Paper No. 54
Date Filed: October 23, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT AND TRIAL APPEAL BOARD

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

Petitioner

v.

COCHLEAR BONE ANCHORED SOLUTIONS AB

Patent Owner

Case No. IPR2017-01018[1]
U.S. Patent No. 7,043,040 B2

OTICON MEDICAL AB, OTICON MEDICAL LLC, AND WILLIAM DEMANT HOLDING A/S'S NOTICE OF APPEAL

[1] Case No. IPR2017-01019 has been consolidated with the instant proceeding.

Petitioner Oticon Medical AB, Oticon Medical LLC, and William Demant Holding A/S ("Petitioner") hereby gives notice to the Director of the Patent and Trademark Office, pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. § 90.2(a), of its appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board ("the Board"), entered on August 21, 2018 (the "Final Written Decision," Paper 52) and all underlying orders, decisions, rulings, and opinions. A copy of the Final Written Decision is attached.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioner indicates that the issues on appeal include, but are not limited to: (1) whether the Board erred in finding that claims 7-10 of U.S. Patent No. 7,043,040 ("the '040 patent") have not been shown to be unpatentable; (2) whether the Board erred in finding that claims 7-10 cannot be compared to the prior art because these claims invoke "means plus function" interpretation under 35 U.S.C. § 112, ¶ 6, but the '040 patent specification fails to disclose structure corresponding to the recited function(s); and (3) any and all findings or determinations supporting or related to the aforementioned issues as well as other issues decided adversely to Petitioner in any orders, decisions, rulings, and opinions.

Copies of Petitioner's Notice of Appeal are being filed simultaneously with the Director, the Board, and the Clerk of the United States Court of Appeals for the

Federal Circuit.

Dated: October 23, 2018

Respectfully submitted,

/D. Richard Anderson/

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of October, 2018, a copy of the foregoing NOTICE OF APPEAL was served upon the following persons via email:

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Pursuant to 37 C.F.R. § 90.2(a)(1), I hereby certify that a copy of the foregoing NOTICE OF APPEAL was electronically filed with the Patent Trial and Appeal Board on this 23rd day of October, 2018, in accordance with 37 C.F.R. § 42.6(b), and that an original version was filed by hand on this 23rd day of October, 2018, with the Director of the United States Patent and Trademark Office, at the following address:

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Moreover, I certify that on this 23rd day of October, 2018, three true and correct courtesy copies of the foregoing NOTICE OF APPEAL were filed by hand

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Paper No. 52
Entered: August 21, 2018

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 BONE ANCHORED SOLUTIONS AB,
Patent Owner.

Case IPR2017-01018[1]
Patent 7,043,040 B2

Before JAMES B. ARPIN, BARBARA A. PARVIS, and AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] Case IPR2017-01019 has been consolidated with the instant proceeding.

I. INTRODUCTION

A. Background

In IPR2017-01018, Oticon Medical AB, Oticon Medical LLC, and William Demant Holding A/S ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–10 and 13 of U.S. Patent No. 7,043,040 B2 (Ex. 1001, "the '040 patent"). Paper 1 ("Pet."). Cochlear Bone Anchored Solutions AB ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). We instituted an *inter partes* review of claims 1–6 and 13 on two grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 7 ("Dec. on Inst."), 27.

In IPR2017-01019, Petitioner requested a further *inter partes* review of claims 1, 11, and 12 of the '040 patent. IPR2017-01019, Paper 1 ("–1019 Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 6 ("–1019 Prelim. Resp."). We instituted an *inter partes* review of claims 1, 11, and 12 on two grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 7 ("–1019 Dec. on Inst."), 20.

Subsequent to our decisions instituting *inter partes* reviews of claims 1–6 and 11–13, we issued an Order consolidating the trial in IPR2017-01019 with that in IPR2017-01018, such that IPR2017-01019 was terminated as a separate proceeding. Paper 9. Accordingly, all subsequent filings and exhibits were made in the record of IPR2017-01018.[2]

[2] Unless noted by the prefix "–1019," all citations to papers or exhibits herein refer to filings in IPR2017-01018.

After institution, Patent Owner filed a Response (Paper 23, "PO Resp.") to the Petitions, as well as a statutory disclaimer of claims 1–3 and 13 (Paper 24). Petitioner filed a Reply (Paper 28, "Reply").

Additionally, after Petitioner filed its Reply, the U.S. Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *See* Papers 32–33. Pursuant to *SAS Institute*, a decision to institute an *inter partes* review under 35 U.S.C. § 314 may not institute trial on fewer than all claims challenged in the petition. *Id.* at 1355–56, 1358. In this proceeding, however, the Board had denied institution of an *inter partes* review of challenged claims 7–10. *See* Dec. on Inst. 9–11, 24, 26. Accordingly, we modified our Decision on Institution in IPR2017-01018 to include review of challenged claims 7–10, on the grounds presented in the Petition. Paper 33, 3. We authorized the parties to conduct supplemental briefing directed to these claims and grounds. *Id.* at 3–5.

Specifically, Patent Owner filed a Supplemental Response (Paper 35, "Supp. Resp."), addressing the newly-added challenges to claims 7–10, and Petitioner filed a Supplemental Reply (Paper 40, "Supp. Reply"). Patent Owner also filed a Motion to Exclude Exhibit 1131, which was filed with Petitioner's Supplemental Reply. Paper 43 ("Mot. Exclude"). Petitioner filed an Opposition, with our authorization. Paper 50 ("Opp. Mot. Exclude"); *see also* Paper 46, 2 (denying Patent Owner's Alternative Motion to Sur-Reply, which was filed without authorization).

An oral hearing was held on July 11, 2018, and a transcript of the hearing is included in the record. Paper 51 ("Tr."). Prior to the oral hearing,

the parties filed a joint List of Objections to Demonstrative Exhibits. Paper 47.[3]

To summarize, over the course of this consolidated proceeding, we instituted an *inter partes* review with respect to all claims challenged on all grounds asserted by Petitioner across both proceedings i.e., we instituted review of all challenged claims 1–13, and on all grounds presented in both Petitions. *See* Dec. on Inst. 27 (instituting claims 1–6 and 13); –1019 Dec. on Inst. 20 (instituting claims 1, 11, and 12); Paper 33, 3 (instituting claims 7–10). Due to Patent Owner's statutory disclaimer, claims 1–3 and 13 are no longer at issue. Paper 24. Accordingly, only claims 4–12 are addressed in this Final Written Decision.

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has met its burden of demonstrating that challenged claims 4–6, 11, and 12 are unpatentable by a preponderance of the evidence. *See infra* Section II.D–G. Also for the reasons set forth below, Petitioner has *not* met its burden of demonstrating that challenged claims 7–10 are unpatentable by a preponderance of the evidence. *See infra* Section II.A.1.

B. Related Proceedings

The parties represent that the '040 patent is at issue in district court litigation, *Cochlear Ltd. et al. v. Oticon Medical AB et al.*, No. 1:16-cv-01700 (D. Colo.), and in an arbitration proceeding under the Arbitration

[3] Because neither party discussed the objected-to demonstratives during the oral hearing, we deem those objections moot. *See generally* Tr.; Paper 39, 3 ("[W]e consider demonstrative exhibits only to the extent . . . they elucidate the parties' arguments presented during the hearing.").

Rules of the Arbitration Institute of the Stockholm Chamber of Commerce (SCC Arbitration No V2016/181). Pet. 1–2; –1019 Pet. 5–6; Paper 4, 2; –1019 Paper 4, 2.

C. The '040 Patent

The '040 patent, entitled "Hearing Aid Apparatus," issued on May 9, 2006. Ex. 1001, (45), (54). The '040 patent explains that prior art bone anchored hearing aids were useful in treating certain types of hearing loss. *Id.* at 1:45–50, 1:62–67. The '040 patent describes operation of these devices as follows:

> In such a bone anchored hearing aid the sound information is mechanically transmitted by means of a vibrator via the skull bone to the inner ear of a patient. The hearing aid device is connected to an implanted titanium screw installed in the bone behind the poor, external ear[, i.e., the external portion of a deaf ear,] and the sound is transmitted via the skull bone to the cochlea (inner ear) of this poor ear.

Id. at 1:52–58. According to the '040 patent, however, these devices were not used for patients with "unilateral hearing loss, i.e.[,] individuals with [] normal or [] slightly impaired hearing on one ear and a profound hearing loss in the inner ear on the other side of the head." *Id.* at 1:8–11, 2:1–5. Consequently, the '040 patent seeks to provide a hearing aid for rehabilitation of unilateral hearing loss based on this bone conducting principle. *Id.* at 2:5–12.

Figure 1 of the ’040 patent is reproduced below.

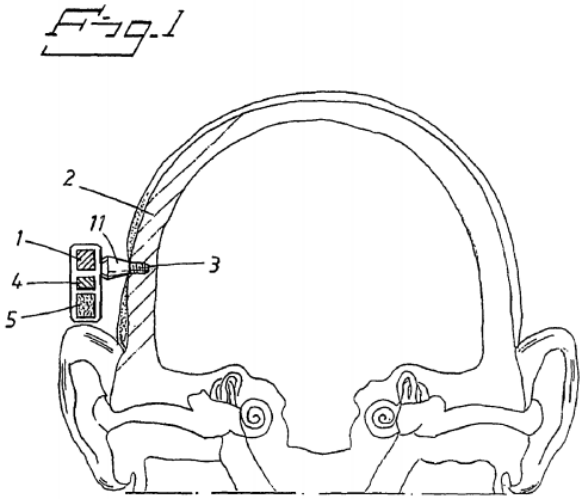


Figure 1 depicts a patient’s skull with a hearing aid located near the patient’s deaf ear. *Id.* at 2:33, 2:44–50 (also noting that the patient’s other ear is “normal or [has] only [] slightly impaired hearing”). Skin penetrating spacer 11 is anchored to skull bone 2 by fixture 3. *Id.* at 2:50–53. A housing at the opposite end of spacer 11 includes vibrator 1, microphone 5, and electronic circuitry 4. *Id.* at 2:50–55. Because high frequencies are attenuated during bone conduction across the skull, the frequency characteristics of the hearing aid are adapted such that “the amplification is higher in the treble . . . than in the bass.” *Id.* at 2:56–62.

The ’040 patent also discloses alternative embodiments that avoid skin penetration, shown in Figures 2 and 3 below. *Id.* at 2:34–39.

Fig. 2

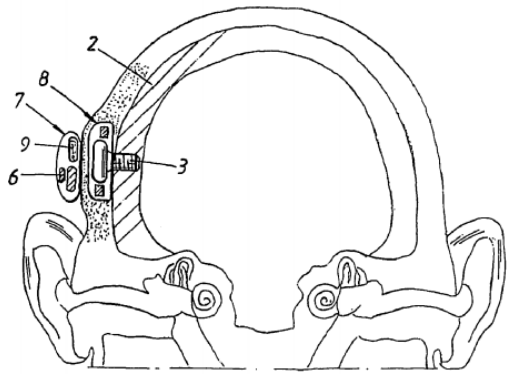
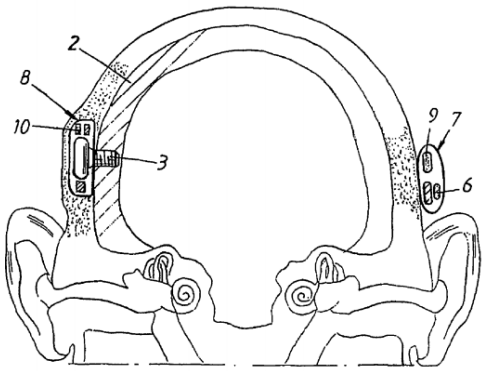


Fig. 3



Figures 2 and 3 depict schematic views of a skull in which a hearing aid is partially implanted. *Id.* at 2:34–39, 3:9–11. As shown in Figure 2, implantable part 8 includes a vibrator, while external part 7 includes microphone 6 and battery 9. *Id.* at 3:9–12. “[P]ower is transmitted to the implanted part 8 of the hearing aid by means of induction.” *Id.* at 3:12–14.

In the embodiment shown in Figure 3, implantable part 8 is arranged on the non-deaf side, and includes rechargeable battery 10, which is charged by induction from an external power supply. *Id.* at 3:15–20. External part 7, including microphone 6 and battery 9, is located on the deaf side of the skull, and the signal is transmitted from external part 7 to implantable part 8 by radio signal. *Id.* at 3:20–24.

D. Illustrative Claim

As noted above, claims 4–12 remain at issue in this proceeding. Each of these claims depends, directly or indirectly, from independent claim 1, which is reproduced below.

> 1. A bone-conducting bone-anchored hearing aid apparatus for sound transmission from one side of a patient’s head to the

> patient's cochlea on another side of the patient's head for rehabilitation of unilateral hearing loss, the hearing aid apparatus comprising:
>
> a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient; and
>
> an implantable part operative to mechanically anchor the vibratory generating part, the implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient.

Ex. 1001, 3:29–41. Dependent claims 4 and 5 further require that the apparatus transmits vibrations from one side of the skull to the other, and amplifies treble frequencies, including those over 1 kHz, more than bass frequencies. *Id.* at 3:48–53. Dependent claims 6–10 require that the apparatus includes electronic circuitry and/or "signal processing means." *Id.* at 4:1–25. Dependent claims 11 and 12 specify that the implantable part and vibratory generating part comprise an internal part, wherein power is transmitted to the internal part by induction. *Id.* at 4:26–36.

E. Applied References

Petitioner relies upon the following references. Pet. 4–6; –1019 Pet. 8–9.

Name	Reference	Date	Exhibit No.
Vaneecloo	F.M. Vaneecloo et al., *Prosthetic Rehabilitation of Unilateral Anakusis: Study by stereo-audiometry*, 117 ANN. OTOLARYNGOL. CHIR. CERVICOFAC. 410 (2000)		Ex. 1003[4]
Carlsson	Peder U. Carlsson, *On Direct Bone Conduction Hearing Devices*, Technical Report 195, Dept. of Applied Electronics, Chalmers University of Technology (1990)		Ex. 1007
Leysieffer	CA 2301437 A1	Published Oct. 8, 2000	Ex. 1009
Hough	J.V.D. Hough et al., *Long-Term Results for the Xomed Audiant Bone Conductor*, 28 Otolaryngologic Clinics of North America 43 (1995)		Ex. 1012[5]
Lesinski	U.S. Patent No. 5,881,158	Issued Mar. 9, 1999	Ex. 1018
Schaefer	U.S. Patent No. 4,729,366	Issued Mar. 8, 1988	Ex. 1019

[4] Petitioner provides an original version of the Vaneecloo reference in French. *See* Ex. 1004. In this Decision, we cite to the English translation of Vaneecloo, which was submitted with a sworn statement attesting to its accuracy. Ex. 1003, 1.

[5] In the –1019 Petition, Petitioner provided this document as Exhibit 1112. For convenience, we cite to Exhibit 1012, the version of Hough of record in IPR2017-01018.

Petitioner also relies upon the Declaration of Dr. Gerald R. Popelka (Ex. 1002), and the –1019 Declaration of Dr. Gerald R. Popelka (Ex. 1102[6]), each filed with the respective Petition.

Patent Owner relies upon the Declaration of Jay Rubinstein (Ex. 2002), and the –1019 Declaration of Jay Rubinstein (Ex. 2003[7]), each filed with the respective Preliminary Response. Patent Owner additionally relies on a December 21, 2017, Declaration of Jay Rubinstein (Ex. 2004), filed with the Patent Owner Response, as well as a June 5, 2018, Declaration of Jay Rubinstein (Ex. 2031), filed with the Supplemental Patent Owner Response.

Finally, the parties provide citations to deposition testimony of Dr. Popelka and Dr. Rubinstein. *See* Ex. 1121 (Mar. 29, 2018, deposition of Dr. Rubinstein); Ex. 1127 (June 20, 2018, deposition of Dr. Rubinstein); Ex. 2008 (Nov. 29, 2017, deposition of Dr. Popelka).

[6] In the –1019 Petition, Petitioner provided this document as Exhibit 1102. At our request, *see* Paper 9, 3, the document was entered into the record of IPR2017-01018, also as Exhibit 1102.

[7] In the –1019 Preliminary Response, Patent Owner provided this document as Exhibit 2002. At our request, *see* Paper 9, 3, the document was entered into the record of IPR2017-01018, as Exhibit 2003, which we cite herein.

F. Asserted Grounds of Unpatentability

We instituted *inter partes* review on the following grounds. Dec. on Inst. 27; –1019 Dec. on Inst. 20; Paper 33, 2–3. Because claims 1–3 and 13 have been statutorily disclaimed, they are not included in the table below. Paper 24.

