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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner

v.

COCHLEAR BONE ANCHORED SOLUTIONS AB
Patent Owner of
U.S. Patent No. 7,043,040 to P. Westerkull
Issued May 9, 2006

Case IPR2017-01019

**PETITION FOR *INTER PARTES* REVIEW OF
CLAIMS 1, 11 AND 12 OF U.S. PATENT NO. 7,043,040
PURSUANT TO 35 U.S.C. § 311**

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I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-42.80 and 42.100-42.123, OTICON MEDICAL AB, OTICON MEDICAL LLC and WILLIAM DEMANT HOLDING A/S (hereinafter “Petitioner”) submits this Petition to institute an *Inter Partes* Review (IPR) of claims 1, 11 and 12 (“challenged claims”) of U.S. Patent 7,043,040 (“the ‘040 Patent”) (Ex. 1101). This Petition shows by a preponderance of the evidence that there is a reasonable likelihood that Petitioner will prevail in proving that claims 1, 11 and 12 of the ‘040 Patent are unpatentable based on prior art that the Patent Office did not have before it or did not fully consider during prosecution.

II. MANDATORY REQUIREMENTS, NOTICES AND FEES

A. Real Party-In-Interest

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

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

The ‘040 Patent is subject to concurrent litigation of: Civil Action No. 1:16-cv-01700, filed July 1, 2016, in the United States District Court for the District of

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Colorado. Service by Petitioner was accepted on September 28, 2016.

The '040 Patent is also at issue in an arbitration proceeding being conducted between William Demant Holding A/S, on the one side, and Patent Owner, on the other side, under the Arbitration Rules of the Arbitration Institute of the Stockholm Chamber of Commerce (SCC) in Stockholm, Sweden (SCC Arbitration No. V2016/181).

Concurrently with this Petition for *Inter Partes* Review, Petitioner is also filing a Petition for *Inter Partes* Review of claims 1-10 and 13 of the '040 Patent. The present Petition raises different, non-redundant grounds of unpatentability. Although different sets of claims are involved in the concurrently filed Petition, independent claim 1 is asserted to be unpatentable in both Petitions.

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

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

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

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

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Back-up Counsel: Eugene T. Perez, Reg. No. 48,501 (email: etp@bskb.com); and Lynde F. Herzbach, Reg. No. 74,886 (email: Lynde.Herzbach@bskb.com).

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

As identified in the attached Certificate of Service, a copy of the present petition, in its entirety, including all Exhibits and a power of attorney, is being served by USPS EXPRESS MAIL, costs prepaid, to the address of the attorney or agent of record for the '040 Patent: Hauptam Ham, LLP. Petitioner may be served at the lead counsel address provided in Section **II.C** of this Petition. Petitioner consents to electronic service by email at the email addresses above.

E. Power of Attorney

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

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

The required fees are submitted herewith in accordance with 37 C.F.R. § 42.103(a) and § 42.15, as required by 35 U.S.C. § 312(a)(1).

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

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

Petitioner certifies that the ‘040 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an IPR for the challenged claims of the ‘040 Patent.

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

Petitioner respectfully requests *inter partes* review of claims 1, 11 and 12 of the ‘040 Patent on the grounds set forth below. Petitioner asks that the Board cancel each challenged claim as unpatentable. In support of the proposed grounds for unpatentability, this Petition is accompanied by a declaration of Dr. Gerald R. Popelka (Ex. 1102).

1. The Specific Art on Which the Challenge is Based

The ‘040 Patent issued from U.S. Application No. 10/481,587 (“the ‘587 application”), which was a U.S. national phase of International Application No.

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PCT/SE02/01089 filed June 6, 2002. Thus, the ‘040 Patent has a U.S. filing date of June 6, 2002. Pre-AIA 35 U.S.C. § 363; *see also* M.P.E.P. § 1893.03(b). The ‘040 Patent claims priority to Swedish Application No. 0102208-6, filed June 21, 2001. Each reference relied on herein precedes the earliest claimed priority date of the ‘040 Patent. Thus, Petitioner need not address whether the ‘040 Patent is entitled to its claimed priority date, and reserves the right to challenge the priority claim of the ‘040 Patent. Petitioner relies on the following prior art.

Exhibit 1112 (Hough) – “Long-Term Results for the Xomed Bone Conductor,” *Otolaryngologic Clinics of North America*, Vol. 28, No. 1, pp. 43-52, to J. Hough et al. (“Hough”; Ex. 1112), was published in Feb. of 1995. Hough is prior art under pre-AIA 35 U.S.C. § 102(b) against the ‘040 Patent.

Exhibit 1109 (Leysieffer) – Canadian Patent Document No. CA 2 301 437 (A1) to H. Leysieffer (“Leysieffer”; Ex. 1109) published on October 8, 2000. Leysieffer is prior art under pre-AIA 35 U.S.C. § 102(b) against the ‘040 Patent.

2. The Specific Grounds on Which the Challenge is Based

Petitioner respectfully requests cancellation of claims 1, 11 and 12 of the ‘040 Patent on the following grounds:

Ground	‘040 Patent Claims	Basis
No. 1	1, 11	Anticipated under pre-AIA 35 U.S.C. § 102(b) by Hough

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Ground	'040 Patent Claims	Basis
		(Ex. 1112)
No. 2	12	Obvious under pre-AIA 35 U.S.C. § 103(a) over Hough (Ex. 1112) in view of Leysieffer (Ex. 1109)

Each reference relied upon in the grounds set forth above qualifies as prior art under pre-AIA 35 U.S.C. § 102(b). This Petition and the Declaration of Dr. Popelka (Ex. 1102), submitted herewith, cite additional prior art materials to provide background of the relevant technology and, in some instances, to further explain why one of ordinary skill in the art would have found it obvious combine the cited references to arrive at the claimed invention.

