Filed via PRPS on March 3, 2017

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 IPR2017-01018

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-10 AND 13 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 1-10 and 13 ("challenged claims") of U.S. Patent 7,043,040 ("the '040 Patent") (Ex. 1001). This Petition shows by a preponderance of the evidence that there is a reasonable likelihood that Petitioner will prevail in proving that claims 1-10 and 13 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 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 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).

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

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

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

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

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

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

As identified in the attached Certificate of Service, a copy of the present petition, in its entirety, including a declaration, all Exhibits and a power of attorney, is being served by 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 1-10 and 13 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. 1002).

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. 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.

Exhibits 1003 and 1004 (Vaneecloo)

"Réhabilitation prothétique B.A.H.A. des cophoses unilatérales: Etude par la stéréaudiométrie," Ann. Otolaryngol. Chir. Cervicofac., Vol. 117, No. 6, pp. 410-417 (2000) to F.M. Vaneecloo et al. was published (in the French

language) December, 2000 (Ex. 1004). A verified English translation of Vaneecloo is herein provided as Ex. 1003 ("Prosthetic Rehabilitation of Unilateral Anakusis: Study by stereo-audiometry," Ann. Otolaryngol. Chir. Cervicofac., Vol. 117, No. 6, pp. 410-417 (2000)). Citations herein are to the English translation (Ex. 1003). Vaneecloo is prior art under pre-AIA 35 U.S.C. § 102(b) against the '040 Patent.

Exhibit 1007 (Carlsson) - "On Direct Bone Conduction Hearing Devices: advances in transducer technology and measure methods," Technical Report No. 195, Department of Applied Electronics, Chalmers University of Technology, published in 1990. Carlsson is prior art under pre-AIA 35 U.S.C. § 102(b) against the '040 Patent.

Exhibit 1009 (Leysieffer) - Canadian Patent Document No. CA 2 301 437 (A1) to H. Leysieffer ("Leysieffer") published on October 8, 2000. Leysieffer is prior art under pre-AIA 35 U.S.C. § 102(b) against the '040 Patent.

Exhibit 1018 (Lesinski) - U.S. Patent No. 5,881,158 to S. Lesinski et al. ("Lesinski") issued March 9, 1999. Lesinski is prior art under pre-AIA 35 U.S.C. § 102(b) against the '040 Patent.

Exhibit 1019 (Schaefer) - U.S. Patent No. 4,729,366 to D. Schaefer ("Schaefer") published March 8, 1988. Schaefer 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 1-10 and 13 of the '040 Patent on the following grounds:

Ground	'040 Patent Claims	Basis
No. 1	1-5 and 13	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Vaneecloo* (Exs. 1003, 1004) in view of *Carlsson* (Ex. 1007)
No. 2	6, 7 and 9	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Vaneecloo* (Exs. 1003, 1004) in view of *Carlsson* (Ex. 1007) and *Leysieffer* (Ex. 1009)
No. 3	8	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Vaneecloo* (Exs. 1003, 1004) in view of either *Carlsson* (Ex. 1007), *Leysieffer* (Ex. 1009) and *Schaefer* (Ex. 1019)
No. 4	10	Obvious under pre-AIA 35 U.S.C. § 103(a) by *Vaneecloo* (Exs. 1003, 1004) in view of *Carlsson* (Ex. 1007), *Leysieffer* (Ex. 1009) and *Lesinski* (Ex. 1018)

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

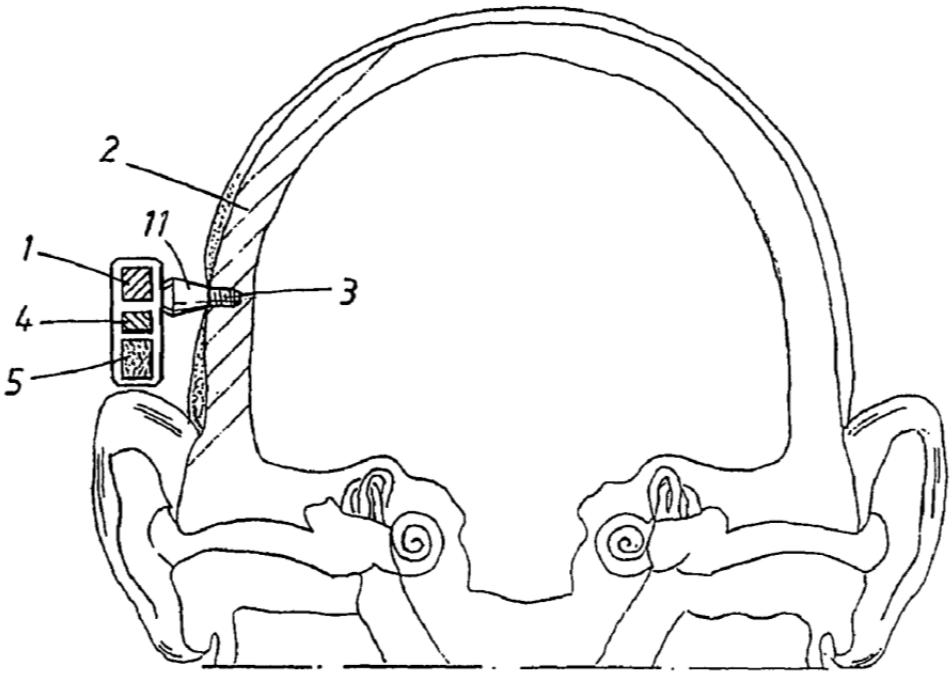
IV. The '040 Patent, the State of the Art Prior to the Relevant Date, and the Person of Ordinary Skill in the Art

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. 1001, Abstract. The hearing aid apparatus is configured as a bone-anchored device for conducting sound. Ex. 1002, ¶¶ 33-51. The hearing aid apparatus includes a vibratory generating part that 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. 1001, Abstract. Osseointegration refers to the direct structural and functional connection between living bone and the surface of a load-bearing artificial implant. Ex. 1002, ¶ 34. In the context of hearing aids, the artificial implant is typically a titanium anchor. Ex. 1002, ¶ 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