Petition	Reference(s)	Basis	Claim(s) Challenged
–1018	Vaneecloo and Carlsson	§ 103(a)	4, 5
–1018	Vaneecloo, Carlsson, and Leysieffer	§ 103(a)	6, 7, 9
–1018	Vaneecloo, Carlsson, Leysieffer, and Schaefer	§ 103(a)	8
–1018	Vaneecloo, Carlsson, Leysieffer, and Lesinski	§ 103(a)	10
–1019	Hough	§ 102(b)	11
–1019	Hough and Leysieffer	§ 103(a)	12

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, we generally give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

1. Claims 7–10: Means-Plus-Function Limitations

i. Legal Basis

Pursuant to 35 U.S.C. § 112, ¶ 6, claims may be drafted in "means-plus-function" format. The statute provides:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and *such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents* thereof.[8]

35 U.S.C. § 112, ¶ 6 (emphasis added).

Claim limitations that include the word "means" are presumed to invoke 35 U.S.C. § 112, ¶ 6. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348–49 (Fed. Cir. 2015) (en banc in relevant part) ("[U]se of the word 'means' creates a presumption that § 112, ¶ 6 applies.") (quoting *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998)); *see also Greenberg v. Ethicon Endo–Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996).

This presumption may be rebutted, however, "if the evidence intrinsic to the patent and any relevant extrinsic evidence so warrant." *Personalized Media Commc'ns*, 161 F.3d at 704. For example, the presumption may be overcome where the claim specifically identifies structure sufficient to perform the recited function. *See TriMed, Inc. v. Stryker Corp.*, 514 F.3d

[8] Section 4(c) of the Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA") re-designated 35 U.S.C. § 112 ¶ 6, as 35 U.S.C. § 112(f). However, because the '040 patent has a filing date before September 16, 2012, the effective date of § 4(c) of the AIA, we will refer to the pre-AIA version of 35 U.S.C. § 112.

1256, 1259–60 (Fed. Cir. 2008); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427–28 (Fed. Cir. 1997). Indeed, the Federal Circuit has been clear that "the essential inquiry is not merely the presence or absence of the word 'means' but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Williamson*, 792 F.3d at 1348.

If it is determined that a claim invokes 35 U.S.C. § 112, ¶ 6, the claim must be construed in a "two-step process," whereby we "first identify the claimed function," and then "determine what structure, if any, disclosed in the specification corresponds to the claimed function." *Williamson*, 792 F.3d at 1351. Then, to demonstrate that the claim, so construed, is unpatentable in light of asserted prior art, a petitioner must show that the prior art teaches the *same structure* that is disclosed in the patent's specification as corresponding to the claimed function, or its equivalent. *See, e.g., Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1299–1300 (Fed. Cir. 2009) ("It is firmly established in our precedent that a structural analysis is required when means-plus-function limitations are at issue; a functional analysis alone will not suffice.").

ii. Preliminary Determination at Institution

In this case, challenged claims 7–10 recite the word "means." Specifically, claim 7 recites that "the electronic circuity [recited in claim 6, and 'operative to convert a signal . . . from an analog signal to a digital signal'] comprises digital signal processing means." Ex. 1001, 4:1–9. Claim 8 depends from claim 7 and recites that "the signal processing means adapts frequency characteristics" to various features, e.g., to a sound environment or to a patient's skull resonance. *Id.* at 4:10–15. Claim 9

recites "signal processing means for actively counteracting acoustic feedback problems." *Id.* at 4:16–19. And claim 10 recites "directivity means comprising at least one directivity dependent microphone and/or signal processing means." *Id.* at 4:20–25.

In the –1018 Petition, Petitioner stated that it "does not concede that the '040 Patent discloses adequate structure for performing the functions associated with any claimed 'means,'" and Petitioner reserved its right to argue, in other forums, that the "means" language is indefinite. Pet. 22.[9] Petitioner further argued that the '040 patent specification does not disclose "any specific structure or algorithm for performing the recited functions." *Id.* at 24. Accordingly, Petitioner proposed that we construe this limitation

[9] If a patent specification fails to disclose structure corresponding to a claimed function, in a claim subject to 35 U.S.C. § 112, ¶ 6, ordinarily that claim is indefinite under 35 U.S.C. § 112, ¶ 2. *See, e.g., In re Donaldson*, 16 F.3d 1189, 1194–95 (Fed. Cir. 1994) ("If an applicant fails to set forth [in the specification] an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by [§ 112 ¶ 2]."); *see also IPCom GmbH & Co. v. HTC Corp.*, 861 F.3d 1362, 1370 n.8 (applying *In re Donaldson* to an *inter partes* reexamination proceeding); *but cf.* 35 U.S.C. § 311(b) (restricting permissible grounds in *inter partes* review to "only . . . a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications"). Nevertheless, we may not cancel a claim in an *inter partes* review by finding that claim indefinite. Tr. 19:6–10; *see Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2141–42 (2016) ("[N]or does our interpretation enable the agency to act outside its statutory limits by, for example, canceling a patent claim for 'indefiniteness under § 112' in inter partes review."); *see also SAS Inst.*, 138 S. Ct. at 1358 ftnt. ("That an agency's improvisation might be thought by some more expedient than what the law allows . . . does nothing to commend it either, for lawful ends do not justify unlawful means." (citation omitted)).

as a "digital signal processor, such as hardware, software, or a hardware-software combination, for performing the claimed signal processing functions." *Id.*

In its Preliminary Response, Patent Owner did not address Petitioner's proposed constructions, stating that the "issues raised by this Preliminary Response do not depend on the proper interpretation of means plus function limitations in the claims." Prelim. Resp. 17.

In our Decision on Institution, we determined that Petitioner had not rebutted the presumption that 35 U.S.C. § 112, ¶ 6, applies to these claim limitations. Dec. on Inst. 10.[10] Therefore, according to our Rules governing *inter partes* review practice, Petitioner was required to "identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function," i.e., to construe the claim limitations. 37 C.F.R. § 42.104(b)(3). We determined that Petitioner failed to do so. Dec. on Inst. 11. Specifically, we determined that the portions of the Specification cited by Petitioner merely "reiterate the recited functions but do not provide any structure or algorithm for performing those functions." *Id.* (citing Ex. 1001, 2:63–3:8).

As we stated in our Decision, "[w]hen the specification of a challenged patent lacks sufficient disclosure of structure under 35 U.S.C. § 112, ¶ 6, the scope of the claims cannot be determined without speculation, and, consequently, the differences between the claimed invention and the asserted prior art cannot be ascertained." *Id.*; *see, e.g.*, *Fresenius*, 582 F.3d

[10] We also determined that Petitioner had not rebutted the presumption that claim 6, which does not recite the term "means," is *not* subject to 35 U.S.C. § 112, ¶ 6. Dec. on Inst. 8–9. *See infra* Section II.A.2.i.

at 1299–1300 (requiring a "structural analysis" when comparing means-plus-function limitations to prior art). Accordingly, because Petitioner had not met its burden of identifying structure corresponding to the claimed functions, we determined that claims 7–10 were not amenable to construction and could not be compared to the prior art. *Id.* Thus, we denied institution of an *inter partes* review of claims 7–10. *Id.*

iii. Post-Institution Briefing

As noted above, in *SAS Institute*, the U.S. Supreme Court held that, under 35 U.S.C. § 314, we may not institute an *inter partes* review on fewer than all claims challenged in a Petition, as we did in our Decision on Institution. Paper 32, 3. Accordingly, to comply with *SAS Institute*, we modified our Decision on Institution to include in this trial the challenges presented with respect to claims 7–10. Paper 33, 3. Our Order also authorized the parties to provide additional briefing regarding claims 7–10. *Id.* at 3–5.

Claim 7

Claim 7 recites: "the electronic circuity [recited in claim 6, and 'operative to convert a signal . . . from an analog signal to a digital signal'] comprises digital signal processing means." Ex. 1001, 4:1–9. Because claim 7 recites the word "means" and an associated function, we presume that § 112, ¶ 6 applies. *Williamson*, 792 F.3d at 1348–49. Neither Patent Owner nor Petitioner identify sufficient intrinsic or extrinsic evidence to rebut this presumption. Supp. Resp. 2–5; Supp. Reply 1–2.

In its supplemental briefing, Patent Owner contends that § 112, ¶ 6, does not apply to claim 7, because the claim does not recite a function. Supp. Resp. 3 (citing *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294,

1302 (Fed. Cir. 1999)). According to Patent Owner, the broadest reasonable interpretation of this limitation is "a digital signal processor." *Id.* (citing Ex. 2031 ¶¶ 31–32).

In its supplemental briefing, Petitioner states only that, without waiving "its right to argue for indefiniteness in district court, Petitioner respectfully submits that the Board can and should properly address the instituted grounds for claims 7–10 based on Patent Owner's broad constructions." Supp. Reply 2. At oral argument, Petitioner additionally contended that the likely indefiniteness of, *inter alia*, challenged claim 7 should not shield the patent from being evaluated with respect to the asserted prior art, even if the claims cannot be construed properly. Tr. 19:14–20:7.

We are not persuaded that claim 7 does not invoke 35 U.S.C. § 112, ¶ 6. "Digital signal processing," preceding the word "means" as recited in claim 7, clearly is a function, namely, the processing of digital signals. We are not persuaded by the argument of Patent Owner's counsel that this formulation does not invoke § 112, ¶ 6 because it is not written as "means *for* digital signal processing." Tr. 45:11–47:4. Such an argument elevates form over substance. Indeed, the Federal Circuit, sitting *en banc*, considered such a formulation in *Williamson*, and determined that § 112, ¶ 6, applied to the claimed "distributed learning control module," which also was written in "function-means/module" form, rather than "means/module-for-function" form. *Williamson*, 792 F.3d at 1349–50. Similarly, we are unpersuaded by the unsubstantiated argument of counsel that digital signal processing is not a function in *this* case, although it might be otherwise. Tr. 46:8–47:4.

Moreover, claim 7 recites that the "digital signal processing means" is part of the "electronic circuitry" recited in claim 6, which "convert[s] . . . an

analog signal to a digital signal." We recognize that claim 7 does not specify that the "digital signal processing means" is the sole element of the "electronic circuitry" recited in claim 6, i.e., claim 7 does not use "consisting of" or other limiting language. Nonetheless, the interplay between claims 6 and 7, especially when considered in light of the '040 patent specification, supports our understanding that "digital signal processing" is a function, one aspect of which includes converting analog signals to digital signals. Indeed, the '040 patent states that

> electronic circuitry 4 comprises means for converting the signal from the microphone 5 from an analog [signal] to a digital signal for the necessary signal processing. Such signal processing means can then be used for adapting for instance the frequency characteristics to individual differences in the head shadow effect, [etc.].

Ex. 1001, 2:66–3:6.

Similar to the "distributed learning control module" considered in *Williamson*, here, the prefix "digital signal processing" does not impart any sufficiently definite structure to the word "means." We have considered Dr. Rubinstein's testimony that, based on his personal experience, a person of ordinary skill in the art would have understood "digital signal processor" and "digital signal processing means" to be synonymous. Ex. 2031 ¶ 32. However, Dr. Rubinstein does not explain how or why "digital signal processing means" would have been understood as a name for a specific structure. Although Dr. Rubinstein references his experience "reading and writing articles in the field, and discussing the design and operation of various hearing devices with other [persons of ordinary skill in the art (POSAs)]," Dr. Rubinstein does not provide any evidence, for example, a contemporaneous "article[] in the field," to corroborate this otherwise

conclusory testimony. Nor does Dr. Rubinstein tie this opinion to the intrinsic record of the '040 patent at all. *See Williamson*, 792 F.3d at 1354 ("The testimony of one of ordinary skill in the art cannot supplant the total absence of structure from the specification."); *see also Default Proof Credit Card Sys. Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1302 (Fed. Cir. 2005) ("[W]hile it is true that the patentee need not disclose details of structures well known in the art, . . . the specification must nonetheless disclose some structure. . . . Because the specification of the '182 patent discloses no structure corresponding to the claimed function of the 'means for dispensing,' [the patentee] cannot use the declaration of its expert to rewrite the patent's specification." (citations omitted)); *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1332 (Fed. Cir. 2003) (discussing similar limits on declarant testimony). As such, we afford this testimony little weight. *See* 37 C.F.R. § 42.65(a); *In re Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.").[11]

In sum, the evidence of record is consistent with the presumption that 35 U.S.C. § 112, ¶ 6 applies to claim 7. Neither party has presented

[11] Petitioner's willingness to agree to Patent Owner's "broad construction" of this phrase, for purposes of this proceeding (Supp. Reply 2), does not absolve the panel of its obligation to determine the legally appropriate construction of the claim. Claim 7 recites the word "means," which invokes the presumption that § 112, ¶ 6, applies. On the record before us, which lacks supported testimony explaining why "digital signal processing means" would be understood as a "digital signal processor," we are not persuaded that the presumption has been rebutted.

sufficient evidence to rebut this presumption. Supp. Resp. 2–5; Supp. Reply 1–2.

Next, we construe the claim language. *Williamson*, 792 F.3d at 1351. As discussed above, the claimed function is "digital signal processing." Although Patent Owner takes the position that this limitation would be understood as a "digital signal processor," neither Petitioner nor Patent Owner have identified, in the specification, any structure, and, in particular, any disclosure of a "digital signal processor," that corresponds to and performs the recited function. Indeed, counsel for both parties acknowledged that the specification does not disclose a "digital signal processor" or any other structure for performing this function. Tr. 20:8–21:4 (Petitioner's counsel stating that he does not believe the phrase appears in the patent), 45:1–4 (Patent Owner's counsel stating that she does not believe the phrase appears in the specification), 47:10–16 (stating that "other than identifying digital signal processing means, there isn't any other structure disclosed," and referencing Dr. Rubinstein's opinion that a skilled artisan "would understand how to implement for . . . these claim embodiments").

We have reviewed the '040 patent specification, of which only 51 lines are devoted to describing the purported invention. Ex. 1001, 2:44–3:27. The 13 lines of the specification devoted to signal processing do not include any reference to a "digital signal processor" or any other structure for performing "digital signal processing." *Id.* at 2:66–3:8. Instead, the specification simply references "means" for performing the signal processing functions. *Id.* at 2:66, 3:2. That said, it is Petitioner's duty to identify the necessary structure. 37 C.F.R. § 42.104(b)(3).

Moreover, in order to avoid purely functional claiming, the corresponding structure of a means-plus-function limitation must be more than a general-purpose processor. *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008). The specification must disclose "enough of an algorithm to provide the necessary structure under § 112, ¶ 6." *Finisar Corp. v. The DirectTV Group*, 523 F.3d 1323, 1340 (Fed. Cir. 2008). The algorithm may be expressed as a mathematical formula, in prose, as a flow chart, or in any other manner that provides sufficient structure. *Williamson*, 792 F.3d at 1352. Here, however, Petitioner has not identified any such structure in the specification or the figures of the '040 patent to provide any kind of algorithm, whether in the form of a formula, prose, or flow chart.

The unsupported testimony of Dr. Rubinstein does not remedy the silence of the specification. Ex. 2031 ¶¶ 31–32. "The testimony of one of ordinary skill in the art cannot supplant the total absence of structure from the specification. The prohibition against using expert testimony to create structure where none otherwise exists is a direct consequence of the requirement that the specification adequately disclose corresponding structure." *Williamson*, 792 F.3d at 1354 (citations omitted).

Accordingly, for the foregoing reasons, we determine that claim 7 invokes 35 U.S.C. § 112, ¶ 6, and that Petitioner has failed to identify, in the '040 patent specification, structure that corresponds to the recited function of "digital signal processing."

Claim 8

Claim 8 recites: "the signal processing means adapts frequency characteristics to individual differences in an acoustic head shadow effect, to

a sound environment, to a resonance of the patient's skull, or to a hearing capacity of a functioning ear of the patient." Ex. 1001, 4:10–15. Again, because the claim recites the word "means" and an associated function, we presume that this claim invokes 35 U.S.C. § 112, ¶ 6. *Williamson*, 792 F.3d at 1348–49. Neither Patent Owner nor Petitioner identify sufficient intrinsic or extrinsic evidence to rebut this presumption. Supp. Resp. 2–5; Supp. Reply 1–2.

In its supplemental briefing, Petitioner relies on Patent Owner's asserted structure as identified for claim 7. Supp. Reply 1; *see* Pet. 22–24.