IV. The '040 Patent, the State of the Art Prior to the Relevant Date, and the Person of Ordinary Skill in the Art

A. Embodiment(s) of the '040 Patent

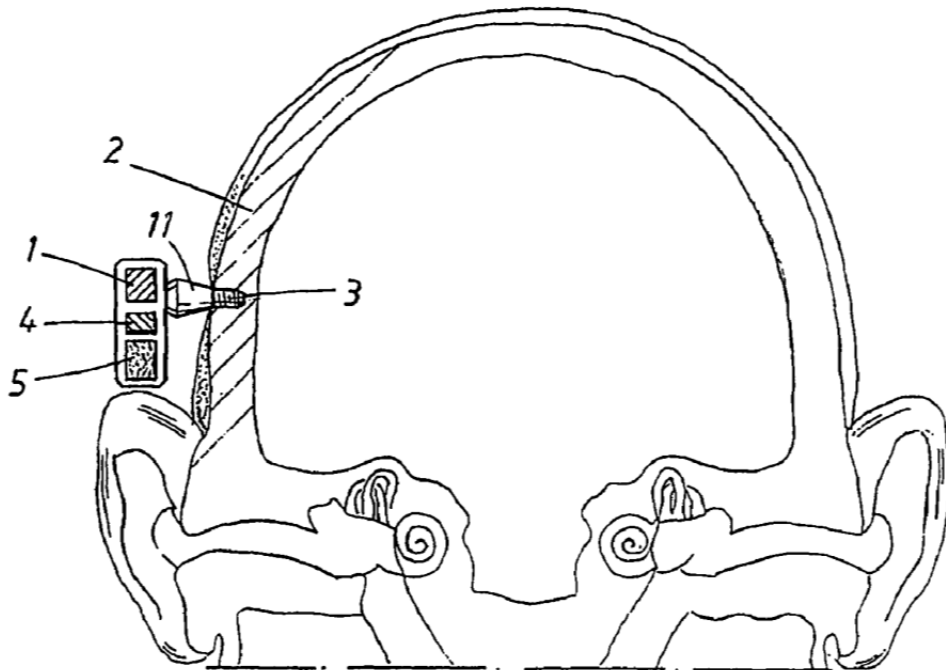
The '040 Patent relates to a hearing aid apparatus for treating patients suffering from unilateral hearing loss. Ex. 1101, Abstract. The hearing aid apparatus is configured as a bone-anchored device for conducting sound. Ex. 1102, ¶¶ 33-51. The hearing aid apparatus includes a vibratory generating part that

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is mechanically connected via “osseointegration” of an implanted fixture to the deaf side of patient’s skull bone and arranged to transmit vibrations through the skull bone from the deaf side to the inner ear on the other side (hearing side) of the patient. Ex. 1101, Abstract. Osseointegration refers to the direct structural and functional connection between living bone and the surface of a load-bearing artificial implant. Ex. 1102, ¶ 34. In the context of hearing aids, the artificial implant is typically a titanium anchor. Ex. 1102, ¶ 34.

The ‘040 Patent includes three drawing Figures, which show distinct and separate embodiments of a hearing aid apparatus. Fig. 1 (reproduced below) is representative of a first hearing aid apparatus embodiment (see corresponding description at col. 2, lines 44-55):

Fig. 1



1 = vibrator

2 = skull bone

3 = fixture

4 = electronic circuitry

5 = microphone

11 = skin penetrating spacer

As shown in in Fig. 1, the hearing aid apparatus includes a housing that contains a vibrator 1. The housing is mechanically coupled to in the skull bone 2 by a fixture 3. Ex. 1101, col. 2, lines 50-53. Sound is picked by a microphone 5 and amplified and filtered by electronic circuitry 4. Ex. 1101, col. 2, lines 53-55.

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Thus, the hearing aid apparatus of Fig. 1 includes a vibratory generating part for generating vibrations that are mechanically transmitted through the skull bone from the patient's deaf side to the patient's inner ear on the other, non-deaf side. The hearing aid apparatus includes a fixture 3 that is implanted (osseointegrated) in the patient's skull bone behind an external ear at the deaf side of a patient. Ex. 1101, Fig. 1. A spacer 11 penetrates the patient's skin, but the housing containing the vibrator 1, microphone 5 and electronic circuitry 4 is positioned outside of the patient's skin. This arrangement, having a fixture that penetrates the patient's skin, is considered "percutaneous." Ex. 1102, ¶ 37.

The '040 Patent specification discloses that the frequency characteristics of the hearing aid are such that the amplification is greater for treble frequencies (e.g., above 1 kHz) than bass frequencies. Ex. 1101, col. 2, lines 59-61.

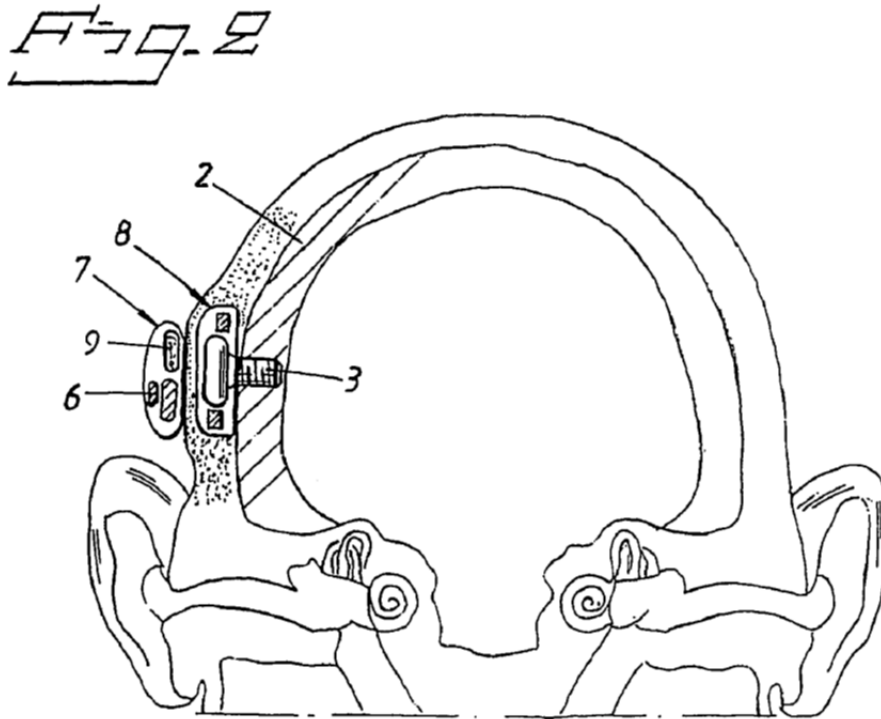
The electronic circuitry 4 of the hearing aid apparatus includes "means" for "converting the signal from the microphone 5 from an analog to a digital signal for the necessary signal processing". Ex. 1101, col. 2, line 66 to col. 3, line 2. The electronic circuitry 4 includes "signal processing means" to actively counteract acoustic feed-back and adapt the frequency characteristics to the hearing capacity of the well-functioning ear. Ex. 1101, col. 3, lines 2-8.