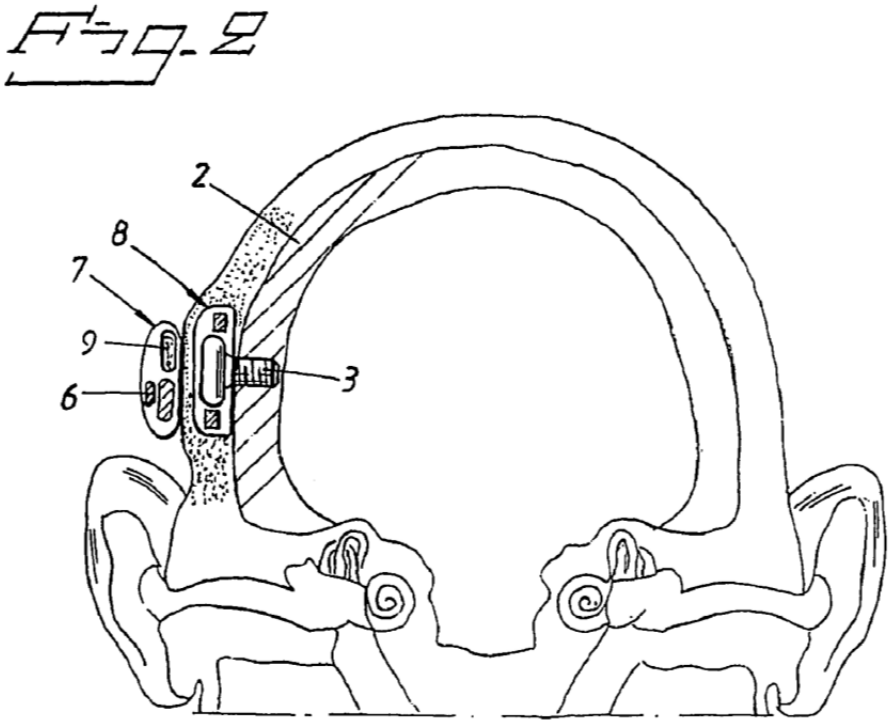
As shown in in Fig. 1, the hearing aid apparatus includes a housing that contains a vibrator 1. The housing is mechanically coupled to the skull bone 2 by a fixture 3. Ex. 1001, col. 2, lines 50-53. Sound is picked by a microphone 5 and amplified and filtered by electronic circuitry 4. Ex. 1001, col. 2, lines 53-55. 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. 1001, 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. Ex. 1001, col. 2, lines 50-53; Fig. 1. This arrangement, having a fixture that penetrates the patient's skin, is considered "percutaneous." Ex. 1002, ¶ 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. 1001, 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. 1001, 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. 1001, 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 implanted part 8 to avoid skin penetration (i.e., a "transcutaneous" configuration; Ex. 1002, ¶¶ 40-41) (Ex. 1001, col. 3, lines 9-14):



2 = skull bone

3 = fixture

6 = microphone

7 = external part (outside skin)

8 = implanted part

9 = battery

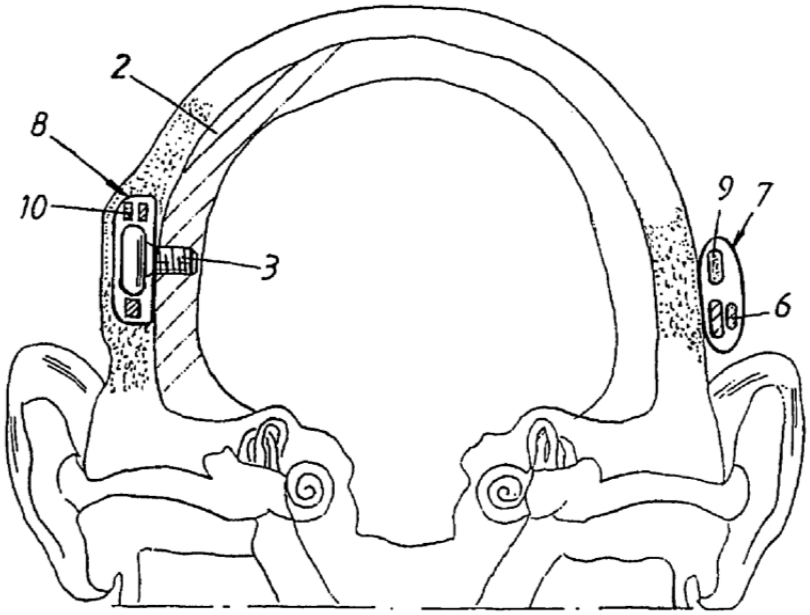
This alternative hearing aid embodiment does not use a fixture that penetrates the patient's skin, and instead includes an "implantable part including the vibrator" positioned under the patient's skin and an external part 7 positioned outside the patient's skin. The external part 7 includes the microphone 6 and battery 9. Ex. 1001, col. 3, lines 9-12. This arrangement having external and implanted parts 7, 8 separated by the patient's skin is considered transcutaneous. Ex. 1002, ¶¶ 40-41. With this arrangement, "[p]ower is transmitted to the implanted part 8 of the hearing aid by means of induction". Ex. 1001, 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). Ex. 1002, ¶¶ 40, 41.

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. 1001, 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. 1001, col. 3, lines 18-22; Ex. 1002, ¶42. The signal transmitted in the hearing aid

apparatus of Fig. 3 can be an analog signal or a digital radio signal. Ex. 1001, 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. 1002, ¶ 43.

Fig. 3



2 = skull bone

3 = fixture (on on-deaf side)

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. 1001, col. 3, lines 18-22; Ex. 1002 ¶ 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. 1010, pp. 119-146 of 146. A preliminary amendment was filed on December 22, 2003, including minor amendments the original claims. Ex. 1010, pp. 102-106/146. An Information Disclosure Statement was filed on October 6, 2004. Ex. 1010, pp. 51-52/146.

The USPTO issued a non-final Office Action on March 31, 2005. Ex. 1010, 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. 1010, 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. 1010, 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." Ex. 1010, p. 23/146.

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. 1010, 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 known prior to the critical date. The concept of hearing by bone

conduction (via the human skull) has been known since at least 1960. Ex. 1015 (Fowler), p. 57/41, paragraph bridging left-right columns. 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. 1015, p. 57/41, paragraph bridging left and right columns; Ex. 1002, ¶ 54. Generally, prior to the earliest priority date of the '040 Patent, one type of a known 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, producing sound perception on the deaf side. Ex. 1002, ¶¶ 54, 57-59, 63, 67, 94. To install the BAHA, a titanium post was surgically embedded into the skull with a small section exposed outside of the skin (i.e., a "percutaneous" arrangement). A sound processor was positioned on the exposed section to transmit sound vibrations via the titanium post. Ex. 1007 (Carlsson 1990), Fig. 1 on p. 3, p. 4, left column, first full ¶; Ex. 1002, ¶¶ 59, 60.

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. 1002, ¶ 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

[1] BAHA is a registered trademark currently owned by Cochlear Bone Anchored Solutions AB; in 1997, as explained in Ex. 1008, ¶ 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).

bone-conducted. Ex. 1002, ¶ 35; Ex. 1007, pp. 9-11, section "Hearing by bone conduction".