In its supplemental briefing, Patent Owner contends that "'the signal processing means' in claim 8 should be construed as noted for claim 7" because, "by using the word 'the,' this element in claim 8 plainly refers back to the 'digital signal processing means' in claim 7." Supp. Resp. 3–4. Thus, Patent Owner argues that we should construe this claim in accordance with its ordinary meaning as identified for claim 7. *Id.* at 4 (citing Ex. 2031 ¶ 33 (providing substantively identical testimony)).

We agree that claim 7 provides antecedent basis for "*the* signal processing means" in claim 8. However, as above, neither Petitioner nor Patent Owner have rebutted the presumption that §112, ¶ 6 applies to claim 7. Neither party provides any additional evidence regarding claim 8.

Patent Owner further contends that if claim 8 is determined to invoke § 112, ¶ 6, "[t]he specification of the patent clearly links the function recited in the foregoing limitation to the structure of electronic circuitry." *Id.* at 3 (citing Ex. 1001, 2:63–3:6).

We disagree. Claim 8 recites that the signal processing means performs at least one of four functions, i.e., it "adapts frequency

characteristics" of the hearing aid to (a) differences in head shadow effect, (b) a sound environment, (c) skull resonance, or (d) hearing capacity of a functioning ear. The cited portion of the specification discloses "electronic circuitry 4" and states that "signal processing means can then be used for adapting for instance the frequency characteristics," as claimed. Ex. 1001, 2:63–3:6. As discussed with claim 7, however, the specification does not refer to a digital signal processor for performing these functions. Nor does the specification disclose an algorithm or special processing that would be implemented to perform these functions.

Accordingly, for the foregoing reasons, we determine that claim 8 invokes 35 U.S.C. § 112, ¶ 6, and that Petitioner has failed to identify, in the '040 patent specification, any structure that corresponds to the recited function of "adapt[ing] frequency characteristics," as claimed.

Claim 9

Claim 9 recites: "the electronic circuity [recited in claim 6, and 'operative to convert a signal . . . from an analog signal to a digital signal'] comprises signal processing means for actively counteracting acoustic feed-back problems in the apparatus." Ex. 1001, 4:16–19. Because claim 9 recites the word "means" and an associated function, we presume that § 112, ¶ 6, applies. *Williamson*, 792 F.3d at 1348–49. Neither Patent Owner nor Petitioner identify sufficient intrinsic or extrinsic evidence to rebut this presumption. Supp. Resp. 2–5; Supp. Reply 1–2.

In its supplemental briefing, Petitioner relies on Patent Owner's asserted structure as identified for claim 7. Supp. Reply 1; *see* Pet. 22–24.

In its supplemental briefing, Patent Owner contends that this limitation should be construed in accordance with its ordinary meaning as "a

digital signal processor configured to actively counteract acoustic feedback problems in the apparatus." Supp. Resp. 4 (citing Ex. 2031 ¶ 34). However, Patent Owner fails to explain why § 112, ¶ 6, should not apply to this claim. Claim 9 explicitly recites "means for" performing a function, i.e., "actively counteracting acoustic feed-back problems." Supp. Resp. 4 (Patent Owner acknowledging this is a "recited function"). Indeed, claim 9 reflects the "means-for-function" language Patent Owner contends was required in claim 7. Tr. 45:13–46:10. Patent Owner's citation to Dr. Rubinstein's testimony, which simply incorporates opinions provided with respect to claims 7 and 8, is also unpersuasive to rebut the presumption, for the reasons discussed regarding those claims. Ex. 2031 ¶ 34.

Patent Owner further contends that, if claim 9 is determined to invoke § 112, ¶ 6, "[t]he specification of the '040 patent clearly links the recited function ('for actively counteracting acoustic feed-back problems') to the structure of electronic circuitry." *Id.* at 4 (citing Ex. 1001, 2:63–3:8).

We are not persuaded that the cited portion of the specification is sufficient to disclose the necessary structure. The cited portion of the specification discloses "electronic circuitry 4" and states that "[t]he signal processing means can also be used for actively counteracting acoustic feed-back problems." Ex. 1001, 2:63–3:8. As with claims 7 and 8, the specification does not refer to a digital signal processor for performing this function. Nor does the specification disclose an algorithm or special processing that would be implemented to perform this function. Petitioner identifies no other structure or disclosed algorithm.

As above, neither Petitioner nor Patent Owner has rebutted the presumption that §112, ¶ 6 applies to claim 9. Accordingly, for the

foregoing reasons, we determine that claim 9 invokes 35 U.S.C. § 112, ¶ 6, and that Petitioner has failed to identify, in the '040 patent specification, any structure that corresponds to the recited function of "actively counteracting acoustic feed-back problems."

Claim 10

Claim 10 recites: "[1] directivity means comprising at least one directivity dependent microphone and/or [2] signal processing means in the electronic circuitry." Ex. 1001, 4:22–24. Thus, because claim 10 recites the word "means" and associated functions, we presume that § 112, ¶ 6, applies. *Williamson*, 792 F.3d at 1348–49. Neither Patent Owner nor Petitioner identify sufficient intrinsic or extrinsic evidence to rebut this presumption. Supp. Resp. 2–5; Supp. Reply 1–2.

In is supplemental briefing, Petitioner again relies on Patent Owner's asserted structure. Supp. Reply 1; *see* Pet. 23–24.

In its supplemental briefing, Patent Owner contends that § 112, ¶ 6, does not apply, because claim 10 does not recite a function. Supp. Resp. 4–5 (citing *Rodime*, 174 F.3d at 1302). Relying on its previously proposed construction of "signal processing means" as "a digital signal processor," Patent Owner contends that a person of ordinary skill in the art would have understood this limitation to mean "a directivity dependent microphone [] and/or a digital signal processor." *Id.* at 5 (citing Ex. 2031 ¶ 35).

Patent Owner's argument that the claim does not recite a function is unpersuasive. "[S]ignal processing," preceding the word "means" as recited in claim 10, clearly is a function, namely, the processing of signals. For the reasons discussed above regarding claim 7, we are not persuaded that the

formulation of this limitation as "function-means," rather than "means-for-function" is dispositive.

In light of the full record developed during trial, we also understand "directivity," as the term is used in claim 10, to describe a function. The relevant discussion in the '040 patent specification states that "[s]uch signal processing means can then be used for adapting for instance the frequency characteristics to . . . sound direction." Ex. 1001, 2:66–3:6. Further, Dr. Rubinstein explains that "a directivity dependent microphone or signal processing means in the electronic circuitry" would be used "for example, to provide directivity of sound." Ex. 2031 ¶ 76; *see also*, *e.g.*, WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 358 (1985) (Ex. 3002) (defining "directivity" as "the property of being directional"; defining "directional" as, *inter alia*, "suitable for detecting the direction from which radio signals come or for sending out radio signals in one direction only"). Accordingly, "directivity means" is understood as "means for providing directivity of sound."

We recognize that claim 10 identifies a specific and discrete structure that *may* constitute the claimed "directivity means," i.e., a directivity dependent microphone. Ex. 1001, 4:22–23. However, claim 10 includes "and/or" language, such that the claim also covers "directivity means" in the form of "signal processing means," without the microphone. Here, the recitation of a "directivity dependent microphone" only explains the "directivity" function of the recited means; it does not address the "signal processing" recited in the claims. Therefore, the inclusion of a microphone in the claim language is insufficient to take the claim out of the ambit of § 112 ¶ 6, because of the "and/or" claim language. *Laitram Corp. v.*

Rexnord, Inc., 939 F.2d 1533, 1536 (Fed. Cir. 1991) ("The recitation of some structure in a means-plus-function element does not preclude the applicability of [§ 112, ¶ 6 when it] merely serves to further specify the function of the means. The recited structure tells only what the means-for-joining does, not what it is structurally.").

As in *Williamson*, the prefixes "signal processing" and "directivity" do not impart any structure to the word "means," and these words do not describe a sufficiently definite structure for performing the claimed function. We have considered the cited testimony of Dr. Rubinstein. Ex. 2031 ¶ 35. Dr. Rubinstein states that a person of ordinary skill in the art would have understood "directivity means" to include a "directivity dependent microphone (or directional microphone) and/or a digital signal processor." *Id.* ¶ 35. However, Dr. Rubinstein does not explain how or why this would be the understanding of a person of ordinary skill in the art or that such a person would equate the "directivity means" with a "directivity dependent microphone," and we find this testimony to be conclusory. As such, we afford this testimony little weight. *See* 37 C.F.R. § 42.65(a).

In sum, the plain claim language and the intrinsic record, as a whole, are consistent with the presumption that 35 U.S.C. § 112, ¶ 6, applies to these claim terms. Neither party has presented sufficient evidence to rebut this presumption.

Next, we construe the claim language. *Williamson*, 792 F.3d at 1351. As discussed above, the claimed functions are "providing directivity of sound" and "signal processing." Although Patent Owner takes the position that this limitation would be understood as "a directivity dependent microphone and/or digital signal processor," Patent Owner's counsel

acknowledged that the specification does not reference a "digital signal processor" at all. Tr. 45:1–4. We have reviewed the specification and we do not discern any structure identified as performing the signal processing function. The specification does not include any reference to a "digital signal processor" or any other structure. *Id.* at 2:66–3:8. Instead, the specification simply references "means" for performing the signal processing functions. *Id.* at 2:66, 3:2. Furthermore, the corresponding structure of a means-plus-function limitation must be more than simply a general-purpose processor, and neither the specification nor figures of the '040 patent provide any kind of algorithm, whether in the form of a formula, prose, or flow chart. *See generally* Ex. 1001; *Aristocrat*, 521 F.3d at 1333.

Moreover, although the claim identifies a directivity dependent microphone as an alternative structure to the "signal processing means," that these are identified *alternatives* suggests that the microphone is not corresponding structure for performing the "signal processing" function. Notably, neither Patent Owner nor Dr. Rubinstein argued that the claimed directivity dependent microphone is a structure capable of performing the signal processing function. *See* Supp. Resp. 4–5; Ex. 2031 ¶ 35 (opining that "directivity dependent microphone" is synonymous with "directional microphone," but not opining they perform a "signal processing" function); *Williamson*, 792 F.3d at 1354 (citations omitted) ("The testimony of one of ordinary skill in the art cannot supplant the total absence of structure from the specification.").

As above, neither Petitioner nor Patent Owner has rebutted the presumption that §112, ¶ 6 applies to claim 10. Accordingly, for the foregoing reasons, we determine that claim 10 invokes 35 U.S.C. § 112, ¶ 6,

and that Petitioner has failed to identify, in the ’040 patent specification, any structure that corresponds to the recited function of “signal processing” or “providing sound direction,” in the embodiment in which the “directivity means” includes only “signal processing means.”

iv. Petitioner’s Burden to Demonstrate Unpatentability by a Preponderance of the Evidence

In an *inter partes review* proceeding, it is Petitioner’s burden to “show with particularity why the patent it challenges is unpatentable” in light of the asserted prior art. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

Resolving the patentability of the challenged claims, *Graham v. John Deere Co.*, 383 U.S. 1 (1966), requires that we ascertain the “differences between the prior art and the claims at issue.” *Id.* at 17. More specifically, in the context of claims that invoke 35 U.S.C. § 112, ¶ 6, “a challenger who seeks to demonstrate that a means-plus-function limitation was present in the prior art must prove that the corresponding structure—or an equivalent—was present in the prior art.” *Fresenius*, 582 F.3d at 1299 (citing *Donaldson*, 16 F.3d at 1193). “[I]t is firmly established . . . that a structural analysis is required . . . [and] a functional analysis alone will not suffice.” *Id.*

As discussed above, we have determined that claims 7–10 invoke 35 U.S.C. § 112, ¶ 6, and that Petitioner has not identified, in the specification of the ’040 patent, any structure or algorithm corresponding to the claimed functions. If the scope and meaning of the claims cannot be determined without speculation, the differences between the challenged claims and the prior art cannot be ascertained. *See BlackBerry Corp. v.*

MobileMedia Ideas, LLC, Case IPR2013-00036, slip op. at 19–20 (PTAB Mar. 7, 2014) (Paper 65) (citing *In re Steele*, 305 F.2d 859, 862–63 (CCPA 1962) and reasoning that "the prior art grounds of unpatentability must fall, pro forma, because they are based on speculative assumption as to the meaning of the claims"). Because Petitioner has not identified structure corresponding to the functions recited in claims 7–10, we cannot ascertain the differences between the claimed invention and the asserted prior art, as required by *Graham v. John Deere*, because we cannot determine whether the prior art includes the corresponding structure or its equivalents.

Accordingly, we determine that Petitioner has not met its burden of demonstrating the unpatentability of claims 7–10 by a preponderance of the evidence.

2. Construction of Other Limitations

i. "electronic circuitry"

Claim 6 recites "electronic circuitry operative to convert a signal from a microphone . . . from an analog signal to a digital signal." Ex. 1001, 4:3–5. Petitioner contends that the '040 patent uses "'means' and 'circuitry' interchangeably," such that this limitation "may be interpreted as 'means plus function'" under 35 U.S.C. § 112, ¶ 6. Pet. 23. Petitioner also explains that the specification "refers to the electronic circuitry 4 (generally shown as a block in Figure 1) as having 'means for converting the signal from the microphone 5 from an analog signal to a digital signal." *Id.* at 22–23 (citing Ex. 1001, 2:63–3:8). Thus, Petitioner proposes that we construe this limitation as "an analog-to-digital converter as was known in the art as of the critical date." *Id.* at 23.

We presume that claim terms lacking the word "means" do not invoke § 112, ¶ 6. *Williamson*, 792 F.3d at 1349. That presumption may be overcome "if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites [a] 'function without reciting sufficient structure for performing that function.'" *Id.* (citing *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)).

In our Decision on Institution, we determined that Petitioner had not rebutted the presumption that this limitation does not invoke § 112, ¶ 6. Dec. on Inst. 8–9. Accordingly, we construed this phrase as "an analog-to-digital converter." *Id.* at 9; Ex. 1002 ¶¶ 39 ("[E]lectronic circuitry (4) . . . includes an A/D converter for 'converting the signal from the microphone 5 from an analog to a digital signal for the necessary signal processing.'" (quoting Ex. 1001, 2:66–3:2)), 152.

In the post-institution briefing, the parties do not provide additional argument or evidence regarding the construction of this phrase. As such, we maintain that the construction of this term set forth in our Decision on Institution is the broadest reasonable interpretation of the claim term.

ii. "for rehabilitation of unilateral hearing loss"

The preamble of claim 1 states, *inter alia*, "for rehabilitation of unilateral hearing loss." Ex. 1001, 3:29–33. In our Decision on Institution, we determined that express construction of this phrase was not required, because Petitioner had demonstrated sufficiently that the asserted prior art rendered obvious this phrase, even if considered limiting. Dec. on Inst. 7, 15–16; *see Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). We maintain that position, after consideration of the full record developed at trial. Nonetheless, we discuss Patent Owner's

arguments regarding the preamble, because they relate to arguments presented regarding the prior art. *See infra* Sections II.D.3.i., II.F.2.i.

Petitioner asserts that this phrase should not be given patentable weight because it is merely a statement of intended use. Pet. 19–20. According to Petitioner, the body of claim 1 fully sets forth all of the limitations of the claimed apparatus, and the phrase "for rehabilitation of unilateral hearing loss" "does not provide any distinct definition for structural limitations of the apparatus as recited in the body of the claim." *Id.*

Patent Owner contends that the preamble is limiting, and this phrase should be understood as requiring rehabilitation of unilateral hearing loss that is both "profound" and "sensorineural." PO Resp. 10–15. Patent Owner argues that the preamble gives life, meaning, and vitality to claim 1, because it "makes clear that the hearing aid apparatus is intended only for patients with *unilateral profound sensorineural hearing loss*." *Id.* at 11 (citing Ex. 1001, 1:8–11; Ex. 2004 ¶¶ 71–72).

"Whether to treat a preamble term as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (internal quotation marks omitted). "Absent clear reliance on the preamble in the prosecution history, or in situations where it is necessary to provide antecedent basis for the body of the claim, the preamble 'generally is not limiting.'" *Symantec Corp. v. Computer Assoc. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008). Preamble language that merely states the purpose or intended use of an invention generally is not treated as limiting the scope of a claim. *See Boehringer Ingelheim*

Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1345 (Fed. Cir. 2003); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

However, if the limitations in the body of the claim rely upon or derive essential structure from the preamble, then the preamble acts as a necessary component of the claimed invention, and is limiting. *See Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). Moreover, if the preamble recites a specific characteristic for a component of an invention recited in the body of the claim, then the preamble must be given patentable weight. *See, e.g., Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) (noting that a claim drafter may choose to use both the preamble and the body of the claim to define the subject matter of the claimed invention).