Fig. 2 (reproduced below) illustrates a second embodiment of the hearing aid apparatus. In this second embodiment, the hearing aid apparatus includes an

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implanted part 8 to avoid skin penetration (i.e., a “transcutaneous” configuration).

Ex. 1101, col. 3, lines 9-14):



2 = skull bone

3 = fixture

6 = microphone

7 = external part (outside skin)

8 = implanted part

9 = battery

This alternative hearing aid embodiment does not use a fixture that penetrates the patient’s skin, and instead includes an “implantable part including

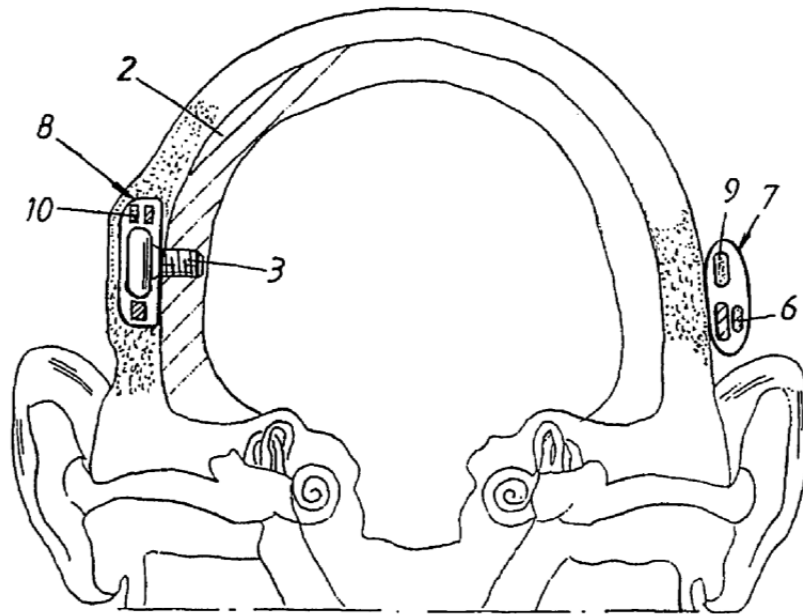
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the vibrator” positioned under the patient’s skin and an external part 7 positioned outside the patient’s skin. The external part 7 includes a microphone 6 and battery 9. Ex. 1101, col. 3, lines 9-12. This arrangement having external and implanted parts 7, 8 separated by the patient’s skin is considered transcutaneous. Ex. 1102, ¶¶ 40-41. With this arrangement, “[p]ower is transmitted to the implanted part 8 of the hearing aid by means of induction”. Ex. 1101, col. 3, lines 12-14. Thus, sound is picked by the external microphone 6, and power is transmitted via induction to implanted part 8 (below the skin).

Fig. 3 (reproduced below) illustrates a third embodiment of the hearing aid apparatus “in which the implanted part also comprises a rechargeable battery 10 which is charged by means of induction from an external power supply”. Ex. 1101, col. 3, lines 15-18. This arrangement is also transcutaneous as having an implanted part on the non-deaf side and an external part on the deaf side. Ex. 1101, col. 3, lines 18-22; Ex. 1102, ¶ 42. The signal transmitted in the hearing aid apparatus of Fig. 3 can be an analog signal or a digital radio signal. Ex. 1101, col. 3, lines 22-24.

Thus, for the embodiment of Fig. 3, positioning the implanted part 8 on the patient’s non-deaf side to receive radio signals from the external part 7 avoids the need to conduct vibrations from the patient’s deaf side to the non-deaf side because the implanted part 8 is already on the non-deaf side. Ex. 1102, ¶ 43.

Fig. 3



2 = skull bone

3 = fixture

6 = microphone

7 = external part (outside skin; on deaf side)

8 = implanted part (on non-deaf side)

9 = battery (on deaf side)

10 = rechargeable battery (on non-deaf side)

Since the embodiment of Fig. 3 positions an external part 7, having the microphone 6 and battery 9, on the patient's deaf side but positions an implanted part 8 on the non-deaf side, this is a distinct arrangement from the embodiments of Fig. 1 and Fig. 2. Ex. 1101, col. 3, lines 18-22; Ex. 1102, ¶ 44.

B. Prosecution History of the '040 Patent

The '040 Patent was filed July 13, 2004 as U.S. Application No. 10/481,587, which was a national phase application of International Application No. PCT/SE02/01089 filed June 6, 2002. Ex. 1110, pp. 119-146 of 146 pages. A preliminary amendment was filed on December 22, 2003, including minor amendments the original claims. Ex. 1110, pp. 102-106/146. An Information Disclosure Statement was filed on October 6, 2004. Ex. 1110, pp. 51-52/146.

The USPTO issued a non-final Office Action on March 31, 2005. Ex. 1110, pp. 37-47/146. Original claims 1-9 were rejected under pre-AIA 35 U.S.C. § 102(e) in view of US 2001/0031996 A1 to Leysieffer (Leysieffer '996). Ex. 1110, pp. 40-42/146.

In response to the Examiner's rejection, the '587 applicant filed a response on July 29, 2005, whereby original claims 1-9 were canceled, and new claims 10-22 were added. Ex. 1110, pp. 18-25/146. Applicant argued that Leysieffer '996 does not disclose the features of independent claim 10, including the recited "bone-anchored bone conducting hearing aid that includes 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."

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Thereafter, the Examiner issued a Notice of Allowability on October 28, 2005 and offered the following reasons for allowance:

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance:

The closest prior art of record to Leysieffer fails to teach or suggest a bone-anchored bone conducting hearing aid that includes a vibratory generating part that generates vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient. Leysieffer teaches a partially implantable microphone that transmits sounds directly to the cochlea of the patient. None of other prior arts teaches this bone-anchored bone conducting hearing aid and its corresponding method.

Ex. 1110, p. 8/146.