The first BAHA device was fitted to a patient in 1977. Ex. 1005 (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. 1006 (Wazen et al.), p. 737, left col., second full ¶ (at bottom). Clinical trials in the U.S. for patients using the BAHA device were conducted in 1984-1987. Ex. 1006 (Wazen), p. 737, right col., lines 1-2 (¶ above "Materials and Methods"). The U.S. FDA approved use of the BAHA for adults in August of 1996. Ex. 1006, p. 737, right col., lines 2-4; Ex. 1002, ¶ 58. The BAHA entered the U.S. market in January of 1997. Ex. 1006, p. 737, right col., lines 4-5. See also Ex. 1002, ¶ 58.

Since the first fitting in 1977, the BAHA device has been tested and refined as exemplified by at least Ex. 1007 (Carlsson) and Ex. 1008 (Chasin 1997). It is evident from these and other prior art publications discussed herein that all of the technical components for a hearing aid apparatus described in the '040 Patent were known prior to the critical date. Such publications describe fitting patients with bone-conducting-type hearing aids that include both a vibratory generating part and an implantable part osseointegrated into a patient's skull to treat hearing loss, including unilateral hearing loss. Ex. 1002, ¶¶ 62, 66, 67.

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. 1002) 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-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 in fitting such devices including bone conduction-type hearing aids or (ii) 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. Ex. 1002, ¶ 32. Graduate work could substitute for work experience, and additional work experience could substitute for formal education. Ex. 1002, ¶ 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 this 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.

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

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. "Means plus Function"

Petitioner recognizes that claim elements of the '040 Patent reciting "means," or some similar generic placeholder, may be subject to interpretation under pre-AIA 35 U.S.C. § 112, ¶ 6. Petitioner does not concede that the '040 Patent discloses adequate structure for performing the functions associated with any claimed "means" and accordingly reserves the right to argue in other forums, such as in district court, that the lack of such adequate structure renders such claimed "means" language as indefinite. Solely for the purpose of aiding the Board's consideration of the '040 Patent claims, Petitioner submits the following.

Claim 6 recites "electronic circuitry operative to convert a signal from a microphone … from an analog signal to a digital signal." Col. 2, line 63 to col. 3,

line 8 of 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.” Since the ‘040 Patent appears to use the terms “means” and “circuitry” interchangeably, Petitioner recognizes that the “electronic circuitry” as recited in claim 6 may be interpreted as “means plus function” under pre-AIA 35 U.S.C. § 112, ¶ 6. For purposes of this IPR proceeding only, and without waiver of its right to argue for indefiniteness in other forums, such as in district court, Petitioner submits that the claimed “electronic circuitry operative to convert…” term should be construed as an analog-to-digital converter as was known in the art as of the critical date.

Claim 7 depends from claim 6 and simply states that the electronic circuitry (as recited in claim 6) “comprises digital signal processing means.” Claim 8 depends from claim 7 and further specifies that the signal processing means “adapts frequency characteristics to individual differences in an acoustic head shadow effect, to a sound environment, to a resonance of the patient's skull, or to a hearing capacity of a functioning ear of the patient.”

Claim 9 depends from claim 6 and states that the electronic circuitry (as recited in claim 6) comprises “signal processing means for actively counteracting acoustic feed-back problems in the apparatus.” Claim 10 also depends from claim 6 and states that the hearing aid apparatus further comprises “directivity means

comprising at least one directivity dependent microphone and/or signal processing means in the electronic circuitry."

The '040 Patent specification does not disclose any specific "digital signal processing" algorithm, and instead generally refers to using "signal processing means … for adapting for instance the frequency characteristics to individual differences in the head shadow effect, the sound environment, the skull resonance, sound direction and the hearing capacity of the well-functioning ear." Ex. 1001, col. 3, lines 2-6. The '040 Patent specification further states that "[t]he signal processing means can also be used for actively counteracting acoustic feed-back problems." Ex. 1001, col. 3, lines 6-8. The description at col. 2, line 63 to col. 3, line 8 of the '040 Patent specification generally mirrors the language in claims 7-9, but does not otherwise disclose details of any specific structure or algorithm for performing the recited functions.

For purposes of this IPR proceeding only, and without waiver of its right to argue for indefiniteness in other forums, such as in district court, Petitioner submits that the claimed "digital signal processing means" term in claims 7 and 8 and the claimed "signal processing means" term in claims 9 and 10 should be construed as a digital signal processor, such as hardware, software, or a hardware-software combination, for performing the claimed signal processing functions.

VI. Ground 1: Claims 1-5 and 13 are unpatentable as obvious under pre-AIA 35 U.S.C. § 103(a) over Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007)

A. Vaneecloo and Carlsson teach all claim features of Claims 1-5 and 13

1. Teachings of Vaneecloo (Exs. 1003, 1004)

Vaneecloo details a clinical study in which two patients each had a BAHA hearing aid apparatus implanted on the deaf side of their head. Ex. 1003, Abstract on p. 410; Ex. 1002, ¶¶ 68, 70. Vaneecloo first explains that sounds of lower frequencies below 800 Hz emitted at one ear of a subject can reach the opposite ear by going around the head "with virtually no attenuation." Ex. 1003, p. 410, "*Introduction*" section on right column. This is not the case, however, for higher pitched sounds such as the human voice. Such higher pitched sounds are attenuated, resulting in difficulties due to the loss of binaural hearing. Ex. 1003, p. 410, "*Introduction*" section, right col.; p. 411, left col., lines 9-13. Vaneecloo describes compensating this type of hearing loss by providing a contralateral routing of signal using a BAHA device for transmitting sound captured on the deaf (anakusis) side, through the human cranium (skull bone) from the deaf side to the side with the functional ear in order to provide bilateral capture of sound. Ex. 1003, p. 411, left col., lines 14-24; Ex. 1002, ¶¶ 70, 71, 73. The patients experienced

improved hearing for higher pitched sounds. Ex. 1003, p. 415, right col., lines 18-21, 25-45; Ex. 1002, ¶¶ 70, 73, 74.

In the study of Vaneecloo, two patients with implanted BAHA devices experienced improved hearing, especially for higher frequency sounds captured on the anacusic (deaf) side and "perceived by transcranial route by the contralateral ear" (non-deaf ear). Ex. 1003, p. 415, right col., fourth ¶ from bottom; Ex. 1002, ¶ 70.

More specifically, Vaneecloo discloses using a BAHA prosthesis attached to a titanium fixture implanted on the deaf side of each patient. Ex. 1003, p. 411, left col., lines 14-24 for patient "*Mr. Claude B*" see p. 412, left col., lines 7-9; see p. 412, right col., lines 9, 17-19 for second patient "*Mr. Alain C*"; Ex. 1002, ¶ 69.

