

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
Patent 7,043,040 B2

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

WIEKER, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

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 (“the challenged claims”) 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. Paper 6 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” *See also* 37 C.F.R § 42.4(a) (“The Board institutes the trial on behalf of the Director.”). Taking into account the arguments presented in the Preliminary Response, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in challenging claims 1–6 and 13 of the ’040 patent. As such, we institute an *inter partes* review as to these claims, but not with respect to claims 7–10.

B. Related Proceeding

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

Claims 1, 11, and 12 of the '040 patent are also the subject of Case IPR2017-01019, which Petitioner filed concurrently with this Petition.

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 the deaf-side ear,] and the sound is transmitted via the skull bone to the cochlea (inner ear) of this poor ear.

Id. at 1:45–58. According to the '040 patent, however, these devices were not used for patients with unilateral hearing loss, i.e., profound hearing loss in only one ear. *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.

Fig. 1

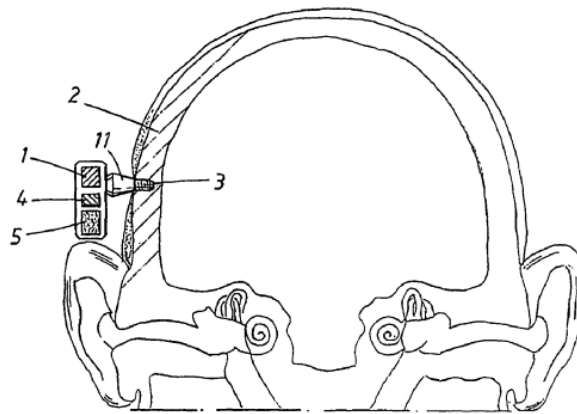


Figure 1 depicts a patient's skull with an attached hearing aid. *Id.* at 2:33, 2:44–50. Skin penetrating spacer 11 is anchored to skull bone 2 by fixture 3. *Id.* at 2:50–53. A housing at the opposite end of spacer 11 includes vibrator 1, microphone 5, and electronic circuitry 4. *Id.* at 2:50–55. Because high frequencies are attenuated during 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, as shown in Figures 2 and 3, reproduced below. *Id.* at 2:34–39.

Fig. 2

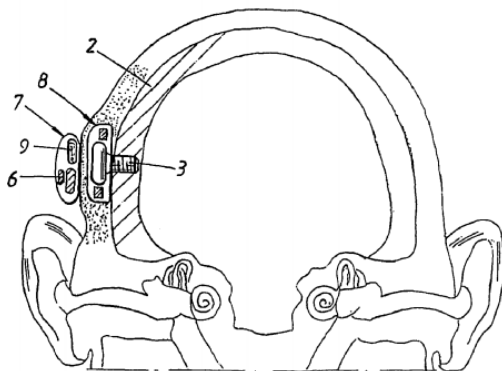
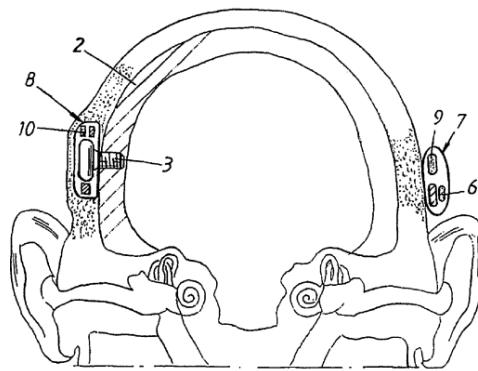


Fig. 3



Figures 2 and 3 depict schematic views of a patient's 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 alternate embodiment shown in Figure 3, implantable part 8 also includes rechargeable battery 10, which is charged by induction from an external power supply. *Id.* at 3:15–18.

D. Illustrative Claim

Challenged claims 1 and 13 are independent, and claim 1 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.

E. Applied References

Petitioner relies upon the following references, and the Declaration of Dr. Gerald R. Popelka (“Popelka Declaration,” Ex. 1002). Pet. 4–6.

Reference	Source	Relevant Date	Exhibit No.
Vaneecloo	F.M. Vaneecloo et al., <i>Prosthetic Rehabilitation of Unilateral Anacusis: Study by stereo-audiometry</i> , 117 ANN. OTOLARYNGOL. CHIR. CERVICOFAC. 410 (2000)		Ex. 1003 ¹
Carlsson	Peder U. Carlsson, <i>On Direct Bone Conduction Hearing Devices</i> , Technical Report 195, Dept. of Applied Electronics, Chalmers University of Technology (1990)		Ex. 1007
Leysieffer	CA 2301437 A1	Published Oct. 8, 2000	Ex. 1009
Lesinski	US 5,881,158	Issued Mar. 9, 1999	Ex. 1018
Schaefer	US 4,729,366	Issued Mar. 8, 1988	Ex. 1019

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–10 and 13 of the ’040 patent based on the following grounds. Pet. 6.