C. The State of the Art Prior to the Relevant Date

As discussed in greater detail below, all components of the challenged claims were described in printed publications prior to the critical date. The concept of hearing by bone conduction (via the human skull) has been known since at least 1960. Ex. 1115 (Fowler), p. 57/41, paragraph bridging left-right columns; Ex. 1102, ¶54. Fowler explains that a bone conduction device can be mounted on the patient's non-hearing side, with sound being transferred to the opposite ear. Ex. 1115 (Fowler), p. 57/41, paragraph bridging left-right columns; Ex. 1002, ¶ 54. Generally, prior to the earliest priority date of the '040 Patent, one type of a known

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bone conducting hearing aid was the bone-anchored hearing aid, or “BAHA.”¹ Early versions of the BAHA transmitted sound vibrations via an implanted part (e.g., titanium post surgically embedded into the skull), producing sound perception on the deaf side. Ex. 1102, ¶¶ 54, 57-59, 62-66. To install the BAHA, a titanium post was surgically embedded into the skull with a small section exposed outside the skin (i.e., a “percutaneous” arrangement). Ex. 1107 (Carlsson 1990), Fig. 1 on p. 3, p. 4, left column, first full ¶; Ex. 1102, ¶ 59.

Using bone conducting hearing aids, hearing was realized as vibrations (representing sound) were delivered via the skull to the inner ear, such that the hair cells of the inner ear were stimulated (thus allowing hearing). Ex. 1102, ¶ 48. Hearing by bone-conduction has been recognized as a natural way of hearing because, even when listening to a person’s own voice, sound is both airborne and bone-conducted. Ex. 1107, p. 9, last ¶; Ex. 1102, ¶ 35.

The first BAHA device was fitted to a patient in 1977. Ex. 1105 (Chasin et al.), p. 12, left col., first full ¶ in section titled “4. When were BAHAs first used and how is this made possible?”; Ex. 1106 (Wazen et al.), p. 737, left col., second full ¶. Clinical trials in the U.S. for patients using the BAHA device were conducted in 1984-1987. Ex. 1106 (Wazen), p. 737, right col., lines 1-2 (¶ above

¹ BAHA is a registered trademark currently owned by Cochlear Bone Anchored Solutions AB; in 1997, as explained in Ex. 1108, ¶ bridging pp. 84-85, BAHA was marketed by Nobel Biocare. Current ownership can be seen in the USPTO trademark registration number 2118182 (Dec. 2, 1997).

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“Materials and Methods”). The U.S. FDA approved use of the BAHA for adults in August of 1996. Ex. 1106, p. 737, right col., lines 2-4; Ex. 1002, ¶ 58. The BAHA entered the U.S. market in January of 1997. Ex. 1106, p. 737, right col., lines 4-5; Ex. 1102, ¶ 58. The BAHA was later tested in patients with unilateral hearing loss. Ex. 1103, 1104 (Vaneecloo), generally; Ex. 1102, ¶¶ 65, 66.

Besides the percutaneous BAHA device, another bone-conduction type hearing aid device was known as “the Audiant” or the Audiant Bone Conductor (“ABC”) hearing device, which used a transcutaneous configuration. Ex. 1112 (Hough); Ex. 1102, ¶¶ 72-75. The ABC hearing device has been described as early as 1986 in *The American Journal of Otology*. Ex. 1111, generally; Ex. 1102, ¶¶ 67-71. Like the BAHA, the ABC hearing device produced the perception of hearing using principles of bone conduction and osseointegration. Ex. 1111, Abstract and first ¶ on p. 315; Ex. 1112, p. 43, first ¶; Ex. 1102, ¶¶ 71, 73, 34. Also like the BAHA device, the ABC device has been used for patients with unilateral hearing loss, with sound energy being mechanically transmitted by bone conduction from the deaf side to the normal ear. Ex. 1112, p. 45, right col., lines 12-20; Ex. 1102, ¶¶ 67, 74.

Leysieffer describes a partial or totally implantable system for rehabilitating hearing disorders by applying electrical, mechanical or acoustic stimulation to the patient’s middle or inner ear. Ex. 1109, p. 1, lines 5-6; p. 2, lines 27-29; p. 7, lines

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15-30; Ex. 1102, ¶ 76. The Leysieffer system is applicable to unilateral hearing losses. Ex. 1109, p. 15, lines 16-17; Ex. 1102, ¶ 76.

In embodiments of Leysieffer, an implanted part includes various electrical components, including a micro-controller 5, a digital signal processor 141, memory S1, S2, S3, a drive unit 80, output stimulators 20a, 20b...20n, and a telemetry system 125. Ex. 1109, Fig. 1, Fig. 3, p. 11, line 9 to p. 12, line 29; Ex. 1102, ¶ 77. The telemetry system 125 communicates with an external unit 120 via induction across the patient's skin 57. Ex. 1109, Fig. 1, Fig. 3, p. 12, lines 20-24; Ex. 1102, ¶ 77. With this arrangement, the implanted part is capable of performing various hearing aid functions, including audio signal processing, noise and feedback suppression, output level limiting for patient protection, wireless communication with the external unit, power management, operation monitoring, data storage and wireless updating of operating parameters and programming. Ex. 1109, p. 7, line 18 to p. 8, line 7; p. 12, line 11 to p. 13, line 9; p. 16, line 28 to p. 17, line 17; Ex. 1102, ¶ 77.

Leysieffer further discloses using a rechargeable battery 60 to supply power to various electronic components of the implanted part. Ex. 1109, Fig. 1, p. 13, lines 10-11, p. 14, line 29 to p. 15, line 2; p. 8, lines 10-11; p. 4, lines 26-28; Ex. 1102, ¶ 78. The external unit 120 wirelessly recharges the implanted-side battery 60 via induction to “allow longer service lives and thus increasing residence times

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in the patients.” Ex. 1109, p. 8, lines 8-11; p. 4, lines 26-28; p. 14, line 29 to p. 15, line 2; Ex. 1102, ¶ 78.

It is evident from the prior art publications discussed above that all technical components of the hearing aid apparatus recited in the challenged claims of the ‘040 Patent were known prior to the critical date. Such prior art publications describe fitting patients with bone-conducting-type hearing aids that include both a vibratory generating part and an implantable part that has been osseointegrated into a patient’s skull to treat hearing loss, including unilateral hearing loss. These bone-conducting-type hearing aids supplied power from an external part to an internal part via induction. Moreover, it was known to use rechargeable batteries in implantable-type hearing aid devices. Ex. 1102, ¶ 78.