The bone-conducting, bone-anchored hearing aid of Vaneecloo is referred to as a BAHA-type apparatus, which is described in Vaneecloo as capturing sound at the patient's deaf side and transmitting such sound through the cranium to the functional ear. Ex. 1003, p. 411, left col., lines 14-24; Abstract; Ex. 1002, ¶¶ 68-71. A POSA would have recognized such a BAHA device as having a vibratory generating part (e.g., transducer) for generating vibrations that are mechanically transmitted through the patient's skull bone from the deaf side to the inner ear on the other side of the patient. Ex. 1002, ¶¶ 71-74, 90-91, 93-97, 99-103.

Further, as mentioned above, Vaneecloo discloses that a titanium fixture was implanted at the temporal bone near the deaf ear of each patient. Ex. 1003, p. 412, left col., lines 7-9 and right col., lines 17-19; Ex. 1002, ¶¶ 69, 98. The BAHA prosthesis was attached to the titanium fixture some months afterwards. Ex. 1003, p. 412, left col., lines 11-13 and right col., lines 20-21; Ex. 1002, ¶¶ 69, 98.

A POSA would have recognized that the BAHA device of Vaneecloo included a titanium implant (an implantable part) configured 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 the patient. Ex. 1002, ¶¶ 98-103, 112.

Vaneecloo describes testing the hearing of each patient at 250 Hz and 2000 Hz (Ex. 1003, p. 415, left col., lines 12-15; corresponding Fig. 11 for patient Claude B and Fig. 12 for patient Alain C on p. 416), and reports that: "we found that the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for significant rise in sound 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." Ex. 1003, p. 415, right col., fourth paragraph from the bottom. Thus, a POSA would have understood that the BAHA device of Vaneecloo amplified

treble frequencies (greater than 1 kHz) more than bass frequencies. Ex. 1002, ¶¶ 73, 74, 117-118.

Vaneecloo concludes by stating that future, promising endeavors should be taken: "We believe that this first approach of this new device placement is very interesting. It must continue in time." Ex. 1003, p. 415, right col., lines 46-47.

Although Vaneecloo describes treating unilateral hearing loss using a BAHA prosthesis attached to a titanium implant that has been osseointegrated to skull bone on the patient's deaf side, configuration of the BAHA hearing apparatus itself is not specifically illustrated or described in detail. Thus, Patent Owner may argue that Vaneecloo does not adequately describe all features of claim 1 of the '040 Patent, including the "vibratory generating part." Patent Owner may further argue that the titanium fixture of Vaneecloo is not specifically illustrated, such that the titanium implant therein does not necessarily comprise an "implant screw" as recited in dependent claim 2. Any such features allegedly not taught by Vaneecloo are clearly taught by the prior art, including Carlsson (Ex. 1007).

2. Teachings of Carlsson (Ex. 1007)

Carlsson describes a Bone-Anchored Hearing Aid ("BAHA") device as a new hearing device as of 1990, stating on p. 4, first full paragraph (emphasis in original):

> A new type of hearing aid has been developed, the Bone-Anchored Hearing Aid (BAHA), which solves some of the problems connected with *ac* and *bc* hearing devices. 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, as illustrated in figure 1. In that way, the patient can hear by *direct bone conduction*, that is, the skin is not included in the vibration transmission between the hearing aid and the skull bone. The BAHA can be considered as "invisible" for patients with normal hair growth.

Thus, the BAHA device described in Carlsson works by bone conduction (see also Abstract of Ex. 1007). Ex. 1002, ¶ 59. The BAHA device of Carlsson is also described as being an improvement over air conduction (*ac*) and bone conduction (*bc*) hearing aids. Ex. 1007, p. 3, left col., last ¶; p. 4, first full ¶. Carlsson describes certain advantages for the BAHA device described therein, including: effective bone conduction; improved speech intelligibility; patient comfort (absence of pain); and a single housing construction. Ex. 1007, p. 4, first full ¶; p. 9, lines 12-14; p. 10, first full ¶; p. 13, lines 2-3, p. 16, last ¶; p. 22, first full ¶ under "Rehabilitation results achieved" section; see also the results in Table IV on p. 23; Ex. 1002, ¶ 61.

Fig. 1 from p. 3 of Carlsson is reproduced below, which shows the BAHA device in more detail:

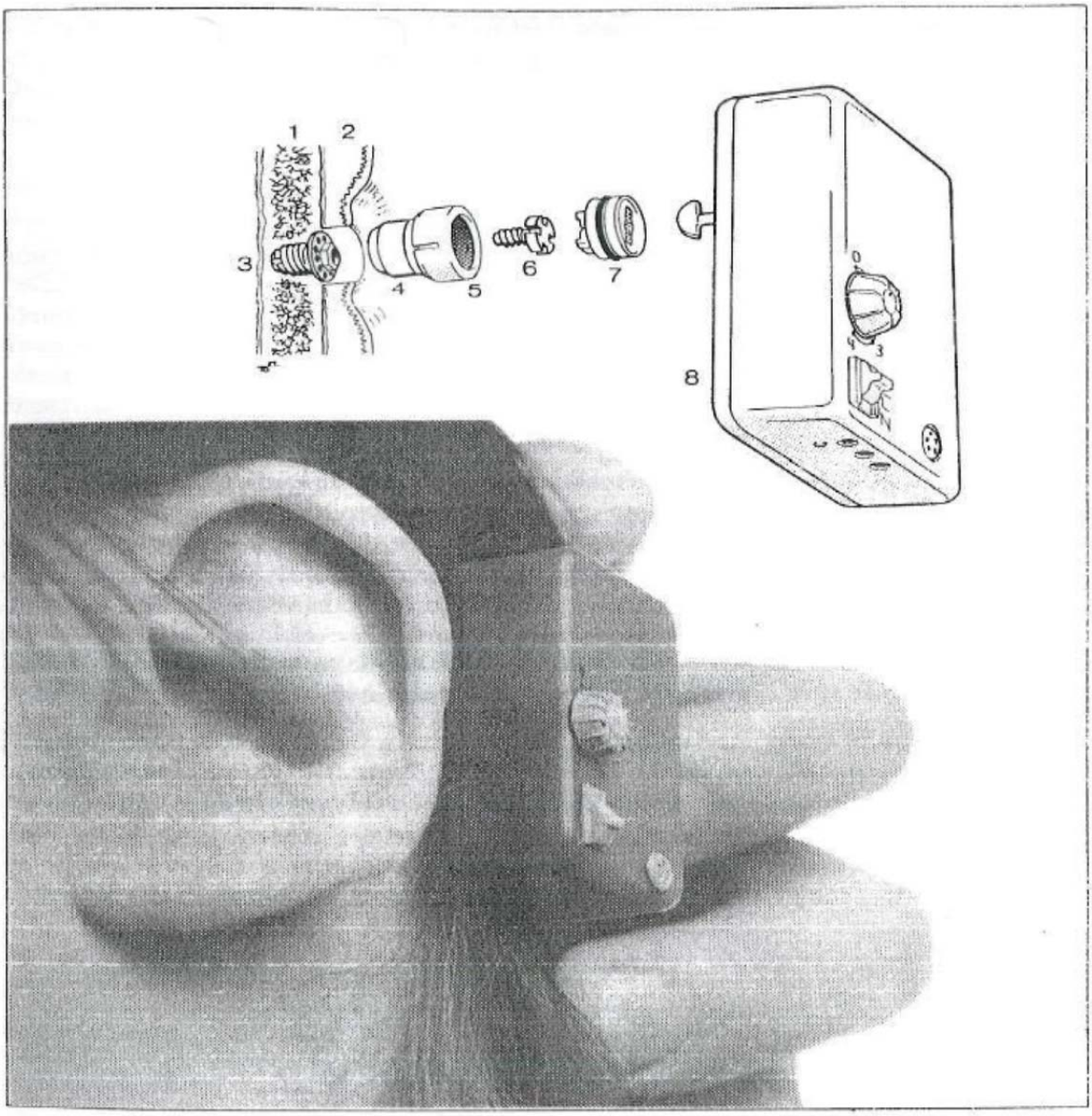


Figure 1. *The BAHA shown* in situ *with the hair lifted away. The schematic drawing shows: 1) skull bone, 2) skin and subcutaneous tissue, 3) titanium fixture, 4) titanium abutment, 5) plastic cover, 6) connection screw, 7) plastic insert, and 8) Sound processor HC-200.*

The BAHA device of Carlsson transmits sound vibrations through the skull bone via a skin-penetrating titanium implant that has been osseointegrated into the patient's skull bone. Such sound vibrations are further transmitted to the

functioning cochlea of the ear, bypassing the middle ear and the external ear. Ex. 1007, Fig. 1 on p. 3, p. 4, left column, first full ¶; Ex. 1002, ¶ 59. Also described is an implantable titanium screw. Ex. 1007, Fig. 1 on p. 3, element of *"3) titanium fixture"*; Ex. 1002, ¶ 59.

The BAHA device of Carlsson includes a sound processor with volume control and an on/off switch, a circuit board containing an amplifier section, and another circuit board containing tone control with filters for bass and treble frequencies. Ex. 1007, pp. 17-19, section titled "**2.5** The HC-200 hearing system" including Fig. 10 on p. 17; Ex. 1002, ¶ 60. Sound is received by a microphone (element 3 in Fig. 10), whereby the microphone transducer converts sound to an electrical signal. Ex. 1002, ¶¶ 60, 62. The BAHA device of Carlsson has a vibratory generating part (see element **4** in Fig. 10 below) arranged to generate vibrations. Ex. 1002, ¶ 62. Fig. 10 from Carlsson (p. 17) is reproduced below:

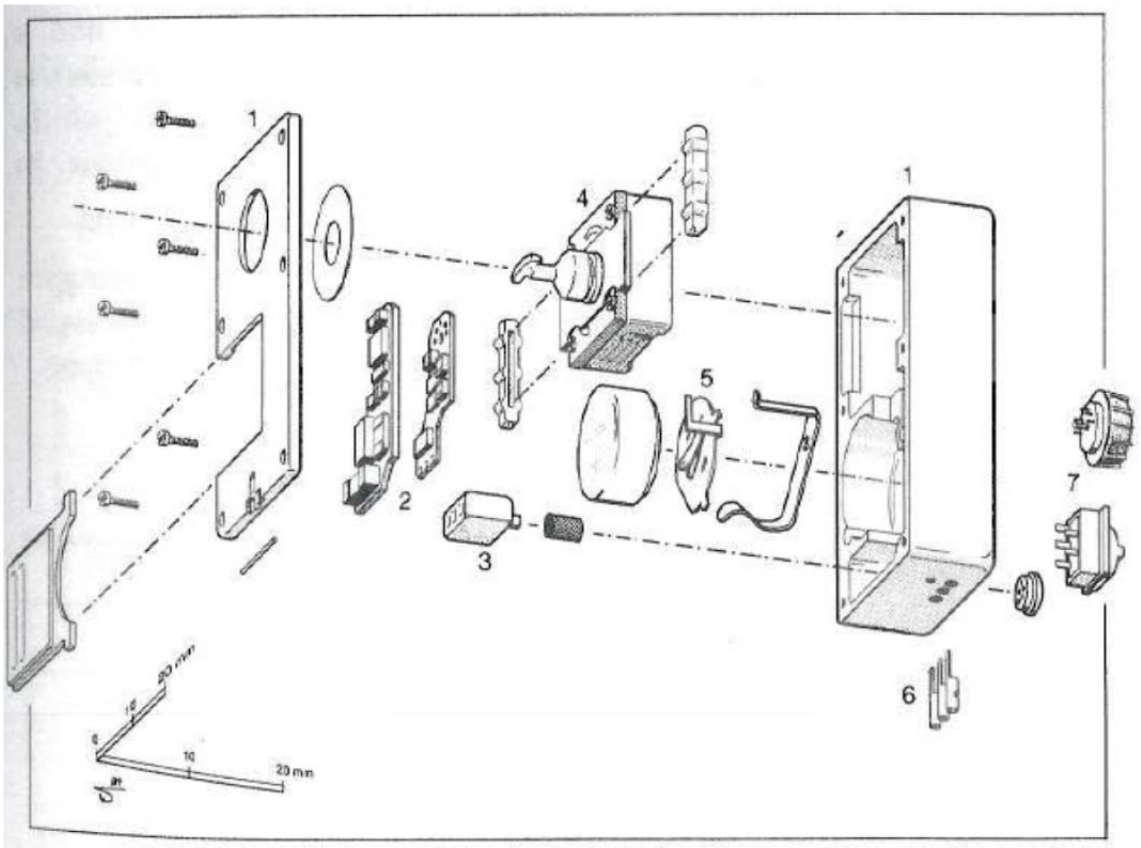


Figure 10 . *Exploded view of the BAHA showing; 1) case and cover, 2) amplifier, 3) microphone, 4) transducer and suspension system, 5) battery and contacts, 6) electrical contacts , and 7) volume and tone controls.*

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 VI.(A.)(1.) above, Vaneecloo describes using a BAHA device to treat patients with unilateral hearing loss. A POSA would have recognized the BAHA device of Vaneecloo as including both a vibratory generating part and an implantable part as claimed, even though the configuration of the BAHA device is not specifically illustrated or described. Ex. 1002, ¶¶ 71-74, 90, 91, 93-97, 99-103. To the extent Patent Owner may argue that Vaneecloo fails to adequately describe, expressly or implicitly, such components of a BAHA device, Carlsson makes up for any such alleged deficiencies.