References	Basis	Claim(s) Challenged
Vaneecloo and Carlsson	§ 103(a)	1–5 and 13
Vaneecloo, Carlsson, and Leysieffer	§ 103(a)	6, 7, and 9
Vaneecloo, Carlsson, Leysieffer, and Schaefer	§ 103(a)	8
Vaneecloo, Carlsson, Leysieffer, and Lesinski	§ 103(a)	10

¹ Petitioner provides an original version of the Vaneecloo reference in the French language. 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.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

1. Constructions Proposed by the Parties

Petitioner and Patent Owner provide their respective positions regarding construction of the following phrases, each appearing in claim 1: “for rehabilitation of unilateral hearing loss”; “mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient”; and “being osseointegrated in the patient’s skull bone behind an external ear at the deaf side of a patient.” Pet. 19–22; Prelim. Resp. 9–17.

Based on the record before us, however, we need not provide express constructions for these phrases to resolve the issues in dispute. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

2. Means-Plus-Function Limitations

35 U.S.C. § 112 ¶ 6 provides that:

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.²

In proceedings before this Board, our Rules require that if a challenged claim contains a means-plus-function limitation under 35 U.S.C. § 112 ¶ 6, Petitioner is required to construe the limitation and to particularly “identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function.” 37 C.F.R. § 42.104(b)(3).

Petitioner contends that claims 6–10 include limitations that “may be subject to interpretation under pre-AIA 35 U.S.C. § 112, ¶ 6,” and states that “Petitioner does not concede that the ’040 Patent discloses adequate structure for performing the [claimed] functions.” Pet. 22. Patent Owner responds that “[t]he issues raised by this Preliminary Response do not depend on the proper interpretation of means plus function limitations in the claims. Therefore, [Patent Owner] does not address those constructions here.” Prelim. Resp. 17.

a. Claim 6

Claim 6 recites “electronic circuitry operative to convert a signal from a microphone . . . from an analog 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

² 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.

that “the ’040 Patent 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 35 U.S.C. § 112 ¶ 6. *See Williamson v. v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc in relevant part). That presumption may be overcome “if the challenger demonstrates that the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’” *Id.* (citing *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)).

Here, Petitioner has not rebutted sufficiently the presumption that “electronic circuitry operative to convert a signal from a microphone . . . from an analog to a digital signal” recites sufficiently definite structure and instead invokes § 112 ¶ 6. *See* Pet. 22–23. Accordingly, at this stage of the proceeding, we give this phrase its plain and ordinary meaning, i.e., an analog-to-digital converter. *See* Ex. 1002 ¶¶ 39 (“The electronic circuitry (4) of the hearing aid apparatus 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.

b. Claims 7–10

Claim 7 recites that the “electronic circuitry” of claim 6 comprises “digital signal processing means”; claim 8 recites that the “signal processing

means” of claim 7 also “adapts frequency characteristics to individual differences . . . of the patient”; claim 9 recites that the “electronic circuitry” of claim 6 comprises “signal processing means for actively counteracting acoustic feed-back problems”; and claim 10 recites “directivity means comprising at least one directivity dependent microphone and/or signal processing means in the electronic circuitry.” Ex. 1001, 4:6–25.

Petitioner reproduces portions of the ’040 patent Specification that relate to these limitations, but states that the Specification “does not otherwise disclose details of any specific structure or algorithm for performing the recited functions.” Pet. 24 (citing Ex. 1001, 2:63–3:8). Accordingly, Petitioner proposes that we construe these limitations as “a digital signal processor, such as hardware, software, or a hardware-software combination, for performing the claimed signal processing functions.” *Id.*

Claim limitations that include the terms “means” or “means for” are presumed to invoke 35 U.S.C. § 112 ¶ 6. *Williamson*, 792 F.3d at 1348. Petitioner has not rebutted sufficiently this presumption. As such, the Petition was required to “identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function.” 37 C.F.R. § 42.104(b)(3). The corresponding structure of a means-plus-function limitation, however, must be more than simply a general-purpose computer or processor to avoid pure functional claiming. *Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008). Rather, 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).