D. Person of Ordinary Skill in the Art

The level of ordinary skill in the art can be evidenced by relevant prior art. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *see also Ex parte Jellá*, No. 2008-1619 (B.P.A.I. Nov. 3, 2008). The field of bone-conduction-type hearing aids involves a relatively advanced understanding and level of ordinary skill. The prior art discussed herein and in the Declaration of Dr. Popelka (Ex. 1102) demonstrates that a person of ordinary skill in the art (“POSA”) in the field would have an advanced understanding of various types of hearing aid devices, and bone-

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conduction-type hearing aids in particular. Such a POSA would likely have (i) at least a Master’s degree in audiology or the equivalent thereof and at least 2 years of clinical experience fitting such devices for patients or (ii) at least a Bachelor’s degree in electrical or computer engineering or the equivalent thereof and at least 2 years designing such devices for use by patients. Ex. 1102, ¶ 32. Graduate work could substitute for work experience, and additional work experience could substitute for formal education. Ex. 1102, ¶ 32.

V. Claim Construction - 37 C.F.R. § 42.100(b)

A. Legal Overview

In an IPR, claim terms of an unexpired patent should be given their broadest reasonable interpretation (“BRI”). 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142-46 (2016). Under the BRI standard, and absent any special definitions, terms used in patent claims are presumed to have their ordinary and customary meaning, as would be understood by the person of ordinary skill in the art (“POSA”). *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Petitioner adopts this standard for this proceeding, but reserves the right to pursue different constructions in other forums, such as in district court, where different claim construction standards apply.

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Where the construction of specific terms is not necessary to resolve the issues before the PTAB, the PTAB can refrain from construing those terms, “leaving that question to a later forum where the issue is determinative.” *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013)

Any claim terms not included in this section have their broadest reasonable meaning in light of the specification as commonly understood by those of ordinary skill in the art. For purposes of this IPR proceeding only, Petitioner has assumed that the term “implantable part” in independent claim 1 may be interpreted under the BRI standard as encompassing a skin-penetrating fixture 3 of the first embodiment illustrated in Fig. 1 in the ‘040 Patent (i.e., a “percutaneous” arrangement). Such an interpretation appears to be the basis for Patent Owner’s infringement allegations in the concurrent litigation referenced above in Section **II.(B.)**.

B. Claim Terms Needing Construction

Petitioner requests that the Board construe certain claim terms of the ‘040 Patent as follows.

1. “for rehabilitation of unilateral hearing loss”

The preamble of claim 1 recites “for rehabilitation of unilateral hearing loss.” Under the BRI standard, this preamble language should be given no

patentable weight.

When the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed limitations, the preamble is not considered a limitation and is of no significance to claim construction. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *see also Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) Here, independent claim 1 recites two components of the hearing aid apparatus: (1) “a vibratory generating part;” and (2) “an implantable part” that mechanically anchors the vibratory generating part. Under the BRI standard, the preamble phrase “for rehabilitation of unilateral hearing loss” is merely an intended use, and does not provide any distinct definition for structural limitations of the apparatus as recited in the body of the claim. Thus, this preamble language should be given no patentable weight under the BRI standard.

2. “mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient”

Claim 1 is directed to a 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.*” (emphasis added). Claim 1 is **not** directed to a method for treating a

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

In *Masham*, the Board focused on the structural limitations of the claimed apparatus. With respect to recited claim language relating to the identity of the material worked upon by the claimed apparatus, the Board stated (emphasis in original):

... At any rate, a recitation with respect to the material intended to be worked upon by a claimed apparatus does not impose any structural limitations upon the claimed apparatus which differentiates it from a prior art apparatus satisfying the *structural* limitations of that claimed. See *In re Rishoi*, 197 F.2d 342, 94 USPQ 71 (CCPA 1952) and *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935). Similarly, a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the *structural* limitations of that claimed. See *In re Yanush*, 477 F.2d 958, 177 USPQ 705 (CCPA 1973), *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA

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1971), *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963).

Masham, 2 U.S.P.Q.2d at 1647.

Here, under the BRI standard, the claim language referring to vibrations “*that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient*” 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.

3. “being osseointegrated in the patient’s skull bone behind an external ear at the deaf side of a patient”

Claim 1 refers to the implantable part as being “*osseointegrated in the patient’s skull bone behind an external ear at the deaf side of a patient.*” Again, claim 1 is directed to the apparatus, and claim language that merely describes the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from any prior art apparatus satisfying the claimed structural limitations. *Id.*

Under the BRI standard, the phrase “*osseointegrated in the patient’s skull bone behind an external ear at the deaf side of a patient*” merely refers to the manner in which the claimed implantable part is intended to be employed.

4. “external part” and “internal part”

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Claim 11 recites “an external part” comprising a microphone and a battery, and specifies that the “external part” transmits power *via induction* to an “internal part.” As explained in section IV.(A.) above, these components are described in the ‘040 Patent specification with respect to Fig. 2 (see col. 3, lines 9-14). See also Ex. 1102, ¶¶ 40, 41, 44, 46, 81-84. The ‘040 Patent specification distinguishes this arrangement from that in Fig. 1 by stating that the Fig. 2 embodiment avoids skin penetration. Ex. 1101, col. 3, lines 9-11 Ex. 1102, ¶¶ 40, 41, 46, 51, 81-84. Therefore, Petitioner submits that the recitation in claim 11 of an “external part” that transmits power to an “internal part” *via induction* is specific to a transcutaneous configuration such as depicted in Fig. 2 of the ‘040 Patent. Ex. 1102, ¶¶ 40, 41, 46, 81-84.

VI. Ground 1: Claims 1 and 11 are anticipated under pre-AIA 35 U.S.C. § 102(b) by Hough (Ex. 1112)

A. Hough teaches all claim features of Claims 1 and 11

The article by J. Hough et al. titled “Long-Term Results for the Xomed Bone Conductor,” *Otolaryngologic Clinics of North America*, Vol. 28, No. 1, pp. 43-52, was published in Feb. of 1995 (Ex. 1112), and is thus prior art under pre-AIA 35 U.S.C. § 102(b) against the ‘040 Patent.

Hough explains, starting at the first paragraph on p. 43, that the ABC hearing device works by transcutaneous inductive electromagnetic energy

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stemming from an external processor, which causes vibrations of an implanted magnet. See also Ex. 1112, p. 44, first ¶ under “Description of the Device” section. These vibrations produce hearing via bone conduction. Ex. 1102, ¶¶ 73, 91, 92. The processor is placed behind the patient’s ear. Ex. 1112, p. 44, first ¶ under “Description of the Device” section. As current passes through an external coil, alternating electromagnetic fields cause the implanted magnet in the temporal bone to vibrate. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 73, 91, 93, 94. Thus, power is transmitted from the external part to the internal part by induction. Ex. 1102, ¶¶ 73, 91. An orthopedic screw is used to attach the implanted magnet for “secure” osseointegration. Ex. 1112, p. 44, third ¶ under “Description of the Device” section; Ex. 1102, ¶ 93.