As explained in section VI.(A.)(2.) above, Carlsson discloses that a BAHA device works via bone conduction, whereby hearing is improved by mechanical transmission of sound through the patients' skull bone. Ex. 1002, ¶¶ 59-62, 92, 97, 102, 103. The prior art BAHA device of Carlsson includes a sound processor and volume control. Ex. 1002, ¶ 60. The BAHA device of Carlsson further 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." See Section VI.(A.)(2.) above; Ex. 1002, ¶¶ 59-62, 92, 97, 101-103.

To the extent it can be reasonably alleged that BAHA device in Vaneecloo does not satisfy all features of claim 1, a POSA would have found it obvious to configure the Vaneecloo BAHA device for treating patients with unilateral hearing loss to include vibratory generating and implantable parts of the Carlsson BAHA device. Ex. 1007, Fig. 1 (p. 3); Ex. 1002, ¶¶ 104-110. Doing so would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, and/or would have involved satisfying a demand for improving known medical devices, to attain predictable, beneficial results. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); Ex. 1002, ¶¶ 108-110. Moreover, a POSA would have been motivated to use the BAHA configuration of Carlsson to achieve one or more of the benefits described therein. Specifically, the BAHA of Carlsson provided a single housing construction, was associated with improved comfort (absence of pain) for patients, and was "invisible" to others (i.e., aesthetic benefit for those patients with normal hair growth). Ex. 1002, ¶ 105. The BAHA device of Carlsson achieved effective bone conduction. Ex. 1007, Fig. 1 (p. 3) generally; p. 4, first full ¶; p. 9, lines 12-14; p. 10, first full ¶; p. 13, lines 2-3, p. 16, last ¶; p. 22, first full ¶ under "Rehabilitation results achieved" section; see also the results in Table IV on p. 23; Ex. 1002 at ¶¶ 105, 61, 62. The POSA would have reasonably expected to be successful using the BAHA device of Carlsson in the patients of Vaneecloo, at least because clinical

studies had already shown success in improving patient hearing, especially in the desired frequency range such as the human voice. *See* Ex. 1003 generally; Ex. 1002 at ¶¶ 106, 107. This obvious combination of Vaneecloo and Carlsson also clearly satisfies all features recited in "method" claim 13. See Section VI.(C) below (claims chart); Ex. 1002 at ¶¶ 132-146.

With respect to claim 2 of the '040 Patent, the BAHA devices of both Vaneecloo and Carlsson use a titanium implant for osseointegration with the patient's skull bone (with final attachment afterwards). Ex. 1003, p. 412, left col., lines 7-9 and right col., lines 17-19; p. 412, left col., lines 11-13 and right col., lines 1-2 from bottom; Ex. 1007, Fig. 1 on p. 3, element "3) titanium fixture"; Ex. 1002 at ¶¶ 112, 59, 62, 69, 98, 101. To the extent Patent Owner could reasonably allege that the titanium fixture of Vaneecloo is not specifically a screw, the titanium fixture of Carlsson is clearly illustrated as a screw. See Section VI.(A.)(2.) above; Ex. 1002 at ¶ 112. A POSA would have found it obvious to configure the titanium fixture of Vaneecloo as a titanium screw as taught by Carlsson. Ex. 1002 at ¶¶ 111-115. Doing so would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, and/or would have satisfied a demand for improving known medical devices, to attain predictable, beneficial results (e.g., effective bone conduction for

treating a patient's hearing loss). *See KSR*, 550 U.S. at 416; Ex. 1002 at ¶¶ 113-115.

With respect to dependent claims 3-5 of the '040 Patent, Vaneecloo describes testing the hearing of each patient at 250 Hz and 2000 Hz (Ex. 1003, p. 415, left col., lines 12-15; corresponding Fig. 11 for patient Claude B and Fig. 12 for patient Alain C on p. 416), and reports that: "we found that the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for significant rise in sound 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." Ex. 1003, p. 415, right col., fourth ¶from the bottom ("The result of this equipment …"); Ex. 1002, ¶ 117. Thus, a POSA would have understood that the BAHA device of Vaneecloo adapted frequency characteristics for transmission from the patient's deaf side, and amplified treble frequencies (greater than 1 kHz) more than bass frequencies to effectively treat the patient's unilateral hearing loss. Ex. 1002 at ¶¶ 118-121, 123-126, 128-131.

C. Claims Chart for Ground 1

The following claims chart further details how the obvious modification of Vaneecloo in view Carlsson satisfies all features recited in claims 1-5 and 13 of the

'040 Patent.

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
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 another side of the patient's head for rehabilitation of unilateral hearing loss,"	Note the proposed claim construction above regarding "for rehabilitation of unilateral hearing loss" (preamble; no patentable weight) (section **V.(B.)(1.)**). Should the Board conclude otherwise, the prior art still discloses this feature as explained below. Vaneecloo describes treating patients with unilateral hearing loss using a bone-conducting, bone-anchored hearing aid (BAHA) device. A titanium implant is implanted on a deaf side of a patient's head. The BAHA device is designed to capture and transmit sound information received on the deaf side of the patient through the cranium to the functional ear via the titanium implant. Ex. 1003, Abstract on page 410; p. 411, left col., lines 14-24 ("To remedy this major disability …"); p. 415, right col., fourth ¶ from bottom ("The result of this equipment …"). See also Section VI(A.)(1.) above; Ex. 1002 at ¶¶ 91, 90, 68-70. Further, as described in Carlsson (Ex. 1007), it was well known in the art that a BAHA device provides hearing based on the bone conduction principle. Ex. 1007, p. 10, left column, first full ¶; p. 4, left column, first full ¶; Fig. 10; Abstract; Ex. 1002 at ¶¶ 92, 94, 59.
"the hearing aid apparatus	Note the proposed claim construction