In this case, "for rehabilitation of unilateral hearing loss" merely states an intended use of the "hearing aid apparatus" defined by the claim. The claim body recites a structurally complete hearing aid, which includes a vibratory generating part and an implantable part that anchors the vibratory generating part to the patient's skull. Ex. 1001, 3:29–41. Accordingly, the claim does not rely upon the preamble to define the invention (i.e., a hearing aid), because that subject matter is recited completely in the body of the claim. The preamble simply presents the environment in which the structurally complete hearing aid may be used. *See, e.g., Boehringer*, 320 F.3d at 1345 ("An intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates."). Patent Owner's arguments reflect that this phrase is merely a statement of intended use. PO Resp. 11 ("[T]he

hearing aid apparatus *is intended only for patients* with unilateral profound sensorineural hearing loss" (emphasis altered)); *see also* Ex. 2004 ¶ 72.

Patent Owner also argues that the preamble defines the orientation of the hearing aid with respect to the side of the head with a non-functioning cochlea, making this phrase essential to understanding the invention. PO Resp. 11. According to Patent Owner, the preamble provides antecedent basis for the type of patient and the orientation of the device with respect to the "side" of the patient's head. *Id.* at 15.

We disagree. The body of claim 1 already "defines the orientation of the hearing aid apparatus with respect to the side of the head with a non-functioning cochlea" (PO Resp. 11), because it recites that the vibratory generating part is anchored to "the patient's skull bone behind an external ear *at the deaf side* of a patient." Ex. 1001, 3:38–41 (emphasis added). Likewise, the claim body specifies that the generated vibrations are transmitted "from a deaf side to the inner ear on the other side of the patient," thus, identifying the patient as one having "a deaf side" and an "other side." Ex. 1001, 3:34–37. Therefore, the preamble is not necessary to define the type of patient or the position of the device.

Patent Owner also argues that, without understanding this phrase as limiting, the hearing aid of claim 1 would be non-functional if used on patients with other types of hearing loss, for example, patients with bilateral deafness or without deafness on either side. PO Resp. 12–13.

We are unpersuaded by this argument. First, Patent Owner does not present any evidence in support of this argument. "Attorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974). Additionally, this argument ignores express limitations

recited in the body of claim 1, which require use with a patient that has a "deaf side" and an "other side," which strongly implies that such a patient has a *single* deaf side. *See* Ex. 1001, 3:29–41 (anchoring the hearing aid on a patient's "deaf side" and, thus, directing against use with patients having bilateral deafness or without deafness).

Patent Owner also argues that construing the preamble as limiting is consistent with the specification. PO Resp. 14–15 (citing Ex. 1001, 1:5–8, 2:3–5, 2:16–18). We recognize that the '040 patent specification describes "rehabilitation of patients with unilateral hearing loss, i.e. individuals with . . . a profound hearing loss in the inner ear on [one] side of the head," and states that prior art hearing aids were not "used for rehabilitation of . . . patients with single sided deafness." Ex. 1001, 1:5–8, 2:3–5; *see also* Ex. 2004 ¶ 32 (equating sensorineural hearing loss and single-sided deafness). Such disclosures, however, merely reflect intended uses of the referenced hearing aids. *Id.* at 1:5–8 ("intended for"), 2:3–5 ("used for").

Upon review of the entire record, in light of the parties' arguments, we determine that the phrase "for rehabilitation of unilateral hearing loss" is a statement of intended use, and does not limit the claim. Nonetheless, we determine that the prior art renders obvious the preamble language, even if this phrase were deemed limiting. *See infra* Sections II.D.3.i., II.F.2.i.

However, even if the preamble were considered limiting, Patent Owner has not persuaded us that the language "for rehabilitation of unilateral hearing loss" should be construed as requiring rehabilitating "sensorineural" or "profound" hearing loss. PO Resp. 11. First, the specification does not refer to sensorineural hearing loss at all. *See generally* Ex. 1001. Dr. Rubinstein opines that the "type of hearing loss

involving a profound hearing loss in the inner ear (the cochlea) or the auditory nerve . . . is referred to as 'sensorineural' hearing loss" or "single-sided deafness" ("SSD"). Ex. 2004 ¶ 32. However, even accepting that testimony, the '040 patent refers only to "profound hearing loss *in the inner ear*"; the specification does not discuss hearing loss associated with deficits of the auditory nerve. Ex. 1001, 1:10 (emphasis added); *see also* Ex. 2004 ¶¶ 40–41 (explaining that the inner ear (the cochlea) and the auditory nerve are different structures). Accordingly, we see no reason to import into the claim a limitation directed to "sensorineural" hearing loss, which is not discussed in the specification and which includes auditory nerve deficits not discussed in the '040 patent. *See* Ex. 2008, 81:4–18 (Dr. Popelka's opinion that sensorineural hearing loss may be caused by, for example, the lack of a functioning cochlea or a surgically severed nerve).

We also are unpersuaded by Patent Owner's construction of the preamble as requiring rehabilitation of "profound" hearing loss. PO Resp. 11. The claims of the '040 patent do not reference profound hearing loss. Although the specification describes "unilateral hearing loss" as including "a profound hearing loss in the inner ear," the specification does not utilize "words or expressions of manifest exclusion or restriction," indicating that we should import this limitation into the claims. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004); *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) ("Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition."); *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002) ("[A] court may not read into a claim a

limitation from a preferred embodiment, if that limitation is not present in the claim itself.").

Moreover, the evidence indicates that "unilateral hearing loss," recited in the preamble, can include non-profound hearing loss. Ex. 2004 ¶ 32 n.5 (defining "profound" hearing loss as a loss greater than 90 dB); Ex. 2008, 93:6–11 (opining that "profound" indicates magnitude, not type, of hearing loss). Thus, we decline to import that limitation into the claims. Ex. 2008, 75:8–19 (disputing that the '040 patent claims are directed to profound sensorineural hearing loss).

iii. "mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient"

Claim 1 recites "a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient." Ex. 1001, 3:34–37. Petitioner argues that this phrase "merely describes an intended or future use, and simply refers to a physical effect the claimed vibratory generating part is intended to create when worn by a patient." Pet. 20–21. Patent Owner argues that this phrase is limiting, and should be construed in accordance with its ordinary meaning, because it "defines the manner in which the vibratory generating part is positioned relative to the skull bone of the patient" and "requires that the vibrations be 'mechanically transmitted' through the skull bone." PO Resp. 15–17.

In our Decision on Institution, we determined that express construction of this phrase was not required, because Petitioner had demonstrated sufficiently that the asserted prior art satisfied this phrase, even if considered to be limiting, as argued by Patent Owner. Dec. on

Inst. 7, 16–18; *Vivid Techs.*, 200 F.3d at 803. Upon consideration of the full record developed during trial, we maintain that no express construction of this term is required. *See infra* Sections II.D.3.ii., II.F.2.ii.

iv. "being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient"

Claim 1 recites an "implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient." Ex. 1001, 3:38–41. Petitioner argues that this phrase "merely describes the manner in which a claimed apparatus is intended to be employed [and] does not differentiate the claimed apparatus from any prior art apparatus satisfying the claimed structural limitations." Pet. 22. Patent Owner argues that this phrase is limiting, and should be construed in accordance with its ordinary meaning, because it "defines the invention as including an implanted part that is osseointegrated into the skull bone in a particular location relative to the deaf side of the patient." PO Resp. 17–18.

In our Decision on Institution, we determined that express construction of this phrase was not required, because Petitioner had demonstrated sufficiently that the asserted prior art satisfied this phrase, even if considered to be limiting, as argued by Patent Owner. Dec. on Inst. 7, 18–19 *Vivid Techs.*, 200 F.3d at 803. Upon consideration of the full record developed during trial, we maintain that no express construction of this term is required. *See infra* Sections II.D.3.iii., II.F.2.iii.

v. "the frequency characteristics of the apparatus are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side"

Patent Owner contends that this phrase, appearing in claim 3, should be construed as "the frequency characteristics of the apparatus are

specifically adapted to account for the mechanics of the skull when transmitting vibrations in the skull bone from one side of the skull to the other side." PO Resp. 18–19 (underlining reflecting additions to the claim language). According to Patent Owner, the '040 patent specification indicates that the device's frequency characteristics are adapted to account for transcranial attenuation of high frequency sound. *Id.* (citing Ex. 1001, 2:56–62; Ex. 2004 ¶¶ 59–60).

Petitioner disputes Patent Owner's position, arguing that the claims do not reference skull mechanics or transcranial attenuation. Reply. 7. Petitioner also contends that this construction conflicts with the testimony of Dr. Rubinstein, who opined that the frequency characteristics of the device do not change even if the vibrations need not travel across the skull. *Id.* at 7–8 (citing Ex. 1121, 35:5–36:3 (discussing Figure 3 of the '040 patent)). Petitioner notes that the '040 patent fails to identify any specific circuitry or structure for adapting the frequency characteristics. *Id.* at 8.

We do not agree with Patent Owner's proposed construction, which improperly imports limitations into the claim. Claim 1 requires that "a vibratory generating part . . . generate[s] vibrations that are mechanically transmitted through the skull bone from a deaf side to . . . the other side." Claim 3 further limits claim 1 by requiring that the "frequency characteristics of the apparatus are specifically adapted to transmit vibrations" across the skull. Claim 3 does not further specify *why* or *how* this is done, i.e., to account for skull mechanics or transcranial attenuation, as argued by Patent Owner.

Nor does the specification explain that specific adaptation of frequency characteristics, as recited in claim 3, involves accounting for skull

mechanics or transcranial attenuation. The portion of the '040 patent cited by Patent Owner explains:

> As it is mainly the high frequencies which are attenuated at the bone conduction from one side of the skull to the other, the frequency characteristics of the hearing aid [are] preferably adapted for this application which means that the amplification is higher in the treble, frequencies above 1 kHz, than in the bass.

Ex. 1001, 2:56–61. Thus, if anything, the cited portion suggests that specifically adapting frequency characteristics, as recited in claim 3, simply involves amplifying treble frequencies higher than bass, as recited in claim 4.

Moreover, although this portion of the specification appears to explain that amplifying treble frequencies higher than bass frequencies, as recited by claim 4, accounts for the attenuation of high frequency sounds by the skull (*see id.*), Patent Owner does not propose construing *claim 4* to require that limitation. Rather, Patent Owner proposes inserting a mechanism and purpose into *claim 3* that is not required, and is not specifically supported by the specification. We are not persuaded that such a construction is appropriate.[12] Nothing in the cited portion of the specification associates the broader specific adaptation of frequency characteristics, recited in claim 3, with "account[ing] for the mechanics of the skull," as reflected by Patent Owner's construction. *See, e.g.*, Ex. 1121, 37:10–18. Thus, the specification does not support Patent Owner's argument that we should

[12] Additionally, the specification refers to skull mechanics, i.e., "specific resonance and attenuation characteristics in the skull," in relation to electronic circuitry 4, which converts a microphone signal from analog to digital. *Id.* at 2:63–3:2. Patent Owner has not explained whether this has any bearing on the limitation recited in claim 3. *See* Reply 8.

import into claim 3 the proposed limitation. *Liebel-Flarsheim*, 358 F.3d at 906 ("[T]he claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction'.").

We determine that the plain language of claim 3 is sufficiently clear on its face, in that it requires that the "frequency characteristics of the apparatus are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side," without specifying why or how that is performed. *See* Ex. 1121, 37:10–18 (Dr. Rubinstein testifying that the specification "talks about how the skull attenuates high frequency sounds relative to a low frequency sound as you cross from one side of the skull to the other [but] doesn't specify the precise nature of that frequency, other than the treble is more than bass"). We determine that no further construction is required. *Vivid Techs.*, 200 F.3d at 803.

vi. "power" and "induction"

Claim 11 recites that "power to the internal part is transmitted from the external part by induction." Ex. 1001, 4:31–32. Claim 12 depends from claim 11 and recites that "the internal part comprises a rechargeable battery arranged to be charged by induction from an external power supply." Ex. 1001, 4:33–36.

Patent Owner argues that "power" should be construed as "electric power." PO Resp. 20–21 (citing Ex. 2004 ¶¶ 61–63). Patent Owner contends that the specification discloses that the external part of the device includes a battery, wherein "power is transmitted to the implanted part 8 of the hearing aid by means of induction." *Id.* at 20 (quoting Ex. 1001, 3:9–14, Fig. 2). According to Patent Owner, "the powered components of the

implanted part require electric power and there are no wires running from the external part to the implantable part," therefore, "a POSA would readily understand that the implantable part requires electric power to be wirelessly transmitted from the external part to the implantable [part] by induction." *Id.* at 21.

Patent Owner also argues that "induction" should be construed as "electromagnetic induction." PO Resp. 21–24 (citing Ex. 2004 ¶¶ 64–69). Patent Owner relies upon the specification's discussion of Figure 3, which discloses "a rechargeable battery 10 which is charged by means of induction from an external power supply." *Id.* at 22 (quoting Ex. 1001, 3:15–18). According to Patent Owner, this "would refer to electromagnetic induction—the principle that makes inductive charging possible." *Id.* Patent Owner contends that a person of ordinary skill in the art "would have understood that transmitting power by induction would have required a transmitting conductor and a receiving conductor (*i.e.*, an inductive coupling)," to cause the production of voltage across the conductor and induce a current. *Id.* at 22–23, 23 n.7 (citing, e.g., Ex. 1009; Ex. 2013, 4).

Regarding both constructions, Petitioner disagrees. Petitioner points to the description of Figure 2 in the '040 patent, in which power is transmitted to the internal part by means of induction, but wherein the specification does not disclose any internal battery or other structure for inducing electric current in the implanted part. Reply. 18. Petitioner also provides a partial translation of the original Swedish filing that led to the '040 patent. *Id.* Petitioner contends that the original filing used the term "energin," meaning "energy," not "power." *Id.* at 18–19 (citing Ex. 1122; 1126, 9, 12; Ex. 1001, 1; Ex. 1010, 107–118). Petitioner also notes that the

specification does not utilize the term "electromagnetic." *Id.* at 19. Thus, Petitioner contends that it would be improper to construe "power" as "electric power," or "induction" as "electromagnetic induction."

Regarding "power," we agree with Petitioner. Excluding the description of Figure 3,[13] the specification utilizes the term "power" once, and without providing any more detail or specificity than the body of claim 11. Specifically, in discussing the embodiment of Figure 2, the specification states that "[t]he external part 7 then also comprises a battery 9 and the power is transmitted to the implanted part 8 of the hearing aid by means of induction." Ex. 1001, 3:11–14.

We are also persuaded by the partial translation of the original Swedish filing provided by Petitioner, which utilized the term "energin." Ex. 1122, 1. Petitioner shows that the Swedish filing is translated as: "[t]he external part 7 then contains a battery 9 and the *energy* is then transferred inductively to the implanted part 8 in the hearing aid." *Id.* at 3 (emphasis added). This evidence suggests that "power" should be read broadly, and should not narrowed to require only "electrical power." Accordingly, we do not adopt Patent Owner's construction of "power." We determine that further construction is not required. *Vivid Techs.*, 200 F.3d at 803. This conclusion is consistent with our determination, in our Decision on

[13] The specification's description of Figure 3 is not helpful in resolving the proper construction of terms appearing in claims 11 and 12, because Patent Owner states that claim 1 (from which these claims depend) does not encompass the embodiment of Figure 3. Tr. 26:17–20 (stating that claim 1 does not cover Figure 3). Accordingly, the Specification's description of Figure 3 (*see* Ex. 1001, 3:15–24) is not persuasive.

Institution, that "power" did not require "electric current," and that causing a magnet to vibrate was a transmission of power. Dec. on Inst. 14–16.

Regarding "induction," the '040 patent specification again utilizes the term only once (outside of its description of Figure 3), as quoted above. *See* Ex. 1001, 3:11–14. The '040 patent does not describe electromagnetic induction, an "inductive coupling," or transmitting and receiving conductors, for producing a voltage across the conductor and inducing a current. *See id.*; *cf.* PO Resp. 22–23. Rather, the implanted part is disclosed as including only a vibrator. Ex. 1001, 3:9–11.