Hough further describes using the ABC hearing aid device for unilateral sensorineural deafness, stating that this is a “desirable application” that allows “sound energy to be transmitted by bone conduction across the head from a microphone on the deaf side (across the skull to the normal ear).” Ex. 1112, p. 45, lines 12-16; Ex. 1102, ¶¶ 74, 91, 92. Further, based at least on this disclosure, a POSA would have understood that the ABC hearing device as described in Hough is implanted on the patient’s deaf side, where sound is mechanically transmitted via vibrations to the other, non-deaf side. Ex. 1102, ¶¶ 92, 94, 95.

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It would have further been apparent to a POSA that the ABC hearing device disclosed in Hough (Ex. 1112) necessarily includes a battery to power various components therein, including the microphone, amplifier and the external coil. Ex. 1102, ¶¶ 75, 99-102. See also, Ex. 1111, p. 316, third ¶ in “Description of the ABC Device” section. Hough (Ex. 1112) specifically cites to Ex. 1111 when referring to the ABC device. Ex. 1112, end note 4 (p. 43, first full ¶; p. 44 third full ¶ in “Description of the Device” section; second full ¶ in “Indications for Use” section).

B. Hough Anticipates Claims 1 and 11 of the ‘040 Patent

Petitioner notes the proposed claim construction above for language in claim 1 that reads: 1. “for rehabilitation of unilateral hearing loss” (preamble, no patentable weight); 2. “mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient” (intended use); and 3. “being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient” (intended use) (sections **V.(B.)**(1.)-**V.(B.)**(3.), respectively). Even if such claim constructions are only partially adopted, or not adopted at all, Hough still discloses all claimed features.

Specifically, a POSA would have recognized that Hough discloses the ABC hearing device as including an implantable part (including an orthopedic screw

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implant) configured to mechanically anchor a vibratory generating part (including an implanted magnet), the implantable part being “osseointegrated” in the patient’s skull bone behind an external ear at the deaf side of the patient. Ex. 1112, p. 43, first ¶; p. 44, first and third ¶s under “Description of the Device” section; Ex. 1102, ¶¶ 90-95. Further, Hough describes implanting the ABC hearing aid device on the deaf side of a patient having unilateral sensorineural deafness, such that sound energy is transmitted by bone conduction across the head from the microphone on the deaf side and across the skull to the normal ear. Ex. 1112, p. 45, lines 12-16; Ex. 1102, ¶¶ 74, 91, 92. Thus, Hough discloses all features of claim 1.

For claim 11, Petitioner notes the proposed claim construction above for “external part” and “internal part” (section **V.(B.)(4.)**). Even if such claim construction is not specifically adopted, Hough discloses all features recited in claim 11.

Hough describes the ABC hearing device as having external and internal parts, with the external part (“external processor”) having a microphone, an amplifier and an electromagnetic coil, with power being transmitted from the external part to the internal part by induction. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 100, 101, 73, 74, 91, 93. It would have further been apparent to a POSA that that the ABC hearing device disclosed in Hough (Ex. 1112) necessarily included a battery to power various

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components therein, including the microphone, amplifier and the external coil. Ex. 1102, ¶¶ 75, 99-102. See also, Ex. 1111, p. 316, third ¶ in “Description of the ABC Device” section. The ABC device described by Hough (Ex. 1112) was known to have such a battery, and its presence would have been apparent to a POSA. Such a battery has been specifically described as a component of the external ABC device. See e.g., Ex. 1111 (which is cited by Hough at p. 43, first full ¶; p. 44 third full ¶ in “Description of the Device” section; second full ¶ in “Indications for Use” section), p. 316, third ¶ in “Description of the ABC Device” section; Ex. 1002, ¶¶ 75, 100. Thus, Hough discloses all features of claim 11. Ex. 1102, ¶¶ 95, 101, 102.

C. Claims Chart for Ground 1

The following claims chart further details how Hough discloses all features in claims 1 and 11 of the ‘040 Patent. Accordingly, these claims should be canceled as being anticipated by Hough.

Claims 1 and 11 of the ‘040 Patent	Exemplary Citations in Hough (Ex. 1112)
Claim 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	Note the proposed claim construction for language in claim 1 that reads “for rehabilitation of unilateral hearing loss” (preamble, no patentable weight) (section V.(B).(1.)). Should the Board decide otherwise, as explained below, Hough still discloses this feature.

<p>Claims 1 and 11 of the '040 Patent</p>	<p>Exemplary Citations in Hough (Ex. 1112)</p>
<p>another side of the patient's head for rehabilitation of unilateral hearing loss,”</p>	<p>Hough describes the ABC hearing device as being implanted on the deaf side, such that sound is mechanically transmitted via vibrations to the other, non-deaf side. Ex. 1112, p. 45, lines 12-16; Ex. 1102, ¶¶ 73, 91, 92. Hough describes using the ABC hearing aid device for unilateral sensorineural deafness . Ex. 1112, p. 45, lines 12-16; Ex. 1102, ¶¶ 74, 91, 92. Transcutaneous inductive electromagnetic energy stemming from an external processor causes vibrations of an implanted magnet, such vibrations producing hearing via bone conduction from one side of the patient’s head to the patient’s cochlea on the non-deaf side. Ex. 1112, p. 44, first ¶ and third ¶ under “Description of Device”; Ex. 1102, ¶¶ 73, 91, 93, 94.</p>
<p>“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”</p>	<p>Note the proposed claim construction above for “mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient” (intended use) (section V.(B).(2.)). Should the Board decide otherwise, as explained below, Hough still discloses this feature.</p> <p>Hough discloses the ABC hearing aid device as having an external part equipped with a microphone, amplifier and electromagnetic coil having a magnetic core. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 75, 99-102. Current passes through the external coil, such that alternating electromagnetic fields cause the implanted magnet to vibrate to produce vibratory energy to the inner ear on the non-deaf side of the patient. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 73, 74, 93, 94.</p>