Here, the Petition fails to identify in the '040 patent Specification sufficiently definite structure that corresponds to the functions recited in claims 7–10, and we do not find any. *See* Ex. 1001, 2:63–3:8. Specifically, the cited portions of the Specification reiterate the recited functions but do not provide any structure or algorithm for performing those functions. *Id.* Nor do the patent Figures provide any kind of structure, algorithm, or flow chart. *Id.* at Figs. 1–3. Petitioner’s proposed construction of these limitations as “a digital signal processor” is similarly deficient.

When 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. In this case, because Petitioner has not shown that the '040 patent has sufficient structure corresponding to the recited functions, we determine that claims 7–10 are not amenable to construction, and, thus, we deny institution of an *inter partes* review with respect to those claims.

B. Principles of Law

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) objective evidence of nonobviousness, i.e., secondary considerations.³ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“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 Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

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). Patent Owner does not provide an assessment of a relevant skill level. *See generally* Prelim. Resp.

Based on our review of the ’040 patent, the types of problems and solutions described in the ’040 patent and applied prior art, and the

³ The Preliminary Response does not identify any secondary considerations.

testimony of Dr. Popelka, we apply Petitioner’s assessment for purposes of this Decision. Further, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Obviousness over the Combined Teachings of Vaneecloo and Carlsson

Petitioner contends that challenged claims 1–5 and 13 are unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Vaneecloo and Carlsson. Pet. 25–45. Patent Owner disputes Petitioner’s contentions regarding only claims 4–5. Prelim. Resp. 18–23.⁴ For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to the challenged claims.

1. Overview of Vaneecloo (Ex. 1003)

Vaneecloo is an article entitled “Prosthetic Rehabilitation of Unilateral Anacusis: Study by stereo-audiometry,” which discusses clinical and stereo-audiometric results for two patients with unilateral hearing loss who were treated with bone-transmission prostheses (“BAHA” devices) on the deaf side. Ex. 1003, 410. According to Vaneecloo, the BAHA devices were “anchored directly in the bone” with “titanium fixture[s]” and were

⁴ Patent Owner anticipates arguing in its Patent Owner Response that the invention of the ’040 patent was conceived and reduced to practice prior to Vaneecloo’s publication date. Prelim. Resp. 1. No such evidence is before us at this time. *See id.*

“designed to capture and transmit transcranially to the remaining functional ear the information received from the side of the anakusis.” *Id.* at 410–412.⁵

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 the subject 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 explains that these 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.

2. Overview of Carlsson (Ex. 1007)

Carlsson is an article entitled “On Direct Bone Conduction Hearing Devices,” which discusses Bone-Anchored Hearing Aid (“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 bone. *Id.*; *see also id.* at 4, 10.

⁵ The term “anakusis” or “anacusis” 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.

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 Applied Art*

a. *Independent Claim 1*

(1) *preamble: “[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”*

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious the preamble of claim 1, even if the language “for rehabilitation of unilateral hearing loss” is considered to be limiting. Pet. 37. Petitioner contends that the BAHA device disclosed by Vaneecloo is implanted on a patient’s deaf side and transmits vibrations across the head 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 BAHA devices operating through bone conduction. *Id.* at 29, 37 (citing Ex. 1007, 4, 10, Fig. 10; Ex. 1002 ¶¶ 59, 92, 94).

On this record, we are persuaded by Petitioner. Vaneecloo teaches a “semi-implantable bone-anchored hearing aid (BAHA)” for use in patients

with “unilateral anakusis.” Ex. 1003, 410. Vaneecloo explains that the device is “anchored directly in the bone . . . to capture and transmit transcranially to the remaining functional ear the information received from the side of the anakusis.” *Id.* Similarly, Carlsson teaches transmission of sound information through the skull by “percutaneous direct bone conduction.” Ex. 1007, Abstract.

(2) “*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*”

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious this limitation, even if the “mechanically transmitted . . .” language is considered to be more than an intended use. 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.* (citing Ex. 1003, 411–412; Ex. 1002 ¶¶ 70–74, 93–96, 103); *see also id.* at 26 (also citing Ex. 1002 ¶¶ 90–91, 97, 99–102).

To the extent Vaneecloo does not teach adequately 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 (citing Ex. 1007, 4, Fig. 1; Ex. 1002 ¶ 59); *see also id.* at 39 (also citing Ex. 1002 ¶¶ 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 vibratory generating . . . parts of the Carlsson BAHA device.” *Id.* at 33. Petitioner contends that such a modification would have combined known prior art elements in known ways to attain predictable results and would have attained 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).

