hayes Reply Declaration and the Reply, Patent Owner does not explain how Petitioner has circumvented the word count in the Reply. Second, Patent Owner seeks to exclude paragraphs 8–14, 15–20, 21–23, 25–30, 32–39, 40–45, 46–48, 52–53, 54–56, and 57–60 of the Hayes Reply Declaration for lack of relevance under FRE 402 because they include additional arguments that were not expressly addressed in Petitioner's Reply. Paper 43, 2. We deny this aspect of the motion. Where, as here, the decision is by an administrative agency, rather than a jury, there is a diminished concern that such exhibits would be prejudicial. *See Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) (sitting as a non-jury tribunal, the Board may assign appropriate weight to evidence presented) (citing *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941)). Further, because we find that the challenged claims have not been shown to be unpatentable, we observe having considered the motion to exclude and given it appropriate weight, that it does not change the result.

Patent Owner also argues that Exhibits 1032–1036 and 1039 should be excluded for lack of relevance under FRE 402 because they are not cited

anywhere in Petitioner's Reply. Paper 43, 2. Patent Owner acknowledges that the opinions in paragraphs 15–20 of the Hayes Reply Declaration cite these exhibits but argues that they are not addressed in Petitioner's Reply other than for a "single conclusory assertion." For the same reason as for Exhibit 1028, we deny this aspect of the motion, i.e., there is a diminished concern that these exhibits would be prejudicial in a non-jury trial before an administrative agency. *See Corning*, Paper 66 at 19.[25] Further, because we find that the challenged claims have not been shown to be unpatentable, we observe, having considered the motion to exclude and given it appropriate weight, that it does not change the result.

IV. CONCLUSION

We conclude that Petitioner has not established that any of the challenged claims are unpatentable.[26]

V. ORDER

In consideration of the foregoing, it is hereby:

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[25] We note that Patent Owner also filed an objection to Petitioner's demonstrative exhibits in advance of the oral hearing. Paper 47, 1. The issues raised were not material to the disposition of this appeal and are moot. We also note that demonstrative exhibits are not considered substantive evidence. Paper 45, 4 (Hearing Order).

[26] Although we find the challenged claims not unpatentable, we do reach an additional issue raised by Patent Owner. Patent Owner argues that the Federal Circuit's remedy in *Arthrex* is inadequate to cure a constitutional violation. PO Resp. 73. We deny Patent Owner's Appointments Clause challenge because we conclude that any Appointments Clause concerns have been addressed by the Federal Circuit's opinion, subject to any further process in that case. *Arthrex, Inc. v. Smith & Nephew*, Inc., 941 F.3d 1320 (Fed. Cir. 2019), *cert. granted sub nom. United States v. Arthrex, Inc.*, 2020 WL 6037206 (Oct. 13, 2020).

ORDERED that on the record before us, Petitioner has not shown by a preponderance of the evidence that claims 1–12, 14, 16, 17, 25, 28, 33–35, 37–41, and 45–47 of the '807 patent are unpatentable.

FURTHER ORDERED that Patent Owner's Motion to Exclude is denied;

FURTHER ORDERED that this is a Final Written Decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims	**35 U.S.C. §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
1–12, 14, 16, 25, 28, 33–35, 38, 39, 45, 46	103	Westerkull '794, Choi		1–12, 14, 16, 25, 28, 33–35, 38, 39, 45, 46
17	103	Westerkull '794, Choi, Håkansson		17
37, 47	103	Westerkull '794, Choi, Westerkull '222		37, 47
28, 40, 41	103	Westerkull '794, Choi, Brånemark		28, 40, 41
Overall Outcome				1–12, 14, 16, 17, 25, 28, 33–35, 37–41, 45–47

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