Nonetheless, we agree with Patent Owner that the plain and ordinary meaning of "induction" is "electromagnetic induction." *See, e.g.*, Ex. 2004 ¶ 64 (opining that this would be the understanding of a person of skill in the art would); *see also* MICROSOFT COMPUTER DICTIONARY 270 (5th ed. 2002) (Ex. 3003) (defining "induction" as "The creation of a voltage or current in a material by means of electric or magnetic fields, as in the secondary winding of a transformer when exposed to the changing magnetic field caused by an alternating current in the primary winding"); IEEE 100 The Authoritative Dictionary of IEEE Standards Terms 550 (7th ed. 2000) (Ex. 3004) (defining "induction" as "The process of generating time-varying voltages and/or currents in conductive objects or electric circuits by the influence of the time-varying electric, magnetic, or electromagnetic fields").[14]

[14] Patent Owner provides a definition of "electromagnetic induction" to support its argument. PO Resp. 22 (citing Ex. 2013, 4). However, this definition presumes its conclusion, and is not persuasive as to the meaning of "induction," without the modifying word "electromagnetic."

Although we agree with Patent Owner that "induction" ordinarily means "electromagnetic induction," we do not read into claims 11 and 12 the additional requirements proposed by Patent Owner, e.g., "a transmitting conductor and a receiving conductor (*i.e.*, an inductive coupling)," or the actual "production of a voltage" and induction of a current in the implanted part of the device. PO Resp. 22–23. As discussed above, the '408 patent specification and its Figure 2 do not describe transmitting or receiving conductors, or the generation of voltage or the induction of current in the implanted part. Instead, the implanted part is described as including only a vibrator, without a receiving conductor or any components that require voltage or current. Accordingly, we adopt Patent Owner's construction of "induction" as "electromagnetic induction," but do not construe claims 11 and 12 as requiring transmitting or receiving conductors, or the actual generation of voltage or current in the implanted part. This conclusion is consistent with our determination, in our Decision on Institution, that the claims do not require "implanted structure (such as an internal coil)." Dec. on Inst. 14–16.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 102(b) if a prior art reference discloses every limitation of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present" in the single anticipating reference. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented 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." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of 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 skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham*, 383 U.S. at 17–18. When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic*, 815 F.3d at 1363. The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware*, 800 F.3d at 1378. To prevail, Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17.

Petitioner relies on Dr. Popelka's testimony and contends that a person of ordinary skill in the art would have, either, "at least a Master's degree in audiology or the equivalent thereof and at least 2 years of clinical experience in fitting such devices" for patients, or "at least a Bachelor's degree in electrical or computer engineering or the equivalent thereof and at least 2 years in audio signal processing for audiological products or designing such devices for use by patients." Pet. 17 (citing Ex. 1002 ¶ 32); *see also* –1019 Pet. 22–23 (same).

Patent Owner agrees with Petitioner's assessment of the level of skill in the art. PO Resp. 6. However, Patent Owner disagrees with what it understands to be Petitioner's implicit identification of the field of art. *Id.* "Petitioner[] appear[s] to characterize the technology field pertinent to the '040 patent as hearing aid devices generally, and bone-conducting hearing aid devices more specifically." *Id.* (citing Ex. 1002 ¶ 31; Ex. 1102 ¶ 31). According to Patent Owner, the field of art "should be limited to hearing aid devices used to treat patients with unilateral profound sensorineural hearing loss (*i.e.*, 'individuals with a normal or a slightly impaired hearing on one ear and a profound hearing loss in the inner ear on the other side of the head')." *Id.* at 6–7 (citing Ex. 1001, 1:9–11; Ex. 2004 ¶ 29).

Based on our review of the '040 patent, the types of problems and solutions described in the '040 patent and the applied prior art, and the cited testimony of Dr. Popelka and Dr. Rubinstein, we adopt Petitioner's

assessment of the level of skill in the art. Further, the applied prior art reflects this level of skill. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). We do not agree with Patent Owner that the field of art is as limited as Patent Owner argues. *See supra* Section II.A.2.ii. (rejecting Patent Owner's construction of the preamble of claim 1 to require rehabilitation of unilateral hearing loss that is both "profound" and "sensorineural").

D. Claims 4 and 5: Obviousness over the Combined Teachings of Vaneecloo and Carlsson

Petitioner contends that claims 4 and 5 of the '040 patent are unpatentable, under 35 U.S.C. § 103, as obvious over the combined teachings of Vaneecloo and Carlsson. Pet. 27–28, 36, 42 (chart). Patent Owner disputes Petitioner's contentions, focusing its arguments on claim 4. PO Resp. 31–42. For reasons that follow, we determine Petitioner has demonstrated that claims 4 and 5 are unpatentable by a preponderance of the evidence.

1. Overview of Vaneecloo (Ex. 1003)

Vaneecloo is an article entitled "Prosthetic Rehabilitation of Unilateral Anakusis: Study by stereo-audiometry," which discusses clinical and stereo-audiometric results for two patients with unilateral hearing loss who were treated with a "semi-implantable bone-anchored hearing aid (BAHA)," placed on the deaf side. Ex. 1003, 410.[15] According to

[15] We recognize that "BAHA" is a trademarked term. Reg. No. 2118182 (Dec. 2, 1997) (live). However, Vaneecloo utilizes this term without indicating whether it refers to a device manufactured by registered

Vaneecloo, the BAHA devices were "anchored directly in the bone" with "titanium fixture[s]" and were "designed to capture and transmit transcranially to the remaining functional ear the information received from the side of the anakusis." *Id.* at 410–12.[16]

Vaneecloo explains that, although low-pitched sounds bypass the patient's head with little attenuation, this is not the case on the deaf side, where "due to the diffraction effect, high-pitched sounds reach the ear opposite the source with an attenuation that increases proportionately with the frequency of the sound." *Id.* at 410. In patients implanted with the BAHA device, however, Vaneecloo reports that:

> [D]ue to the multidirectional control tests of the prosthetic gain, we found that the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for a significant rise in sound perception thresholds of frequencies between 1,000 and 4,000 Hz, when the source of the sound was located on the anakusis side of the auditory hemifield.

Id. at 415. Vaneecloo states that the tests were "performed with a fixed loudspeaker and a swivel chair," at 2000 Hz and 250 Hz. *Id.* at 414; *see also id.* at Figs. 11–12

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trademark owner Cochlear Bone Anchored Solutions AB (Patent Owner in this proceeding). For consistency with Vaneecloo's disclosure, we utilize the same term.

[16] The term "anakusic" or "anacusic" refers to a patient's deaf ear, and "contralateral" refers to a patient's non-deaf ear, in patients with unilateral hearing loss. Ex. 1002 ¶¶ 68, 70; Ex. 1003, 410, 415.

2. Overview of Carlsson (Ex. 1007)

Carlsson is an article entitled "On Direct Bone Conduction Hearing Devices," which discusses BAHA devices. Ex. 1007, Abstract. Carlsson explains that such devices transmit sound information "by percutaneous direct bone conduction," which transmits vibrations from the device to the skull. *Id.*; *see also id.* at 4, 10. According to Carlsson, "[a] skin-penetrating abutment is attached to an implanted titanium fixture situated behind the pinna. The abutment contains a bayonet coupling to which the BAHA is connected." *Id.* at 4–6, Fig. 1. The attached BAHA component includes, *inter alia*, a microphone and transducer. *Id.* at 18–20, Fig. 10.

According to Carlsson, BAHA devices present several advantages over the prior art, including superior technical performance, "increased speech intelligibility," and "improved wearing comfort." *Id.* at Abstract, 22.

3. Analysis of Claims 4 and 5

Claim 4 depends from claim 3, which in turn depends from claim 1. Claim 5 depends from claim 4.

i. "A bone-conducting bone-anchored hearing aid apparatus for sound transmission from one side of a patient's head to the patient's cochlea on another side of the patient's head for rehabilitation of unilateral hearing loss" (claim 1)

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious the preamble of claim 1, even if the preamble is considered to be limiting. Pet. 37. Petitioner contends that the bone-anchored hearing aid (BAHA) disclosed by Vaneecloo is implanted on a patient's deaf side, and captures and transmits vibrations across the skull, to the functional ear, treating unilateral hearing loss. *See, e.g., id.* at 25, 37

(citing Ex. 1003, Abstract, 411, 415; Ex. 1002 ¶¶ 68–71, 73, 90–91). Petitioner contends that Carlsson also describes that BAHA devices operate through direct bone conduction through the skull. *Id.* at 29, 37 (citing Ex. 1007, 4, 10, Fig. 10; Ex. 1002 ¶¶ 59, 92, 94).

Patent Owner does not dispute Petitioner's positions regarding Vaneecloo. PO Resp. 31–41. However, Patent Owner contends that Carlsson teaches away from treating profound hearing loss. *Id.* at 41.

We are persuaded by Petitioner's contentions. Vaneecloo teaches a "semi-implantable bone-anchored hearing aid (BAHA)" for use in patients with "unilateral anakusis," i.e., unilateral hearing loss. Ex. 1003, 410. Vaneecloo explains that the device "transmit[s] transcranially to the remaining functional ear the information received from the side of the anakusis." *Id.* at 411. Carlsson also teaches transmission of sound information through the skull by "percutaneous direct bone conduction." Ex. 1007, Abstract.

As discussed in Section II.A.2.ii., we do not read limitations regarding "profound" or "sensorineural" hearing loss into the claims. Accordingly, Patent Owner's argument that Carlsson teaches away from treating profound hearing loss is unpersuasive.

Thus, we are persuaded that the combined teachings of Vaneecloo and Carlsson provide for a bone-conducting, bone-anchored hearing aid (Ex. 1003, 410; Ex. 1007, Abstract) that transmits sound from one side of the patient's head to the patient's cochlea on another side of the patient's head (Ex. 1003, 410) for rehabilitation of unilateral hearing loss (*id.*).

ii. "a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient" (claim 1)

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious this limitation, even if "mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient" is limiting. Pet. 38. Petitioner contends that because Vaneecloo's BAHA device is implanted on the deaf side and transmits sound information to the functional ear, a person of ordinary skill in the art "would have recognized that such a BAHA device would have included a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from the deaf side to the inner ear on the other side of the patient." *Id.* at 38, 26 (citing Ex. 1003, 411–12; Ex. 1002 ¶¶ 70–74, 90, 91, 93–97, 99–103).

To the extent Vaneecloo does not teach specifically the vibratory generating part, Petitioner relies upon Carlsson. *Id.* at 33, 38–39. According to Petitioner, Carlsson teaches that "[s]ound is received by a microphone (element 3 in Fig. 10)," and "a vibratory generating part (see element 4 in Fig. 10 below) [is] arranged to generate vibrations." *Id.* at 31 (citing Ex. 1002 ¶¶ 60, 62; Ex. 1007, 17–19, Fig. 10). "Such sound vibrations are further transmitted to the functioning cochlea of the ear . . . ." *Id.* at 30–31, 39 (citing Ex. 1007, 4, Fig. 1; Ex. 1002 ¶¶ 59, 95–96).

Petitioner alleges that a person of ordinary skill in the art "would have found it obvious to configure the Vaneecloo BAHA device . . . to include [the] vibratory generating . . . parts of the Carlsson BAHA device." *Id.* at 34. Petitioner contends that such a modification would have combined known elements from similar devices in known ways to attain predictable

results and known benefits, such as improved comfort, aesthetics, and bone conduction. *Id.* (citing Ex. 1002 ¶¶ 104–110; Ex. 1007, 4, 9–10, 13, 22, Fig. 1).

Patent Owner does not dispute Petitioner's contentions regarding this limitation. PO Resp. 31–42.

We are persuaded by Petitioner's contentions. Vaneecloo teaches that the BAHA device is anchored to the skull at the deaf side and "transmit[s] transcranially to the remaining functional ear the information received" from the deaf side. Ex. 1003, 411. Although Vaneecloo does not explicitly state the mechanism by which the sound information is transmitted through the skull, i.e., by vibration, Petitioner has shown sufficiently that Carlsson teaches a BAHA device with a vibratory generating part that generates vibrations that are transmitted mechanically through the skull. Ex. 1007, 4 (explaining that skin is not included in the vibration transmission through the skull), 10, Fig. 10 (transducer 4); Ex. 1002 ¶ 62. We also are persuaded by Petitioner's position that modifying Vaneecloo's BAHA device to include a vibratory generating part, as taught by Carlsson, would have been obvious to a skilled artisan to, *inter alia*, improve the comfort, aesthetics, and effectiveness of the device. *See, e.g.*, Ex. 1007, Abstract, 22; Ex. 1002 ¶¶ 105, 107–108.

iii. "an implantable part operative to mechanically anchor the vibratory generating part, the implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient" (claim 1)

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious this limitation, even if "being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient" is

limiting. Pet. 39. Petitioner contends that Vaneecloo teaches a titanium implant that is implanted in the temporal bone near the deaf ear, to which the BAHA device is attached. *Id.* at 27, 39–40 (citing Ex. 1003, 412; Ex. 1002 ¶¶ 69–70, 98, 100). According to Petitioner, a person of ordinary skill in the art "would have recognized that the BAHA device of Vaneecloo included a titanium implant (an implantable part) configured to mechanically anchor the vibratory generating part [and] 'osseointegrated' in the patient's skull bone behind an external ear at the deaf side." *Id.* at 27 (citing Ex. 1002 ¶¶ 98–103, 112).

To the extent Vaneecloo does not teach adequately the implantable part, Petitioner also relies upon Carlsson. *Id.* at 33. According to Petitioner, Carlsson teaches "an implantable screw" to which the sound processor is attached, including the vibratory generating part (i.e., transducer 4). *Id.* at 40 (citing Ex. 1007, Fig. 1, Fig. 10; Ex. 1002 ¶¶ 59–60, 62, 100–101); *see also id.* at 28–29 (citing Ex. 1007, 4), 30–31.

Petitioner alleges that a person of ordinary skill in the art "would have found it obvious to configure the Vaneecloo BAHA device . . . to include . . . [the] implantable parts of the Carlsson BAHA device." *Id.* at 34. Petitioner contends that such a modification would have combined known prior art elements in known ways to attain predictable results and known benefits, such as improved comfort, aesthetics, and bone conduction. *Id.* at 34 (citing Ex. 1002 ¶¶ 104–110; Ex. 1007, 4, 9–10, 13, 22, Fig. 1).

Patent Owner does not dispute Petitioner's contentions regarding this limitation. PO Resp. 31–42.

We are persuaded by Petitioner's contentions. Vaneecloo teaches that the BAHA device is anchored to the temporal bone on the deaf side with a

titanium implant. Ex. 1003, 410 (anchoring on the deaf side), 411–412 (implanting 3 mm and 4 mm titanium fixtures in the patients' temporal cortexes). Although Vaneecloo does not specify that the attached BAHA device includes a vibratory generating part, as discussed above, Petitioner has shown sufficiently that Carlsson teaches a BAHA device having a vibratory generating part that is mechanically anchored to the patient's skull by an implantable part. Ex. 1007, 4–5 (describing osseointegration with a titanium fixture), Fig. 1 (depicting a screw); Ex. 1002 ¶ 59. We also are persuaded by Petitioner's position that modifying Vaneecloo's BAHA device to include an implantable part that mechanically anchors the vibratory generating part, as taught by Carlsson, would have been obvious to a skilled artisan to, *inter alia*, improve the comfort, aesthetics, and effectiveness of the device. *See, e.g.*, Ex. 1007, Abstract, 22; Ex. 1002 ¶¶ 105, 107–108

iv. "wherein the frequency characteristics of the apparatus are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side" (claim 3)

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious this limitation. Pet. 36, 41–42. Petitioner explains that because Vaneecloo's device "is designed to capture and transmit sound information" from the deaf side, through the skull, and to the functional ear, "it is evident that the frequency characteristics of the BAHA device are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side." *Id.* at 41. Additionally, Petitioner relies upon Vaneecloo's disclosure that "the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for significant rise in sound perceptions at

thresholds of frequencies between 1,000 Hz and 4,000 Hz, when the source of the sound was located on the anakusis side of the auditory hemifield." *Id.* at 36 (quoting Ex. 1003, 415), 41–42. Thus, Petitioner contends that "a POSA would have understood that the BAHA device of Vaneecloo adapted frequency characteristics for transmission from the patient's deaf side." *Id.* (citing Ex. 1002 ¶¶ 117–121, 123–126, 128–131).