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
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"	above regarding "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 conclude otherwise, the prior art still discloses this feature as explained below. The patients in Vaneecloo had the BAHA device implanted on the deaf side. Ex. 1003, p. 411, left col., lines 14-24 ("To remedy …"); see also p. 411, right col., third full paragraph under "*Mr. Claude B*" ("The audiometric …") and p. 412, left col., lines 7-9 for patient "Mr. Claude B" ("The implantation was carried …"); p. 412, right col., lines 9, 13-19 for second patient "*Mr. Alain C*". Since the bone-conducting, bone-anchored hearing aid of Vaneecloo captures and transmits sound information received on the deaf side of the patient's head through the cranium to the functional ear, a POSA 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. Ex.1003, page 411, lines 14-24 ("To remedy …"); Ex. 1002 at ¶¶ 93-96, 103, 70-74. To the extent Patent Owner may argue that Vaneecloo does not adequately describe the BAHA device therein as having a "vibratory generating part," such a feature

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
	is clearly taught by the prior art. Carlsson (Ex. 1007) describes using a BAHA device for treating hearing loss by bone conduction. Ex. 1007, p. 10, left column, first full ¶; p. 4, left column, first full ¶; Fig. 10 on p. 17; Abstract. In the BAHA device of Carlsson, sound is received by a microphone, whereby the microphone transducer converts sound to an electrical signal. Ex. 1002 at ¶¶ 95, 96, 60, 62. The BAHA device of Carlsson has a vibratory generating part arranged to generate vibrations that are mechanically transmitted, thereby providing sound to the deaf ear. Also, the BAHA device described in Carlsson has a sound processor with a volume control, a circuit board containing an amplifier section, and another circuit board containing tone control with filters for bass and treble attenuation. Ex. 1007, pp. 17-19, section titled "2.5 The HC-200 hearing system"; Fig. 10 (p. 17); Ex. 1002 at ¶ 60.
"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."	Note the proposed claim construction above regarding "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 conclude otherwise, the prior art still discloses this feature as explained below. Vaneecloo further discloses that a titanium implant is implanted at the temporal bone near the deaf ear of the patient. Ex. 1003, p. 412, left col., lines 7-9 (i.e., 3 mm titanium fixture) and right col., lines 17-19

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
	(i.e., 4 mm titanium fixture). Ex. 1002 at ¶¶ 98, 100, 69, 70. Thus, the titanium implant includes an implantable part operative to mechanically anchor a vibratory generating part, the implantable part being "osseointegrated" in the patient's skull bone behind an external ear at the deaf side of the patient. Ex. 1002 at ¶¶ 98-100, 103, 69, 70. Further, the placement of the prosthesis for patient "Claude B" was 3 months later (p. 412, left col., lines 11-13, and that for patient "Alain C" six weeks later (p. 412, right col., lines 1-2 from bottom), thus indicating osseointegration. Ex. 1002 at ¶¶ 98, 69, 70. Carlsson describes an implantable screw. Ex. 1007, Fig. 1 on p. 3, element "3) titanium fixture". Further, Fig. 1 of Carlsson also shows attachment to element "8) Sound processor HC-200". The exploded view in Fig. 10 further shows the vibratory generating part (see element 4 of the "transducer and suspension system"). Ex. 1002 at ¶¶ 100, 101, 59, 60, 62.
Claim 2. "The hearing aid apparatus according to claim 1, wherein the implantable part comprises an implant screw."	A bone-conducting, bone-anchored hearing aid apparatus of Vaneecloo includes a titanium fixture (implant). Ex. 1003, p. 412, left col., lines 7-9 and right col., lines 17-19. The BAHA prosthesis was attached to the titanium fixture some weeks or months afterwards. Ex. 1003, p. 412, left col., lines 11-13 and right col.,

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
	lines 1-2 from bottom. Ex. 1002 at ¶¶ 112, 98, 69, 70. Patent Owner may argue that the titanium implant is not specifically illustrated in Vaneecloo, and that the titanium implant therein does not necessarily comprise an "implant screw." Such a feature is clearly taught in the prior art. Ex. 1002 at ¶ 113. Carlsson describes a titanium implant that is specifically illustrated as a screw. Ex. 1008, Fig. 1 on p. 3, element "3) titanium fixture". Ex. 1002 at ¶¶ 112, 59, 69.
Claim 3. "The hearing aid apparatus according to claim 1, wherein the frequency characteristics of the apparatus are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side."	Since the bone-conducting, bone-anchored hearing aid of Vaneecloo is designed to capture and transmit sound information received on the deaf side of the patient's head through the cranium to the functional ear, it is evident that the frequency characteristics of the BAHA device are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side. Ex. 1002 at ¶¶ 117, 118, 70, 73, 74, 90. Further, Vaneecloo discloses testing the hearing of each patient at 250 Hz and 2000 Hz (Ex. 1003, p. 415, left col., lines 12-15; corresponding Fig. 11 for patient Claude B and Fig. 12 for patient Alain C on p. 416), and the results were: "Indeed, … we found that the *amplification* of the high-pitched *sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear* allowed for *significant rise in sound perception* thresholds of

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
	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." (emphasis added) Ex. 1003, p. 415, right col., fourth ¶ from the bottom. Thus, it is understood that the BAHA device of Vaneecloo amplifies treble frequencies more than bass frequencies and that the treble frequencies have a frequency greater than 1 kHz. Ex. 1002 at ¶¶ 117, 118, 70, 73, 74.
Claim 4. "The hearing aid apparatus according to claim 3, wherein the hearing aid apparatus amplifies treble frequencies more than bass frequencies."	Vaneecloo discloses that the BAHA device therein amplifies high-pitched sound (treble frequencies) more that bass frequencies. Ex. 1003, p. 415, right col., fourth full ¶ from bottom. Vaneecloo further discloses that the patient with the BAHA device on the deaf side showed an overall improvement in the perception thresholds at frequencies between 1 kHz to 4 kHz by the functional ear. Ex.1003, p. 415, right col., fourth ¶from the bottom; Ex. 1002 at ¶¶ 123, 117, 118, 70, 73, 74.
Claim 5. "The hearing aid apparatus according to claim 4, wherein the treble frequencies have a frequency greater than 1 kHz."	Vaneecloo discloses that patients with the BAHA device on the deaf side showed an overall improvement in the perception thresholds at frequencies between 1 kHz to 4 kHz by the functional ear. Ex. 1003, p. 415, right col., fourth ¶ from the bottom; Ex. 1002 at ¶¶ 128, 123, 117, 118, 70, 73, 74.