On this record, we are persuaded by Petitioner. Vaneecloo teaches that the BAHA device is anchored to the skull bone 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 bone. Ex. 1007, 4 (explaining that skin is not included in the vibration transmission to the skull bone), 10, Fig. 10 (transducer 4); Ex. 1002 ¶ 62. On this record, we also are persuaded by Petitioner’s position that modifying Vaneecloo’s teachings regarding its 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.

(3) “*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*”

Petitioner contends that the combined teachings of Vaneecloo and Carlsson render obvious this limitation, even if the “being osseointegrated . . .” language is considered to be more than an intended use. 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 is attached the sound processor, 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 . . .

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 would have attained 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).

On this record, we are persuaded by Petitioner. 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 an osseointegrated implantable part that mechanically anchors the vibratory generating part. Ex. 1007, 4–5 (describing osseointegration with a titanium fixture), Fig. 1 (depicting a screw); Ex. 1002 ¶ 59. On this record, 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.

(4) Summary

Based on the record before us, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the

combined teachings of Vaneecloo and Carlsson render obvious independent claim 1.

b. Dependent Claims 2 and 3

We have reviewed carefully the evidence presented by Petitioner regarding dependent claims 2 and 3. Pet. 35–36, 40–42. Based on the record before us, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combined teachings of Vaneecloo and Carlsson render obvious claims 2 and 3. *See, e.g.*, Ex. 1002 ¶¶ 73, 117 (opining that the frequency characteristics of Vaneecloo’s device transmit vibrations from one side of the skull to the other); Ex. 1003, 410 (transmitting to a functional side); Ex. 1007, Fig. 1 (depicting an implant screw).

c. Dependent Claims 4 and 5

Dependent claim 4 recites that “the hearing aid apparatus amplifies treble frequencies more than base frequencies,” and dependent claim 5 further limits the recited “treble frequencies” to those greater than 1 kHz. Ex. 1001, 3:48–53.

Petitioner contends that Vaneecloo tests 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 anacusis 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 disputes Petitioner’s contentions, relying on the testimony of Jay Rubenstein (Ex. 2002, the “Rubenstein Declaration”). Prelim. Resp. 18–23. Patent Owner argues that the tests disclosed by Vaneecloo are air conduction tests that determined only that “the *perception* in hearing gain experienced by the patients was greater with respect to treble frequencies.” *Id.* at 20 (citing Ex. 2002 ¶¶ 10–11). According to Patent Owner, these tests simply show that “the two patients in Vaneecloo *perceived* sounds transmitted through the air at high frequencies better with the hearing aid device than without it, which says nothing about whether certain frequencies were *amplified* [by the hearing aid apparatus] more than others,” as required by claims 4 and 5. *Id.* at 21 (second emphasis added) (citing Ex. 2002 ¶ 13).

We have considered Petitioner’s and Patent Owner’s positions and determine that, in this preliminary proceeding, Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail on its challenge to claims 4 and 5. Specifically, the portion of Vaneecloo’s disclosure quoted above refers to both “the amplification” of high-pitched sounds, as well as the “perception” of those sounds. Ex. 1003, 415. The use

of separate terms related to amplification and perception suggests that they are separate and independent characteristics. If Vaneecloo intended to refer only to perception, it is unclear why “the amplification of” high-pitched sounds are 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., “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”).

Furthermore, Dr. Popelka testifies that he understands Vaneecloo’s disclosure of the testing results quoted above 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. Dr. Popelka also testifies that prior art publications, such as a 1997 article published by Marshall Chasin (Ex. 1008), support this understanding. *Id.* ¶ 118.⁶

On the other hand, the Rubenstein Declaration, submitted with Patent Owner’s Preliminary Response, states that:

[W]hen Vaneecloo refers to “amplification of the high-pitched sounds captured on the anakusis side” it is referring to an increase in hearing perception of the patients for high frequency sounds which would otherwise be attenuated as they reach the

⁶ Despite Patent Owner’s argument, on this record, we do not find that the Popelka Declaration is conclusory or fails to disclose the facts or data upon which the testimony is based. *See* Prelim. Resp. 18. As noted herein, Dr. Popelka identifies sufficiently the bases for his opinion. *See, e.g.*, Ex. 1002 ¶¶ 117–118 (citing Ex. 1003, 415; Ex. 1008, 89).

opposite side of the head *via air conduction* because of the head shadow effect.

A person skilled in the art cannot draw any conclusions about transcranial attenuation of bone-conducted sound from Vaneecloo, i.e. there is no basis to determine that high frequency sounds are being amplified more than bass frequency sounds.