Patent Owner argues that Vaneecloo's device does not account for transcranial attenuation but, rather, addresses only the head shadow effect—a different phenomenon than transcranial attenuation. PO Resp. 32 (citing Ex. 2004 ¶¶ 101, 102, 104–105), 36; *see also id.* at 31–41.[17]

We are persuaded by Petitioner's contentions. As discussed in Section II.D.3.ii., we are persuaded that the combined teachings of Vaneecloo and Carlsson teach the claimed vibratory generating part. Moreover, Vaneecloo explains that the device is "anchored directly in the bone ['on the anakusis side'] . . . to capture and transmit transcranially to the remaining functional ear the information received from the side of the anakusis." Ex. 1003, 411. Accordingly, the device is specifically adapted to transmit the generated vibrations through the skull from the anakusis side to the other side of the skull, because Vaneecloo explains that the device does just that. *See also* Ex. 1002 ¶¶ 73, 117 (opining that the frequency characteristics of Vaneecloo's device transmit vibrations from one side of

[17] We are unpersuaded by Patent Owner's argument that Carlsson does not teach or provide a reason to adapt frequency characteristics, because Petitioner does not rely upon Carlsson for such a teaching. PO Resp. 41; Pet. 41–42.

the skull to the other); Ex. 1003, 410 (transmitting to a functional side); Ex. 1007, 4, 10, Fig. 10.

Moreover, as discussed in Section II.A.2.v., we reject Patent Owner's construction of this limitation as requiring that the "frequency characteristics of the apparatus are specifically adapted to account for the mechanics of the skull," i.e., to account for transcranial attenuation. As such, we are unpersuaded by Patent Owner's argument that Vaneecloo fails to address transcranial attenuation.

v. "wherein the hearing aid apparatus amplifies treble frequencies more than base frequencies" (claim 4)
and
"wherein the treble frequencies have a frequency greater than 1 kHz" (claim 5)

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious claims 4 and 5. Pet. 27–28, 36, 42. According to Petitioner, Vaneecloo tested the hearing of patients implanted with the BAHA device, at 250 Hz and 2000 Hz. Pet. 27 (citing Ex. 1003, 415–416, Figs. 11–12). Petitioner relies upon Vaneecloo's disclosure that:

> [W]e found that the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for significant rise in sound perceptions at thresholds of frequencies between 1,000 Hz and 4,000 Hz, when the source of the sound was located on the anakusis side of the auditory hemifield.

Id. (quoting Ex. 1003, 415). Thus, Petitioner contends that a person of ordinary skill in the art "would have understood that the BAHA device of Vaneecloo amplified treble frequencies (greater than 1 kHz) more than bass frequencies." *Id.* at 27–28 (citing Ex. 1002 ¶¶ 73–74, 117–118), 36 (citing

also Ex. 1002 ¶¶ 118–121, 123–126, 128–131), 41 (citing also Ex. 1002 ¶ 70).

Patent Owner contends that neither Vaneecloo nor Carlsson amplify treble frequency more than bass. PO Resp. 31–42. According to Patent Owner, the tests disclosed by Vaneecloo are air conduction tests performed on the patient, not performed on the devices themselves, which measured only the patients' *perception* of hearing gain for treble frequencies when using the BAHA device, as compared to without the device. *Id.* at 32–36 (arguing that Figures 4–12 show that the ability to hear treble frequencies varied with the direction of the sound, due to air conduction). Although the patients experienced better perception in hearing gain with the BAHA device, Patent Owner contends that this says nothing about whether the device itself actually amplified treble frequencies more than bass frequencies, as claimed. *Id.* According to Patent Owner, this simply shows that the head shadow effect had been mitigated. *Id.* at 34.

Patent Owner alleges that, if Vaneecloo had modified the BAHA device in some manner, for example, by amplifying treble frequencies more than bass frequencies, Vaneecloo would have indicated so expressly. *Id.* at 34–36. Moreover, Patent Owner contends that the BAHA device in existence at the time—the Baha Classic 300—was not capable of being adapted to the specific hearing loss of the patient, and could not be adjusted, for example, to amplify treble frequencies more than bass frequencies. *Id.* at 35, 38–39.

Patent Owner also argues that the testimony of Dr. Popelka is conclusory, and is entitled to no weight because it lacks any corroboration. PO Resp. 36–41 (citing, e.g., Ex. 2008, 113:13–114:17, 118:10–22, 119:4–

120). Patent Owner alleges that Dr. Popelka's testimony is inconsistent with the capabilities of the devices available at the time. *Id.* at 38–39.

In the Reply, Petitioner responds with evidence that it contends demonstrates that prior BAHA devices were capable of treating unilateral profound sensorineural hearing loss and were capable of adapting the frequency characteristics to amplify treble more than bass. *See, e.g.*, Reply 9 (citing, e.g., Ex. 1124, 19; Ex. 1125, 2), 13–15.

We have reviewed the cited evidence of record, in light of the parties' arguments, and we are persuaded by Petitioner's contentions. We start with Vaneecloo's disclosure. Vaneecloo explains that low-pitched sounds "bypass[] the head with virtually no attenuation," but, "due to the diffraction effect, high-pitched sounds reach the ear opposite the source with an attenuation that increases proportionately with the frequency of the sound." Ex. 1003, 410.[18] Thus, Vaneecloo identifies a problem with attenuation of high frequency, i.e., treble, sounds, which Vaneecloo sought to address.

Vaneecloo also states that:

> we found that *the amplification* of the high-pitched sounds *captured* on the anakusis side and *perceived* by transcranial route by the contralateral ear *allowed for significant rise in sound perception thresholds of frequencies between 1,000 Hz and 4,000 Hz*, when the source of the sound was located on the anakusis side of the auditory hemifield.

[18] We are unpersuaded by Patent Owner's criticism that Vaneecloo addresses only head shadow effect, not transcranial attenuation. The claims do not expressly recite transcranial attenuation, and we do not find the claims otherwise limited to transcranial attenuation. *See supra* Section II.A.2.v.

Ex. 1003, 415 (emphasis added).[19] Thus, Vaneecloo references three distinct actions: (1) the high-pitched sounds are *captured* by the hearing aid on the anakusis (deaf) side of the patient; (2) the high-pitched sounds are *amplified*; and (3) the high-pitched sounds are *perceived* by the contralateral ear. *Id.*; *see also* Tr. 35:14–36:18 (indicating that Vaneecloo's hearing aid captures the high-pitched sounds but disputing that the hearing aid performs amplification). According to Vaneecloo, "the amplification of the high-pitched sounds . . . allowed for a significant rise in sound perceptions" between 1,000 and 4,000 Hz. Ex. 1003, 415.

We have considered Patent Owner's argument that the quoted passage of Vaneecloo indicates only that the *perception* of high-pitched sounds was amplified, but does not indicate that the device actually performed an amplification. PO Resp. 33–36 (citing Ex. 2004 ¶¶ 102, 106–113, 117–120). We find this argument inconsistent with the plain language of Vaneecloo's disclosure, which expressly references "the amplification of high-pitched sounds." *Cf. id.* at 34–36. If Vaneecloo intended to refer only to perception, it is unclear to us why "the amplification of the high-pitched sounds" is discussed; indeed, the sentence would more clearly relate only to *perception* if the phrase "the amplification of" were deleted. *See* Ex. 1003, 415 (e.g.,

[19] We recognize these tests were performed on the patient, not on the BAHA device itself. PO Resp. 33 (citing Ex. 2004 ¶¶ 107–109). However, Dr. Popelka testifies that such testing is an effective proxy for testing the device itself. Ex. 2008, 109:22–111:3 (testifying that such testing was "highly standardized"), 113:22–115:23 (testifying that patient responses are "direct evidence" of "prosthetic gains, how many dB amplified . . . does the device provide for those two frequencies"); Tr. 33:17–34:4. Neither Patent Owner nor Dr. Rubinstein have demonstrated that Dr. Popelka is incorrect in this assessment, or that such testing is inaccurate. *See* Ex. 2004 ¶¶ 107–109.

"we found that . . . the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for significant rise in sound perceptions at thresholds of frequencies between 1,000 and 4,000 Hz"). Patent Owner's argument appears to read out "the amplification of the high-pitched sounds" from the text, without a persuasive justification for doing so.

Dr. Rubinstein's Declaration similarly fails to explain why we should read out "the amplification of the high-pitched sounds" from Vaneecloo's text. *See* Ex. 2004 ¶¶ 104–111. Dr. Rubinstein opines that Vaneecloo is "describing how the sounds received by the patient are perceived, and because the head shadow effect is greater for high-pitched sounds than low-pitched sounds, the perceived benefit of the device is greater for high-pitched sounds than for low-pitched sounds." *Id.* ¶ 111. But again, however, this explanation ignores Vaneecloo's statement that "*the amplification of the high-pitched sounds* captured on the anakusis side and perceived by transcranial route by the contralateral ear *allowed for significant rise in sound perceptions* at thresholds of frequencies between 1,000 Hz and 4,000 Hz." Ex. 1003, 415. We are likewise unpersuaded by Dr. Rubinstein's observation that some patients would experience an improvement in hearing threshold *without* amplification of treble frequencies more than base. Ex. 2004 ¶ 110. This statement, again, ignores Vaneecloo's disclosure that "the amplification of the high-pitched sounds" caused improved perception of high-frequency sounds. Ex. 1003, 415.

Dr. Popelka testifies that he understands this passage to mean that the BAHA device amplified treble frequencies more than bass frequencies. Ex. 1002 ¶¶ 73–74, 117, 123 ("Vaneecloo discloses that the implanted

BAHA hearing aid amplified high-pitched sound."), 124; *see also* Ex. 2008, 113:7–21 (also relying upon Vaneecloo's Figure 12). Dr. Popelka also testifies that prior art publications, such as a 1997 article published by Marshall Chasin (Ex. 1008), support this understanding. *Id.* ¶ 118. For example, Dr. Popelka relies upon Chasin's disclosure of a 1997 BAHA device—the Baha Classic 300—with "low frequency tone control, and high frequency tone control," which constitute "signal processing means where, for example, low or high frequency sounds can be measured and controlled based on individual needs." *Id.* (citing Ex. 1008, 89); Ex. 1008, 89 (discussing the Baha Classic 300, which includes "more potentiometers (overall gain, low frequency and high frequency tone control)").[20]

During his deposition, Dr. Popelka further testified that Vaneecloo's BAHA device, upon receipt from the manufacturer, "is set to amplify a broad range of frequencies equally across that range . . . and the manufacturer also provides adjustments for that frequency region by adjustments on the device that the person fitting it can do." Ex. 2008, 116:3–8. Although Dr. Popelka testifies that Vaneecloo does not specify the precise values of the frequency adjustments that were made for the patients in Vaneecloo's study, "one would expect them to do some adjustments with the high frequencies because both patients had slight high frequency losses in the good ear. So the usual case would be for an adjustment to accommodate . . . the slight mild-to-moderate high-frequency losses."

[20] Patent Owner's argument that Chasin did not treat "unilateral profound sensorineural hearing loss" is unpersuasive because the claims do not require such treatment, and Petitioner does not rely on Chasin for teachings regarding treatment of unilateral hearing loss. PO Resp. 42; Pet. 42.

Ex. 2008, 116:9–19; *but see id.* at 117:3–6 (acknowledging that it is possible that a patient could have a subjective improvement without amplifying treble more than bass), 118:20–22 (acknowledging that Vaneecloo did not report the values of amplification). Dr. Popelka testifies that "it would be outside of standard clinical practice to not adjust" the treble and bass frequencies, and that, for the specific patients tested by Vaneecloo, "it would be [the] standard of care to amplify the highs more than the lows" to "compensate for the patient's slight decrease in sensitivity on the good ear." *Id.* at 117:7–12, 119:4–120:22 (citing Ex. 1003, Figs. 2–3).

We credit the testimony provided by Dr. Popelka in both the Declaration and deposition, and find that it is consistent with Vaneecloo's disclosure and with the capabilities of BAHA devices of the time, as reported by Chasin. Ex. 1002 ¶¶ 73–74, 117–118, 123–124; Ex. 1008, 89; *see also infra* pages 65–67 (discussing capabilities of the Baha Classic 300). Moreover, Dr. Popelka's deposition testimony regarding the standard of care for the specific patients studied by Vaneecloo is supported by Vaneecloo's description of the hearing loss experienced by those patients. Ex. 2008, 116:9–120:22 (citing Ex. 1003, Figs. 2–3). Thus, we find that Dr. Popelka provides a sufficient basis for his opinions. *Cf.* PO Resp. 36–41.

The majority of Patent Owner's briefing concerns Dr. Rubinstein's opinion that BAHA devices of the time, i.e., the Baha Classic 300, were not capable of amplifying high frequency sounds, despite Vaneecloo's discussion of "the amplification" of those sounds, as quoted above. We have considered these arguments and the cited portions of Dr. Rubinstein's Declaration. PO Resp. 35–39; Ex. 2004 ¶¶ 112–122. However, we are persuaded that the evidence indicates that the devices were capable of such

adjustments and that such adjustments were an intended part of the device fitting process. *See also* Ex. 2008, 116:9–120:22 (Dr. Popelka's testimony regarding the standard of care).

Before examining that evidence, however, we again review the claim language. Claim 4 recites that the device "amplifies treble frequencies more than base frequencies." The parties do not construe this language explicitly, and we determine that explicit construction is not necessary, except to note that the parties agree that attenuation of base frequencies is an amplification of treble frequencies, because the amount of bass is reduced relative to treble, such that treble is more pronounced, i.e., amplified. PO Resp. 38; Reply 14; Tr. 17:1–7, 42:2–42. For example, Patent Owner states that "the BAHA Divino was the first BAHA device that was capable of amplifying treble frequencies more than bass." PO Resp. 38 (citing Ex. 2004 ¶ 111; Ex. 2022), 28 n.9 (citing Ex. 2027, 6). Thus, Patent Owner admits that the Divino performed the amplification required by claim 4. Tr. 36–20–22. The exhibits describing the Divino, as cited by Patent Owner, however, do not discuss "amplif[ying] treble frequencies," but, instead, refer to adjustments made to the low frequency, i.e., bass, controls. *See* Ex. 2027, 6 ("[T]he audiologist will set the [Divino] tone and AGCo controls to suit your needs by *increasing or decreasing the low frequency output* and/or compression threshold.") (emphasis added); Ex. 1124, 16 (describing Divino tone control adjustment as "decreas[ing] the low frequency sound"); *see also* Ex. 2022, 3 ("[T]he Divino is functionally equivalent to the BAHA. . . . [T]he BAHA Divino with digital sound processing is substantially equivalent to devices already on the market."); Ex. 1124, 19 (describing Baha Classic 300 tone control adjustment as "decreas[ing] the low frequency sound").

Accordingly, we understand that amplifying treble frequencies may include filtering/decreasing/attenuating bass frequencies.

To support its argument that devices of the time were incapable of amplifying treble frequencies more than bass frequencies, Patent Owner offers Exhibit 2015, a Baha Classic 300 User Manual. PO Resp. 35. Patent Owner characterizes this device as including only rudimentary switches and controls, such as a volume control and tone switch. *Id.*; *see also* Ex. 2015, 3. We have considered this evidence, but find it less persuasive than other exhibits discussing the Baha Classic 300. First, Exhibit 2015 is a User Manual. As such, we find it to be less pertinent than other literature, especially when considering frequency adjustments that would be implemented by a clinician, not a patient. *Compare* Ex. 2015, *with* Exs. 1124, 1125. Second, Exhibit 2015 does not teach or suggest that the Baha Classic 300 was incapable of frequency adjustment; it simply does not present details of how adjustments were made. *Compare* Ex. 2015, *with* Exs. 1124, 1125.

By contrast, the Baha Audiological Manual (Exhibit 1124) explains that when fitting the Baha Classic 300 to the patient, it should be tested to determine "which of the positions, N or L [of the tone switch], the patient prefers," as well as "which tone control (H) . . . setting the patient prefers." Ex. 1124, 19. The Manual further explains that by adjusting the tone control (H), the low frequency response can be adjusted to decrease low frequency sound, i.e., a "bass cut." Likewise, the Baha Classic 300 Instructions for Audiology Assistants (Exhibit 1124) explains that "[t]he hearing aid can be adjusted to the appropriate frequency response." Ex. 1125, 2. For example, "the low-frequency response can be adjusted in order to increase (towards

H_{max}) or decrease (toward H_{min}) the *treble sound relative to the bass*." *Id.* (emphasis added). Thus, Exhibits 1124 and 1125 demonstrate that the Baha Classic 300 was capable of amplifying treble frequencies more than bass frequencies, including by decreasing the low frequency sound, and that the device manufacturer intended the device to accommodate the patient's hearing loss.[21] *Contra* PO Resp. 35; *see also* Ex. 2008, 116:9–120:22 (Dr. Popelka's testimony regarding the standard of care); *see also* Ex. 1002 ¶ 118 (citing Chasin's disclosure of the Baha Classic 300).