<p>Claims 1 and 11 of the '040 Patent</p>	<p>Exemplary Citations in Hough (Ex. 1112)</p>
<p>“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.”</p>	<p>Note the proposed claim construction above for “being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient” (intended use) (section V.(B.)(3.)). Should the Board decide otherwise, as explained below, Hough still discloses this feature.</p> <p>Hough discloses the ABC hearing aid device as having an external part equipped with an electromagnetic coil. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 73, 93. As current passes through the external coil, alternating electromagnetic fields cause the internal implanted magnet to vibrate, thereby producing vibratory energy to the cochlea. An orthopedic screw ensures proper osseointegration of the internal part. Ex. 1112, p. 44, first and third ¶s under “Description of the Device” section; Ex. 1102, ¶¶ 73, 74, 91, 93, 94. Further, the ABC device is described by Hough as being implanted on the deaf side of the patient. Ex. 1112, p. 45, lines 12-16; Ex. 1102, ¶¶ 74, 91, 93.</p>
<p>Claim 11. “The hearing aid apparatus according to claim 1, wherein the implantable part and the vibratory generating part comprise an internal part, the hearing aid apparatus further comprising: an external part comprising a microphone and a battery, wherein power to the internal part is transmitted from the external part by</p>	<p>Petitioner notes the proposed claim construction above for “external part” and “internal part” in claim 11. (section V.(B.)(4.)). Even if such claim construction is not specifically adopted, Hough still discloses all features recited in claim 11.</p> <p>Hough discloses the ABC hearing aid device as having both external and internal parts, the external part having a microphone, an amplifier and external coil. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 73, 99, 100, 101. It would have been apparent to a POSA that the ABC hearing device disclosed in Hough necessarily</p>

Claims 1 and 11 of the '040 Patent	Exemplary Citations in Hough (Ex. 1112)
<p>induction.”</p>	<p>includes a battery to power various components therein, including the microphone, amplifier and external coil. Ex. 1102, ¶¶ 75, 100. See also, Ex. 1111, p. 316, third ¶ in “Description of the ABC Device” section.</p> <p>The ABC device described by Hough (Ex. 1112) was known to have such a battery, and its presence would have been apparent to a POSA. Such a battery has been specifically described as a component of the external ABC device. See e.g., Ex. 1111 (which is cited by Hough at p. 43), p. 316, third ¶ in “Description of the ABC Device” section; Ex. 1002, ¶¶ 75, 100.</p> <p>Alternating electromagnetic fields cause an implanted magnet to vibrate, thereby producing vibratory energy that is transmitted to the cochlea on the patient’s non-deaf side. Ex. 1112, p. 44, first ¶ under “Description of the Device” section; Ex. 1102, ¶¶ 100, 73, 93. Thus, power is transmitted from the external part to an internal part by induction. Ex. 1102, ¶¶ 100, 101, 73, 91, 93.</p>

VII. Ground 2: Claim 12 is unpatentable as being obvious under pre-AIA 35 U.S.C. § 103(a) over Hough (Ex. 1112) in view of Leysieffer (Ex. 1109)

A. Hough Combined with Leysieffer teaches the feature of Claim 12

As stated in **Ground 1**, section **VI(A.)** above, Hough (Ex. 1112) discloses all features of claims 1 and 11. Any additional features of claim 12, which depends on claim 11, are described in Leysieffer (Ex. 1109).²

1. Teachings of Leysieffer (Ex. 1109)

Leysieffer describes a partially or totally implantable system for rehabilitating a hearing disorder by applying electrical, mechanical or acoustic stimulation to the patient's middle or inner ear. Ex. 1109, p. 1, lines 5-6; p. 2, lines 27-29; p. 7, lines 15-30; Ex. 1102, ¶¶ 76, 107-109. The Leysieffer system is applicable to unilateral hearing losses. Ex. 1109, p. 15, lines 16-17; Ex. 1102, ¶¶ 76, 108. With this arrangement, electrical components in the implanted part are capable of performing various hearing aid functions, including audio signal processing, noise and feedback suppression, output level limiting for patient protection, wireless communication with the external unit, power management, operation monitoring, data storage and wireless updating of operating parameters

² The '040 Patent specification only refers to a "rechargeable battery" in the context of the embodiment illustrated in Fig. 3, in which an "internal part" is positioned on the patient's non-deaf side to create vibrations. Ex. 1101, Fig. 3, Col. 3, lines 15-24. Because the implanted part 8 is already positioned on the patient's non-deaf side, such an arrangement does not mechanically transmit vibrations "through the skull bone from a deaf side to the inner ear on the other side of the patient" as recited in claim 1, from which claim 12 depends. At least for this reason, Petitioner does not concede that claim 12 is a proper dependent claim supported by the '040 Patent specification.

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and programming. Ex. 1109, p. 7, line 18 to p. 8, line 7; p. 12, line 11 to p. 13, line 9; p. 16, line 28 to p. 17, line 5; Ex. 1102, ¶¶ 77, 107.

In Leysieffer, an external unit wirelessly recharges an implanted-side power supply unit that contains a rechargeable battery (see e.g., rechargeable battery 60 in Fig. 3) to “allow longer service lives and thus increasing residence times in the patients.” Ex. 1109, p. 8, lines 8-11; p. 4, lines 26-28; p. 14, line 29 to p. 15, line 2; Ex. 1102, ¶¶ 78, 108.

B. *KSR* Rationale to Combine

For obviousness analysis, prior art references must be “considered together with the knowledge of one of ordinary skill in the pertinent art.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (C.C.P.A. 1978)). Moreover, “it is proper to take into account not only specific teachings of the reference, but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (C.C.P.A. 1968).

As explained in section **VII.(A).(1.)** above, Leysieffer teaches a rechargeable battery in the internal part of an implantable hearing device, which is charged by induction from an external unit. Ex. 1109, p. 8, lines 8-11; p. 4, lines 26-28; p. 13, lines 10-11; p. 14, line 29 to p. 15, line 2; Fig. 1; Ex. 1102, ¶¶ 78,

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108. One benefit of wirelessly recharging the rechargeable battery is to “allow longer service lives and thus increasing residence times in the patients.” Ex. 1109, p. 8, lines 8-11; Ex. 1102, ¶¶ 78, 108.

Here, the POSA would have found it obvious to modify the ABC hearing device as described in Hough (Ex. 1112) so that the implanted part includes a rechargeable battery as taught by Leysieffer, thereby satisfying all features recited in claim 12 of the ‘040 Patent. Ex. 1102, ¶¶ 109-113. 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. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); Ex. 1102 at ¶¶ 109-113.