Ex. 2002 ¶¶ 13–14; *see also id.* ¶¶ 10–12. In this preliminary proceeding, we must resolve in Petitioner’s favor this dispute of material fact, i.e., whether Vaneecloo’s testing results indicate that the BAHA device amplified treble frequencies more than bass frequencies or simply indicate that those frequencies were better perceived by the patients than they otherwise would have been without the BAHA. *See* 37 C.F.R. § 42.108(c) (“[A] genuine issue of material fact created by [Patent Owner’s] testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.”).

d. Independent Claim 13

Independent claim 13 presents a method of rehabilitating a patient with unilateral hearing loss and recites steps that are substantially similar to the limitations recited in independent claim 1. *Compare* Ex. 1001, 3:29–41, *with id.* at 4:37–51. We have reviewed carefully the evidence presented by Petitioner regarding independent claim 13. Pet. 35, 43–45; Ex. 1002 ¶¶ 132–146. For substantially the same reasons discussed above regarding claim 1, we are persuaded that Petitioner has established a reasonable likelihood of prevailing on its contention that the combined teachings of Vaneecloo and Carlsson render obvious this claim.

4. *Summary*

On this record, we determine that Petitioner has presented sufficient evidence to establish a reasonable likelihood it would prevail in showing that claims 1–5 and 13 are rendered obvious over the combined teachings of Vaneecloo and Carlsson.

E. Alleged Obviousness over the Combined Teachings of Vaneecloo, Carlsson, and Leysieffer

Petitioner contends that challenged claims 6, 7, and 9 are unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Vaneecloo, Carlsson, and Leysieffer. Pet. 46–52. Patent Owner does not dispute Petitioner’s contentions. *See generally* Prelim. Resp. 1–2, 23. For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to claim 6. As discussed in Section II.A.2, *see supra*, we deny institution of review of claims 7 and 9 and do not address those claims further.

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 that allows operating programs or parameters to be modified or replaced while a component is implanted. Ex. 1009, (57), 9:27–30, Figs. 1, 3.

2. *Analysis of Applied Art*

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 to the extent the combined teachings of Vaneecloo and Carlsson do not include the recited electronic circuitry, a person of ordinary skill in the art would have found it obvious “to include an analog-to-digital converter,” as taught by Leysieffer. *Id.* at 49–50.

Petitioner contends that such a modification would have combined known prior art elements in known ways to attain predictable results and would have achieved 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).

On this record, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combined teachings of Vaneecloo, Carlsson, and Leysieffer render obvious claim 6. *See, e.g.*, Ex. 1009, 11 (explaining 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”). On this record, we also 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.

3. *Summary*

On this record, we determine that Petitioner has presented sufficient evidence to establish a reasonable likelihood it would prevail in showing that claim 6 is rendered obvious over the combined teachings of Vaneecloo, Carlsson, and Leysieffer.

F. Alleged Obviousness over the Combined Teachings of Vaneecloo, Carlsson, Leysieffer, and Schaefer

Petitioner contends that challenged claim 8 is unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Vaneecloo, Carlsson, Leysieffer, and Schaefer. Pet. 52–55. As discussed in Section II.A.2, *see supra*, however, we deny institution of review of claim 8 and do not address that claim further.

G. Alleged Obviousness over the Combined Teachings of Vaneecloo, Carlsson, Leysieffer, and Lesinski

Petitioner contends that challenged claim 10 is unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Vaneecloo, Carlsson, Leysieffer, and Lesinski. Pet. 55–58. As discussed in Section II.A.2, *see supra*, however, we deny institution of review of claim 10 and do not address that claim further.

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claims 1–6 and 13 of the '040 patent.

At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim or as to the construction of any claim term.

IV. ORDER

For the reasons given, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–6 and 13 of the '040 patent on the following asserted grounds:

1. Claims 1–5 and 13 under 35 U.S.C. § 103(a) as unpatentable over Vaneecloo and Carlsson; and
2. Claims 6 under 35 U.S.C. § 103(a) as unpatentable over Vaneecloo, Carlsson, and Leysieffer;

FURTHER ORDERED that the trial is limited to the grounds identified above, and no other grounds are authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this Decision; and

FURTHER ORDERED that Patent Owner's Objections to Evidence (Paper 5) are expunged.⁷

⁷ 37 C.F.R. § 42.64(b)(1) states that “[a]ny objection to evidence submitted during a preliminary proceeding must be filed *within ten business days of the institution of trial.*” Accordingly, Patent Owner's objections filed prior to institution are premature. To the extent Patent Owner desires to preserve its objections, they must be re-filed in accordance with our Rules.

IPR2017-01018
Patent 7,043,040 B2

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