During the oral argument, counsel for Patent Owner argued that the "Influence of Tone Control" graph appearing in Exhibit 1125 demonstrates that the Baha Classic 300 was not capable of amplifying treble frequencies more than bass. Tr. 37:5–39:16 (discussing Ex. 1125, 1). In the absence of declarant testimony explaining the pertinence of this graph,[22] we are unpersuaded by this attorney argument, in light of the exhibit's express disclosure that "the low-frequency response can be adjusted in order to increase . . . the treble sound relative to the bass." Ex. 1125, 2. This disclosure is consistent with other evidence of record, as discussed above. Ex. 1124, 19; Ex. 1008, 6; Ex. 1007, 13 (describing a "tone control with first-order filters for bass and treble attenuation"); Ex. 2008, 116:9–120:22.

In summary, the evidence indicates that Vaneecloo appreciated that, when treating unilateral hearing loss, high-frequency sounds were heavily

[21] The Baha Classic 300 Data Sheet (Exhibit 1123) explains that the device was used to treat single-sided deafness and unilateral, profound sensorineural hearing loss. Ex. 1123, 2.

[22] Patent Owner did not request a Sur-Reply, or an opportunity to respond to Petitioner's Reply evidence.

attenuated (Ex. 1003, 410); that Vaneecloo found that "the amplification of the high-pitched sounds . . . allowed for a significant rise in sound perception thresholds" of those sounds (*id.* at 415); that BAHA devices in existence at the time of Vaneecloo's study were capable of amplifying high-frequency sounds more than bass sounds (*e.g.*, Ex. 1124, 19; Ex. 1125, 2); that audiologists using such devices were instructed to determine which frequency settings the patient prefers (*id.*); and that amplifying high-frequency sounds more than bass sounds would have been the standard of care for the patients included in Vaneecloo's study, due to their particular hearing losses (Ex. 2008, 116:9–120:22).

4. Alleged Objective Evidence of Nonobviousness

Patent Owner argues that evidence of non-obviousness exists. PO Resp. 55–57 (citing Ex. 2004 ¶¶ 136–140). We consider this evidence together with the evidence for and against the obviousness of claims 4 and 5, discussed above.[23] For example, Patent Owner contends that a long-felt, but unsolved, need existed in the art regarding treatment of unilateral, profound, sensorineural hearing loss with BAHA devices. *Id.* at 55. According to Patent Owner, BAHA devices were first introduced in Europe in the 1970s or 1980s, but were used "primarily" to treat conductive hearing loss, despite a worldwide recognition that limited treatment options existed for profound, sensorineural hearing loss. *Id.* at 55. Yet, according to Patent Owner, no one suggested using a BAHA device to treat this condition, and no one

[23] Patent Owner presents these arguments separately from the arguments directed to specific claim limitations. *See* PO Resp. 55–57. Our conclusions regarding Patent Owner's arguments apply equally to all challenged claims.

suggested modifying the frequency characteristics of a BAHA device to amplify treble more than bass, until the '040 patent. *Id.* at 55–56.

Patent Owner further contends that this field was unpredictable and risky—involving invasive surgery and extensive recovery—such that it would not have been obvious to modify existing BAHA devices, which were approved for treating conductive hearing loss, for a distinctly different impairment. *Id.* Finally, Patent Owner contends that "prior attempts to use bone conduction to treat unilateral profound sensorineural hearing loss failed," as demonstrated by Hough. PO Resp. 57.

We have considered Patent Owner's arguments, and the cited testimony of Dr. Rubinstein, but we are not persuaded that Patent Owner puts forth sufficient objective evidence of nonobviousness to overcome the teachings of the prior art. The majority of Patent Owner's arguments concern the purportedly long-felt need, and the failure of existing devices, to treat "unilateral profound sensorineural hearing loss." However, as discussed above, the claims are not restricted to rehabilitation of unilateral hearing loss that is "profound" and "sensorineural." *See supra* Section II.A.2.ii. Nonetheless, evidence of record demonstrates that existing BAHA devices were used at the relevant time to treat "unilateral hearing loss," as claimed (Ex. 1003, 410 (BAHA used to treat "unilateral anakusis"); Ex. 1012, 44 (Audiant Bone Conductor (ABC) used to treat "unilateral . . . conductive hearing loss")), as well as to treat "unilateral profound sensorineural hearing loss," as referenced by Patent Owner (Ex. 1012, 45 (ABC used to treat "unilateral sensorineural deafness"); Ex. 1123, 2 (Baha Classic 300 used to treat "unilateral, profound sensorineural hearing loss")).

Moreover, we agree with Petitioner that these arguments concern alleged aspects only of claim 1, which was disclaimed by Patent Owner. Reply 24.

We also are unpersuaded by Patent Owner's argument that "no one (not even the experts in this proceeding)—until the '040 patent—suggested modifying the frequency characteristics of a BAHA device to amplify treble frequencies more than bass as a means for compensating for transcranial attenuation." PO Resp. 56. As discussed in Section II.A.2.v., the claims do not address transcranial attenuation. Moreover, we are persuaded by the evidence discussed in Section II.D.3.v., which shows sufficiently that the prior art recognized this problem and taught the amplification of treble frequencies more than bass frequencies, prior to the critical date of the '040 patent.

5. Summary

For the foregoing reasons, we are persuaded that Petitioner has demonstrated, by a preponderance of the evidence, that claims 4 and 5 would have been unpatentable over the combined teachings of Vaneecloo and Carlsson, and that a person of ordinary skill in the art would have found it obvious to modify the prior art as proposed. We have considered Patent Owner's arguments and cited evidence to the contrary, but we are persuaded that a preponderance of the evidence of record supports Petitioner's contentions. Patent Owner's weaker evidence of nonobviousness, *see supra* Section II.D.4, is insufficient to offset Petitioner's stronger evidence of obviousness.

E. Claim 6: Obviousness over the Combined Teachings of Veneecloo, Carlsson, and Leysieffer

Petitioner contends that claim 6 of the '040 patent is unpatentable, under 35 U.S.C. § 103, as obvious over the combined teachings of Vaneecloo, Carlsson, and Leysieffer. Pet. 46–50, 51 (chart). Patent Owner disputes Petitioner's contentions. PO Resp. 43–44. For reasons that follow, we determine Petitioner has demonstrated that claim 6 is unpatentable by a preponderance of the evidence.

1. Overview of Leysieffer (Ex. 1009)

Leysieffer is a Canadian Patent Publication entitled "Implantable System for Rehabilitation of a Hearing Disorder." Ex. 1009, (54). Leysieffer teaches a partially implantable hearing aid system including wireless telemetry means that transmit data from an external unit to an implantable component to permit an operating program or parameter to be modified or replaced while the component is implanted. *Id.* at (57), 9:27–30, Figs. 1, 3 (telemetry system 125). Leysieffer's device also includes battery 60 within implant housing 56, wherein the battery may be recharged by induction. *Id.* at 10:20–22, 13:10–11, 14:10–11, 14:29–15:2, Fig. 3.

2. Analysis of Claim 6

Claim 6 further recites "electronic circuitry operative to convert a signal from a microphone of the hearing aid to the vibratory generating part from an analog signal to a digital signal." Ex. 1001, 4:1–5. Petitioner contends that Leysieffer teaches a hearing aid that includes "electronic circuitry with signal conversion with specific components in Fig. 1 including microphones 10a-10n and A/D converter 130." Pet. 51 (citing Ex. 1009, 11; Ex. 1002 ¶¶ 152–156); *see also id.* at 46–47. Petitioner contends that a

person of ordinary skill in the art would have found it obvious "to include an analog-to-digital converter," as taught by Leysieffer, in the device rendered obvious by Vaneecloo and Carlsson. *Id.* at 49–50. Petitioner contends that such a modification would have combined known prior art elements of similar devices in known ways to achieve predictable results and known benefits associated with digital processing, such as, for example, real time and multi-channel audio signal processing, and feedback avoidance. *Id.* at 49–51 (citing Ex. 1002 ¶¶ 155–156, 158–160, 162).

Patent Owner argues that "[a] bone-anchored hearing device would only benefit from digital sound processing of sound . . . if the bone-anchored hearing device could be tailored for a patient's individual hearing impairment." *Id.* at 44; *see also id.* at 43 (citing Ex. 2004 ¶¶ 128, 132–134). Patent Owner alleges that bone-anchored hearing aids prior to the critical period were used "primarily" to treat conductive hearing loss, such that there would be no reason to tailor the device to the patient. *Id.*

We are persuaded by Petitioner's contentions. Leysieffer discloses that "[t]he external acoustic signal is received via one or more acoustic sensors (microphones) 10a to 10n and is converted into electrical signals," which are routed to module 40 for preprocessing, then routed to analog-to-digital converter 130, and then routed to "digital signal processor 141 (DSP) which executes the intended function of the hearing implant." Ex. 1009, 11. We are persuaded by Petitioner's argument that modifying the BAHA device of Vaneecloo and Carlsson to include an analog-to-digital converter as taught by Leysieffer would have been obvious to a skilled artisan, *inter alia*, to obtain advantages associated with digital processing, as explained by Petitioner. *See, e.g.*, Pet. 49–51; Ex. 1002 ¶¶ 155–156.

As discussed above regarding claims 4 and 5, the evidence of record establishes that existing BAHA devices were capable of being specifically adapted to the hearing loss of the patient (Ex. 1124, 19; Ex. 1125, 2) and were not used only for treatment of conductive hearing loss (Ex. 1123, 2 (treating "unilateral, profound sensorineural hearing loss")). As such, we are unpersuaded by Patent Owner's arguments.

3. Summary

For the foregoing reasons, we are persuaded that Petitioner has demonstrated, by a preponderance of the evidence, that claim 6 would have been unpatentable over the combined teachings of Vaneecloo, Carlsson, and Leysieffer, and that a person of ordinary skill in the art would have found it obvious to modify the prior art, as proposed. Patent Owner's weaker alleged evidence of nonobviousness is insufficient to offset Petitioner's stronger evidence of obviousness. *See supra* Section II.D.4 (*see* footnote 24).

F. Claim 11: Anticipation by Hough

Petitioner contends that claim 11 of the '040 patent is unpatentable, under 35 U.S.C. § 102(b), as anticipated by Hough. –1019 Pet. 28–35. Patent Owner disputes Petitioner's contentions. PO Resp. 45–52. For reasons that follow, we determine Petitioner has demonstrated that claim 11 is unpatentable by a preponderance of the evidence.

1. Overview of Hough (Ex. 1012)

Hough is an article entitled "Long-Term Results for the Xomed Audiant Bone Conductor," which discusses clinical use of the Xomed Audient Bone Conductor hearing aid (the "ABC" device). Ex. 1012, 43. According to Hough, the ABC device "utilizes transcutaneous inductive

electromagnetic energy from an external processor," which contains a microphone, an amplifier, and an electromagnetic coil, "to cause vibrations of an implanted osseointegrated rate earth magnet screwed into the temporal bone. This vibration, in turn, produces hearing by bone conduction," by providing "vibratory energy directly to the cochlea." *Id.* at 43–44, 48 (explaining that the magnets produce "bone vibrations from the inductive coils and electromagnetic fields"). Hough explains that the ABC device is approved for use in patients with unilateral or bilateral conductive hearing loss. *Id.*; *but cf. id.* at 45 (noting "equivocal" and "inconsistent" results for unilateral hearing loss).

2. Analysis of Claim 11

Claim 11 depends from independent claim 1.

i. "A bone-conducting bone-anchored hearing aid apparatus for sound transmission from one side of a patient's head to the patient's cochlea on another side of the patient's head for rehabilitation of unilateral hearing loss" (claim 1)

Petitioner contends that Hough discloses the preamble of claim 1, even if the preamble is considered to be limiting. –1019 Pet. 30. Petitioner contends that the ABC device is implanted on a patient's deaf side and transmits vibrations across the head to the non-deaf side, for treating unilateral sensorineural deafness. *See, e.g., id.* at 32–33 (citing Ex. 1012, 44–45; Ex. 1102 ¶¶ 73–74, 91–94).

Patent Owner does not dispute Petitioner's contentions regarding the preamble. PO Resp. 45–52; *but see* Section II.G.1.

We are persuaded by Petitioner's contentions. Hough explains that the ABC device was "approved for use in patients" with "unilateral . . .

conductive hearing loss," and also was tested on "a significant number of patients with unilateral sensorineural deafness." Ex. 1012, 44–45. In use, "sound energy [is] transmitted by bone conduction across the head from a microphone on the deaf side (across the skull to the normal ear)." *Id.* at 45.

ii. "a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient" (claim 1)

Petitioner contends that Hough discloses this limitation, even if "mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient" is limiting. –1019 Pet. 30. Petitioner contends that the implanted magnet of the ABC device is a vibratory generating part that generates vibrations that are transmitted from the deaf side to the inner ear of the other side of the patient. *Id.* at 31, 33 (citing Ex. 1012, 43–44; Ex. 1102 ¶¶ 73–75, 90–95, 99–102).

Patent Owner does not dispute Petitioner's contentions regarding this limitation. PO Resp. 45–52.

We are persuaded by Petitioner's contentions. Hough explains that an external electromagnetic coil creates "alternating electromagnetic fields [that] cause the magnet implanted in the temporal bone to vibrate, producing vibratory energy directly to the cochlea." Ex. 1012, 44; *see also id.* at 45 (discussing conduction of sound energy "across the head from . . . the deaf side"), 48.

iii. "an implantable part operative to mechanically anchor the vibratory generating part, the implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient" (claim 1)

Petitioner contends that Hough discloses this limitation, even if "being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient" is limiting. –1019 Pet. 30. Petitioner contends that the orthopedic screw of the ABC device is an implantable part that is mechanically anchored to the implanted magnet. *Id.* at 30, 34 (citing Ex. 1012, 43–45; Ex. 1102 ¶¶ 73–74, 90–91, 93–94). Petitioner contends that the orthopedic screw is osseointegrated in the patient's skull behind the ear on the deaf side of the patient. *Id.*

Patent Owner disputes Petitioner's contentions. PO Resp. 46–48. Specifically, Patent Owner argues that Hough's orthopedic screw does not anchor the external coil of the ABC device, which Patent Owner argues is part of the claimed vibratory generating part. *Id.* at 46–47. According to Patent Owner, because the external electromagnetic coil *causes* the implanted magnet to vibrate, the external coil is part of the "vibratory generating part," and, therefore, must be anchored to the implantable part (i.e., the screw). *Id.* at 47 (arguing that the magnet "does not vibrate . . . on its own," without the external coil) (citing, e.g., Ex. 2004 ¶¶ 79–80).

We are persuaded by Petitioner's contentions. *See* Pet. 31, 33. As Hough explains, it is the implanted magnet that is "arranged to generate vibrations that are transmitted mechanically through the skull bone," as claimed. *See* Ex. 1012, 44 ("[A]lternating electromagnetic fields cause the magnet implanted in the temporal bone to vibrate, producing vibratory energy directly to the cochlea."), 48 ("[T]he magnets do produce . . . bone

vibrations."); Ex. 1102 ¶ 99. Thus, we agree with Petitioner that the implanted magnet disclosed by Hough satisfies the recited vibratory generating part. We also are persuaded that the identified vibratory generating part is mechanically anchored by an implantable part, as claimed. Hough explains that the implanted magnet is "attached to an orthopedic screw . . . [and] implanted by a very precise double-tapping orthopedic procedure . . . . The double tapping and the application of the screw in the temporal bone results in an extraordinarily secure osseointegrated union with the bone of the skull." Ex. 1012, 44 (stating that the processor is placed "behind the ear"). Hough discloses that, for unilateral hearing loss, the device is located on the deaf side. *Id.* at 45.

We have considered Patent Owner's argument, and the cited testimony of Dr. Rubinstein. PO Resp. 46–47; Ex. 2004 ¶¶ 79–80. That Hough's implanted magnet does not *begin* to vibrate on its own, as Patent Owner argues, is not dispositive because the claim does not require that the vibratory generating part independently initiate vibrations, and the claim does not preclude vibrations from being initiated by another element, e.g., an external electromagnetic coil. Thus, the fact that the external coil causes the implanted magnet to vibrate does not transform the external coil into the claimed "vibratory generating part." It is undisputed that the structure that outputs the vibrations that are "mechanically transmitted through the skull bone" is the implanted magnet. Ex. 1012, 44; Ex. 2004 ¶ 74 ("[A]lternating electromagnetic fields cause the implanted magnet to vibrate, which produces vibrations that directly stimulate the cochlea."); *cf.* Ex. 2004 ¶¶ 79–80.

iv. "wherein the implantable part and the vibratory generating part comprise an internal part" (claim 11)

Petitioner contends that Hough discloses this limitation. –1019 Pet. 34. Petitioner contends that the implantable part and vibratory generating part are osseointegrated into the skull, and the ABC device includes an internal part and external part. *Id.* at 30–31, 34.