Moreover, Leysieffer teaches that providing electronics in an implantable hearing aid unit, and using a rechargeable battery to supply power to such electronics, allows the implantable part to perform various desirable functions, including audio signal processing, noise and feedback suppression, output level limiting for patient protection, wireless communication with an external unit, power management, operation monitoring, data storage and wireless updating of operating parameters and programming. Ex. 1109, p. 7, line 18 to p. 8, line 7; p. 12, line 11 to p. 13, line 9; p. 16, line 28 to p. 17, line 5; Ex. 1102, ¶¶ 109, 76-78, 107, 108. A POSA would have further recognized that using rechargeable battery, and charging such a battery via induction from an external unit, extends service life

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and avoids replacement of a standard (non-chargeable battery). Ex. 1109, p. 8, lines 8-11; Ex. 1102, ¶¶ 78, 108, 109.

Still further, a POSA would have recognized that modifying the ABC hearing device as described in Hough (Ex. 1112) so that the implanted part includes a rechargeable battery as taught by Leysieffer would have satisfied a demand for improving known medical devices to attain predictable, beneficial results. *See KSR*, 550 U.S. at 416; Ex. 1102, ¶¶ 112, 113. More specifically, a POSA would have recognized 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. Ex. 1102, ¶¶ 112, 113. A POSA would have recognized cosmetic concerns associated with hearing aid size as a significant design consideration. Ex. 1102, ¶ 112; Ex. 1120, pg. 4 (referring to customer preference for hearing aid devices that are smaller and less conspicuous).

C. Claim Chart for Ground 2

The following claim chart further details how the obvious modification of Hough in view of Leysieffer satisfies the feature recited in claim 12 of the '040

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Patent. Accordingly, this claim should be canceled as being obvious over Hough in view of Leysieffer.

U.S. Patent No. 7,043,040 – Claim 12	Exemplary Citations in Hough (Ex. 1112) and Leysieffer (Ex. 1109)
Claim 12. “The hearing aid apparatus according to claim 11, wherein the internal part comprises a rechargeable battery arranged to be charged by induction from an external power supply.”	Leysieffer discloses that the implantable hearing aid includes a rechargeable battery (such as element 60 in Fig. 1 and Fig. 3) that can be charged wirelessly by an external unit for the benefit of longer service life and increased residence time in a patient. Ex. 1109, p. 14, line 29 to p. 15, line 2; see also p. 4, line 28; p. 8, line 9; Ex. 1102, ¶¶ 76-78, 107-113.

VIII. CONCLUSION

Petitioner has demonstrated a reasonable likelihood that Petitioner will prevail in demonstrating that claims 1, 11 and 12 of the '040 Patent are unpatentable as being either anticipated or obvious in view of the art discussed above. 35 U.S.C. § 314(a). Petitioner requests that the PTAB institute an *inter partes* review proceeding and cancel claims 1, 11 and 12 of the '040 Patent.

Respectfully submitted,

/D. Richard Anderson/

D. Richard Anderson

Reg. No. 40,439

Attorney for Petitioner

Birch, Stewart, Kolasch & Birch, LLP

Appendix – Exhibit List

APPENDIX – LIST OF EXHIBITS

Ex. No.	Description
1101	U.S. Patent No. 7,043,040 (P. Westerkull)
1102	Expert Declaration by Dr. Gerald R. Popelka, Ph.D.
1103	Verified English language translation of “Baha prosthetic rehabilitation of unilateral anacusis,” <i>Ann. Otolaryngol Chir. Cervicofac.</i> , Vol. 117, No. 6, pp. 410-417 (2000) (F.M. Vaneecloo et al.)
1104	F.M. Vaneecloo et al., “Réhabilitation prothétique B.A.H.A. des cophoses unilatérales: Etude par la stéréaudiométrie,” <i>Ann. Otolaryngol. Chir. Cervicofac.</i> , Vol. 117, No. 6, pp. 410-417 (2000)
1105	[reserved]
1106	J.J. Wazen et al., “Long-Term Results With the Titanium Bone-Anchored Hearing Aid: The U.S. Experience,” <i>The American Journal of Otology</i> , Vol. 19, pp. 737-741 (1998).
1107	Peder U. Carlsson, “On Direct Bone Conduction Hearing Devices: advances in transducer technology and measurement methods,” Technical Report No. 195, (1990), pages 1-183.
1108	M. Chasin et al., “Current Trends in Implantable Hearing Aids,” <i>Trends in Amplification</i> , Vol. 2, No. 3, pp. 84-107, 1997.
1109	CA 2 301 437 A1 (H. Leysieffer)
1110	Prosecution history of U.S. Patent No. 7,043,040 B2 (146 pages)
1111	D.A. Hough et al., ““The Surgical Technique for Implantation of the Temporal Bone Stimulator (Audiant ABC),” <i>The American Journal of Otology</i> , Vol. 7, Issue No. 5, pp. 315-321 (Sept. 1986).
1112	J.V.D. Hough et al., “Long-Term Results for the Xomed Bone Conductor,” <i>Otolaryngologic Clinics of North America</i> , Vol. 28, No. 1, pp. 43-52 (Feb. 1995).
1113	[reserved]
1114	[reserved]
1115	E.P. Fowler, “Bilateral Hearing Aids for Monaural Total Deafness: A Suggestion for Better Hearing,” <i>Arch Otolaryngol</i> , Vol. 72, pp. 57-58 (1960).
1116-1119	[reserved]
1120	Kochkin, “Optimizing The Emerging Market For Completely-in-the-Canal Instruments,” <i>The Hearing Journal</i> , Vol. 47, No. 6, pp. 1-6 (June 1994)

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), Petitioner hereby certifies, in reliance on the word count of the word-processing system (Microsoft Office Word 2010) used to prepare this Petition, that the number of words in this paper is 7,753, which is 14,000 words or less as required by 37 C.F.R. § 42.24(a)(1)(i). This word count excludes the table of contents, table of authorities, certificate of word count, certificate of service, and exhibit list.

/D. Richard Anderson/
D. Richard Anderson
Reg. No. 40,439
Attorney for Petitioner

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing IPR Petition and all Exhibits listed in Appendix 1 of the IPR Petition were served on March 3, 2017, via U.S. Postal Service Express Mail to the correspondence address for the '040 Patent as follows:

Hauptam Ham, LLP
2318 Mill Road
Suite 1400
Alexandria, VA 22314

Dated: March 3, 2017

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