Patent Owner argues that because the electromagnetic coil, which causes the magnet to vibrate, is external to the skull, and the screw is internal, the vibratory generating part and implantable part together do not comprise an "internal part." PO Resp. 48–49.

We are persuaded by Petitioner's contentions. Hough explains that the orthopedic screw (the implantable part) and internal magnet (the vibratory generating part) are "implanted in the skull," i.e., they comprise "an internal part." Ex. 1112, 44. As discussed in Section II.F.2.iii., we are persuaded by Petitioner that the internal magnet is the vibratory generating part, without the external coil.

v. "the hearing aid apparatus further comprising[] an external part comprising a microphone and a battery" (claim 11)

Petitioner contends that Hough discloses this limitation. –1019 Pet. 34. Petitioner contends that the ABC device includes an external part having a microphone, amplifier, and external coil. *Id.* at 31, 34 (citing Ex. 1012, 44; Ex. 1102 ¶¶ 73–74, 91, 93, 99–101). Petitioner further contends that it would have "been apparent" to a person of ordinary skill in the art that the ABC device "necessarily included a battery to power various components therein, including the microphone, amplifier and the external

coil." *Id.* at 31–32, 34–35 (citing Ex. 1102 ¶¶ 75, 99–102; Ex. 1011,[24] 316; Ex. 1012, 43–44).

Patent Owner does not dispute Petitioner's contentions regarding this limitation. PO Resp. 45–52.

We are persuaded by Petitioner's contentions. Hough specifies that the ABC device "has an external processor containing a microphone, an amplifier, and an electromagnetic coil." Ex. 1012, 44. Further, Petitioner has shown that a battery would have been present inherently in the external part to power its components, including the microphone, amplifier, and electromagnetic coil. *See* –1019 Pet. 31–32, 34–35. For example, Dr. Popelka testifies that, "[a]lthough a battery is not explicitly mentioned, it was well known in the art that the external part of ABC device as described in Hough (Ex. [1012]) necessarily included a battery to power the electronic components." Ex. 1102 ¶¶ 75, 100. Dr. Popelka bases his opinion on a prior art publication cited by the Hough reference, which explicitly discusses the presence of a battery. *Id.* ¶ 75 (citing Ex. 1011, 316); Ex. 1011, 316 ("The external processor was first packaged in a small wearable case, powered by a 9-volt battery."), Fig. 1 (identifying a "battery power supply"). We credit Dr. Popelka's unrebutted testimony.

vi. "wherein power to the internal part is transmitted from the external part by induction" (claim 11)

Petitioner contends that because the external inductive coil creates alternating electromagnetic fields, which cause the implanted magnet to

[24] In the –1019 Petition, Petitioner provided this document as Exhibit 1111. For convenience, we cite to the version of this exhibit provided in IPR2017-01018, i.e., Exhibit 1011.

vibrate, power is transmitted from the external part to an internal part by induction. –1019 Pet. 28–29, 35 (citing Ex. 1012, 44; Ex. 1102 ¶¶ 73, 91, 93–94, 100).

Patent Owner disputes Petitioner's position. PO Resp. 49–52 (citing Ex. 2004 ¶¶ 64–65, 82–86). Patent Owner argues that Hough utilizes an electromagnetic coil to produce electromagnetic energy, which causes the implanted magnet to vibrate, but does not transmit any power, as claimed. *Id.* at 50. According to Patent Owner, transmitting power "necessarily requires two conductors—an external transmitting conductor and an internal receiving conductor," such that an electrical current is induced in the conductor. *Id.* at 50–51. Patent Owner argues that in Hough's device, "there is no coil or any electrical components that generate or use an electric current," and "there is no implanted structure (such as an internal coil) . . . capable of converting variations in a magnetic field into current." *Id.* at 51. Patent Owner states that "it cannot be said that induction is occurring unless [Hough's external] coil is working in conjunction with a receiving coil to take energy from that alternating electromagnetic field and convert it back into current." *Id.* at 51–52. Patent Owner also argues that Dr. Popelka's testimony is conclusory and entitled to no weight. *Id.* at 49–50.

We are persuaded by Petitioner's contentions. Hough discloses that the ABC device "utilizes transcutaneous *inductive electromagnetic energy* from an external processor to cause vibrations of an implanted osseointegrated rare earth magnet." Ex. 1012, 43 (emphasis added), 48. Given this express disclosure, we are persuaded that transmitting inductive electromagnetic energy from the external part to the internal part, which induces vibration of the implanted magnet, constitutes transmission of

vibratory power by induction, as claimed. That the transmitted energy is not received by an implanted coil to generate a current is not dispositive, because it is not required by the claims. *See* Section II.A.2.vi.

We have considered Patent Owner's arguments (PO Resp. 49–52), and the cited testimony of Dr. Rubinstein (Ex. 2004 ¶¶ 64–65, 82–86), but we determine that they are not commensurate with the language of claim 11. Moreover, we find that Patent Owner's positions are not consistent with the disclosure of the '040 patent. As discussed in Section II.A.2.vi., we do not adopt Patent Owner's proposed construction of "power." And, although we agree that the plain and ordinary meaning of "induction" is "electromagnetic induction," that is clearly disclosed by Hough. Ex. 1012, 43 ("inductive electromagnetic energy"). As discussed in Section II.A.2.vi., neither the '040 patent claims nor the specification support Patent Owner's argument that transmitting power by induction "necessarily requires two conductors—an external transmitting conductor and an internal receiving conductor," to "convert[] variations in a magnetic field into current." PO Resp. 50–51. Claim 11 broadly requires that power is transmitted from the external part to the internal part via induction; it does not require structure such as an "external transmitting conductor" or an "internal receiving conductor." Nor does it require the conversion of magnetic fields into electric current, the generation of electric current, or the use of electric current, as Patent Owner argues. *See* Ex. 1001, 4:26–32.

Indeed, Hough's structure appears very similar to that disclosed in Figure 2 of the '040 patent, in which "power is transmitted to the implanted part 8 of the hearing aid by means of induction." *Id.* at 3:11–14. The '040 patent does not describe any kind of conductors for converting variations in

magnetic field into current. *See id.*; *cf.* PO Resp. 50–52. Rather, the implanted part is disclosed as including only a vibrator. *Compare* Ex. 1101, 3:9–11 (explaining that the internal part includes an unspecified vibrator), *with* Ex. 1012, 44 (explaining that the internal part includes a vibrator, i.e., the implanted magnet).

3. Summary

For the foregoing reasons, we are persuaded that Petitioner has demonstrated, by a preponderance of the evidence, that claim 11 is anticipated by Hough.

G. Claim 12: Obviousness over the Combined Teachings of Hough and Leysieffer

Petitioner contends that claim 12 of the ’040 patent is unpatentable, under 35 U.S.C. § 103, as obvious over the combined teachings of Hough and Leysieffer. –1019 Pet. 36–40. Patent Owner disputes Petitioner’s contentions. PO Resp. 52–55. For reasons that follow, we determine Petitioner has demonstrated that claim 12 is unpatentable by a preponderance of the evidence.

1. Analysis of Claim 12

Dependent claim 12 depends from dependent claim 11, and recites that “the internal part comprises a rechargeable battery arranged to be charged by induction from an external power supply.” Ex. 1001, 4:33–36. Petitioner contends that it would have been obvious to modify the ABC device disclosed by Hough, “so that the implanted part includes a rechargeable battery as taught by Leysieffer” because this modification would have involved “nothing more than combining known prior art elements in known ways, with no change in their respective functions, to

yield predictable results." –1019 Pet. at 38 (citing Ex. 1102 ¶¶ 109–113). Petitioner contends further that a person of ordinary skill in the art would have "recognized that using [a] rechargeable battery, and charging such a battery via induction from an external unit, extends service life and avoids replacement of a standard (non-chargeable battery)." *Id.* at 38–39 (citing Ex. 1009, 8:8–11; Ex. 1102 ¶¶ 78, 108–109); *see also id.* at 39 (explaining that the modification also "would have satisfied a demand for improving known medical devices to attain predictable, beneficial results," including smaller size and improved aesthetics).

Patent Owner argues that a person of ordinary skill in the art would not have modified Hough's device to include an implanted rechargeable battery because Hough's device does not include any implanted components that require power, i.e., Hough's implanted components include only a magnet and screw. PO Resp. 53–54. Thus, Patent Owner contends that such a modification would require "substantially modifying the device." *Id.* at 53. Similarly, Patent Owner notes that Hough does not include an internal receiving conductor and, therefore, is not capable of charging a rechargeable battery by induction. *Id.* at 54.

Patent Owner also argues that Hough teaches away from using the device to treat patients with unilateral, profound, sensorineural hearing loss, and that adding a rechargeable battery would not make the device any more suitable for treatment of these patients. *Id.* at 53–54.

We are persuaded by Petitioner's contentions. Leysieffer discloses a hearing aid system with an implanted "rechargeable electrochemical cell which can be recharged from the outside, for example, by means of inductive coupling." Ex. 1009, 10:20–22; *see also id.* at 14:29–15:2.

Leysieffer explains that the system includes external and internal components to permit such charging. *See id.* at 14:29–15:2 (disclosing external coil 121 and internal battery 60 having "a power receiving circuit for implant-side preparation of recharging energy"), Fig. 3 (depicting external coil 121 and implanted battery 60).

Moreover, Petitioner presents articulated reasoning with rational underpinning to support its conclusion that a person of ordinary skill in the art would have been motivated to modify Hough's ABC device to include an internal rechargeable battery as taught by Leysieffer. For example, Petitioner contends that "moving processing and control functionality from an external part to the implantable could effectively reduce power (battery) requirements of the external part, thus facilitating designs with smaller size and thereby improving aesthetics of the external part being worn by the patient." –1019 Pet. 39 (citing Ex. 1102 ¶¶ 112, 113; Ex. 1120, 4 (noting customer preference for smaller and less conspicuous devices)). Thus, Petitioner has shown reasonably that such a modification would improve the size and aesthetics of the system. *See* Ex. 1009, 3:30–4:1 (noting that prior art hearing aids "must be worn visible outside on the body in the area of the ear," which "stigmatize[s] the wearer"), 8:8–11; Ex. 1102 ¶¶ 109–110, 112–113; Ex. 1120, 4.

We have considered Patent Owner's arguments, but are persuaded that Petitioner has met its burden. First, we recognize that Hough's device does not include any implanted components that require power. PO Resp. 53–54; *see also* Ex. 1001, Fig. 2 (implanted part also not including any implanted components that require power). However, Petitioner has demonstrated that modifying Hough's device to include an implanted rechargeable battery has

other benefits, besides powering implanted components. As Petitioner explains, "moving processing and control functionality from an external part to the implantable [part] could effectively reduce power (battery) requirements of the external part, thus facilitating designs with smaller size and thereby improving aesthetics of the external part being worn by the patient." –1019 Pet. 39. Thus, we are persuaded that a person of ordinary skill in the art would have been motivated to utilize an implantable rechargeable battery as taught by Leysieffer, despite the absence of implanted components that require power, to improve the size and aesthetics of the external part of the device. This position is supported by Dr. Popelka's testimony (Ex. 1102 ¶ 112), Leysieffer's disclosure (Ex. 1009, 3:30–4:1), and a contemporaneous publication in the field (Ex. 1120, 4).

Second, although Hough does not include an internal receiving conductor and, therefore, is not capable of charging a rechargeable battery by induction, PO Resp. 54, the combination of Hough and Leysieffer includes such components for charging by induction. *See* Ex. 1009, 14:29–15:2; Pet. 37–38; *see also* Ex. 1001, Fig. 2 (implanted part also not including a receiving conductor or a rechargeable battery). The test for obviousness is what the combined teachings of the references as a whole would have suggested to those of ordinary skill in the art, not merely what Hough disclosed. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Additionally, although we do not disagree with Patent Owner's contention that the proposed modification would require "substantially modifying the device" (PO Resp. 53), that alone does not demonstrate that the combination would have been non-obvious. We are persuaded, by the evidence discussed above, that the field recognized a problem associated with bulky external components, and we are persuaded that Petitioner has presented a reasoned basis for the proposed modification. "[T]he fact that [Hough and Leysieffer may] not be combined by businessmen for economic reasons is not the same as saying that it could not be done because skilled persons in the art felt that there was some technological incompatibility that prevented their combination. Only the latter fact is telling on the issue of nonobviousness." *Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983).

Finally, we are unpersuaded by Patent Owner's argument that Hough teaches away from using the device to treat patients with unilateral, profound, sensorineural hearing loss, and that adding a rechargeable battery would not make the device any more suitable for treatment of these patients. PO Resp. 53–54. We recognize Hough's statement that the device was FDA approved for conductive hearing loss, and that the device showed only "equivocal" results when used for patients with unilateral sensorineural hearing loss, such that the authors of Hough joined the Food and Drug Administration in not recommending its use for such patients. Ex. 1012, 44–45. However, as discussed in Section II.A.2.ii., the claims do not recite "unilateral profound sensorineural hearing loss."

2. Summary

For the foregoing reasons, we are persuaded that Petitioner has demonstrated, by a preponderance of the evidence, that claim 11 would have been unpatentable over the combined teachings of Hough and Leysieffer, and that a person of ordinary skill in the art would have found it obvious to modify the prior art as proposed. Patent Owner's argument that the proposed modification would substantially modify the device is insufficient to offset Petitioner's evidence of obviousness. *See supra* Section II.D.4 (*see* footnote 24).

H. Assignor Estoppel

We are unpersuaded by Patent Owner's argument (*see* PO Resp. 57–58), that "[t]he doctrine of assignor estoppel prevents Petitioner[] from challenging the validity of [the] '040 patent in this, and in any other, proceeding." In a precedential opinion, binding on this panel, the Board rejected the applicability of the doctrine of assignor estoppel to *inter partes* review proceedings. *Athena Automation Ltd. v. Husky Injection Molding Syt. Ltd.*, Case IPR2013-00290, slip op. at 12–13 (PTAB Oct. 25, 2013) (Paper 18) (precedential) ("[W]e are not persuaded that assignor estoppel, an equitable doctrine, provides an exception to the statutory mandate that any person who is not the owner of a patent may file a petition for an *inter partes* review."); *see* Reply 25–26.

I. Constitutionality of Inter Partes *Review*

Patent Owner objects to the use of *inter partes* reviews as unconstitutional based, at least, upon the reasons presented in the petition for certiorari that was granted in *Oil States Energy Services, LLC v. Greene's*

Energy Group, LLC. PO Resp. 58–59. On April 24, 2018, the U.S. Supreme Court upheld the constitutionality of *inter partes* review; thus, Patent Owner's arguments are moot. *Oil States Energy Servcs. LLC v. Greene's Energy Grp., LLC*, 138 S.Ct. 1365, 1370 (2018); *see* Reply 26.

III. MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude (Paper 43), in which Patent Owner contended that Exhibit 1131, provided with Petitioner's Supplemental Reply, was presented belatedly and modifies the assertions presented in the Petition. Paper 43, 4–5. Patent Owner also contends that it has been afforded no opportunity to respond to this evidence. *Id.* at 6; *see also* Paper 46, 2 (denying Patent Owner's Alternative Motion to Sur-Reply, which was filed without authorization); 37 C.F.R. § 42.20(b) ("A motion will not be entered without Board authorization. Authorization may be provided in an order of general applicability or during the proceeding."). Petitioner filed an Opposition to the Motion. Paper 50.

As discussed above, *see supra* Section II.A.1.v., we determine that Petitioner has not met its burden of demonstrating the unpatentability of claims 7–10 over the asserted prior art, because Petitioner failed to identify, in the specification of the '040 patent, any structure corresponding to the functions recited in claims 7–10. This failure prevents us from evaluating the asserted prior art with respect to the claims. In reaching this conclusion, our Final Written Decision does not rely on Exhibit 1131.

As such, we *deny* Patent Owner's Motion to Exclude as moot.

IV. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated that challenged claims 4–6, 11, and 12 of the ’040 patent are unpatentable by a preponderance of the evidence, but that Petitioner has not demonstrated that challenged claims 7–10 are unpatentable, by a preponderance of the evidence.

V. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 4–6, 11, and 12 of the ’040 patent are unpatentable;

FURTHER ORDERED that claims 7–10 of the ’040 patent have not been shown to be unpatentable;

FURTHER ORDERED that Patent Owner’s Motion to Exclude (Paper 43) is *denied* as moot; and

FURTHER ORDERED that, because 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.

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