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
Claim 13. "A method of rehabilitating a patient with unilateral hearing loss, the method comprising:"	Vaneecloo discloses treating patients suffering from unilateral hearing loss using a bone-conducting, bone-anchored hearing aid. Ex. 1003, Abstract on p. 410; p. 415, right col., fourth ¶ from bottom ("The result of this equipment …"); Ex. 1002 at ¶¶ 134, 68-70, 90.
"anchoring an implantable part in a skull bone behind an external ear at the deaf side of the patient, such that the implantable part is osseointegrated in the skull bone; and"	Vaneecloo further discloses that a titanium fixture (implantable part) is implanted at the temporal bone near the deaf ear of the patient. Ex. 1003, p. 411, left col., lines 14-24; see also p. 411, right col., third full paragraph under "*Mr. Claude B*" and p. 412, left col., lines 7-9 for patient "Mr. Claude B"; p. 412, right col., lines 9, 13-19 for second patient "*Mr. Alain C*"; Ex. 1002 at ¶¶ 136, 98, 138, 69, 70. The titanium fixture is "osseointegrated" in the patient's skull bone behind an external ear at the deaf side of the patient. Ex. 1003, p. 411, left col., lines 14-24; p. 412, left col., lines 7-9 and right col., lines 13-19. The BAHA prosthesis was then attached to the titanium fixture some months or weeks afterwards. Ex. 1003, p. 412, left col., lines 11-13 and right col., lines 1-2 from bottom, thus indicating osseointegration. Ex. 1002 at ¶¶ 136, 137, 98, 112, 69, 70. Carlsson describes a BAHA device having an implantable screw. Ex. 1008, Fig. 1 on p. 3, element "3) titanium fixture". Ex. 1002 at ¶¶ 112, 59.

Claims 1-5 and 13 of '040 Patent	**Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)**
"interconnecting with the implantable part a vibratory generating part arranged to generate vibrations which are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient, the implantable part mechanically anchoring the vibratory generating part, wherein the implantable part and the vibratory generating part comprise parts of a bone-conducting hearing aid apparatus."	Vaneecloo discloses that the BAHA device therein is designed to capture and transmit sound information received on the deaf side of the patient through the cranium to the functional ear. Ex. 1003, p. 411, left col., lines 14-24; p. 410, Abstract; Ex. 1002 at ¶¶ 140, 139, 90, 91. Further, Vaneecloo discloses using a BAHA with a titanium fixture that is implanted on the deaf side of each patient. Ex. 1003, p. 411, left col., lines 13-17; see also p. 411, right col., third full paragraph under "*Mr. Claude B*" and p. 412, left col., lines 7-9 for patient "Mr. Claude B"; p. 412, right col., lines 9, 13-19 for second patient "*Mr. Alain C*". Ex. 1002 at ¶¶ 137, 138. The bone-conducting, bone-anchored hearing aid of Vaneecloo is designed to capture and transmit sound information received on the deaf side of the patient's head through the cranium to the functional ear. Thus, the BAHA device of Vaneecloo includes 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. Ex.1003, page 411, lines 14-24 ("To remedy …"); Ex. 1002 at ¶¶ 138-140, 90, 91, 93-96. To the extent Patent Owner may argue that Vaneecloo does not adequately describe the BAHA therein as having a "vibratory generating part," such a feature is clearly taught by the prior art

Claims 1-5 and 13 of '040 Patent	Exemplary Citations in Vaneecloo (Ex. 1003) and Carlsson (Ex. 1007)
	(Carlsson). Ex. 1002 at ¶¶ 96, 97. As described in Carlsson (Ex. 1007), a BAHA device provides hearing by mechanical transmission based on the bone conduction principle. Ex. 1007, p. 10, left col., first full ¶; p. 4, left col., first full ¶. In the BAHA device of Carlsson, sound is received by a microphone, whereby a transducer converts sound to an electrical signal. Ex. 1002 at ¶¶ 141, 142, 96, 97. Thus, the BAHA device of Carlsson has a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone. Ex. 1007, Fig. 10 (p. 17); see also, Section VI.(A.)(2.) above; Ex. 1002 at ¶¶ 59, 60, 62, 97, 142. This version of the BAHA device as described in Carlsson has a sound processor with a volume control, a circuit board containing an amplifier section, and another circuit board containing tone control with filters for bass and treble attenuation. Ex. 1007, pp. 17-18, section titled "2.5 The HC-200 hearing system"; Fig. 10 (p. 17); Ex. 1002 at ¶¶ 60, 97, 142.

VII. Ground 2: Claims 6, 7 and 9 are unpatentable under pre-AIA 35 U.S.C. § 103(a) as being obvious over Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007) and Leysieffer (Ex. 1009).

A. Vaneecloo, Carlsson and Leysieffer teach all claim features of Claims 6, 7 and 9

Claim 6 depends directly from independent claim 1. Claim 7 and 9 each further depend from claim 6. As established for Ground 1 (Section VI. above), the obvious combination of Vaneecloo and Carlsson satisfies all features of claim 1. Patent Owner may argue, however, that this combination does not satisfy additional features recited in dependent claims 6, 7 and 9. As detailed below, an obvious modification of Vaneecloo and Carlsson, further in view of Leysieffer satisfies all these claim features.

1. Teachings of Leysieffer (Ex. 1009)

Leysieffer describes a partial or totally implantable system for rehabilitation of a hearing disorder by processing and generating signals, which includes electrical, mechanical or acoustic stimulation to the middle or inner ear. Ex. 1009, p. 1, lines 5-6; p. 2, lines 27-29; p. 7, lines 15-30. An objective of Leysieffer is to improve signal processing and signal generation in existing systems, and to enable matching of system functions to patient-specific circumstances, where existing software can be updated or replaced without removing the implanted part of the hearing aid device. Ex. 1009, p. 6, lines 8-23; p. 16, lines 28-29. The Leysieffer embodiment also applies to unilateral hearing losses. Ex. 1009, p. 15, lines 16-17.

As shown in Fig. 1 (reproduced below), Leysieffer describes an implantable hearing system 1 including microphones 10a-10n that receive external acoustic

signal (sound) and convert sound to electrical signals. The electrical sensor signals are routed to module 40 for preprocessing; the preprocessed sensor signal leads to an analog-digital converter (A/D) 130. Digital signals from A/D converter 130 are supplied to a digital signal processor (DSP) 141 "which executes the intended function of the hearing implant." Ex. 1009, p. 11, lines 9-23. Digital output signals of the DSP 141 are converted by a digital to analog converter (D/A) 150, where the analog out signal(s) of A/D 150 are routed to driver unit 80 "which depending on the implant function triggers output stimulator 20a". Ex. 1009, p. 12, first ¶.

Signal processing algorithms can be used for static or adaptive noise suppression processes or optimizing the signal-to-noise ratio. Ex. 1009, p. 7, last ¶. For mechanical output stimulation, certain algorithms can be used for feedback suppression or reduction. Ex. 1009, p. 8, first ¶.

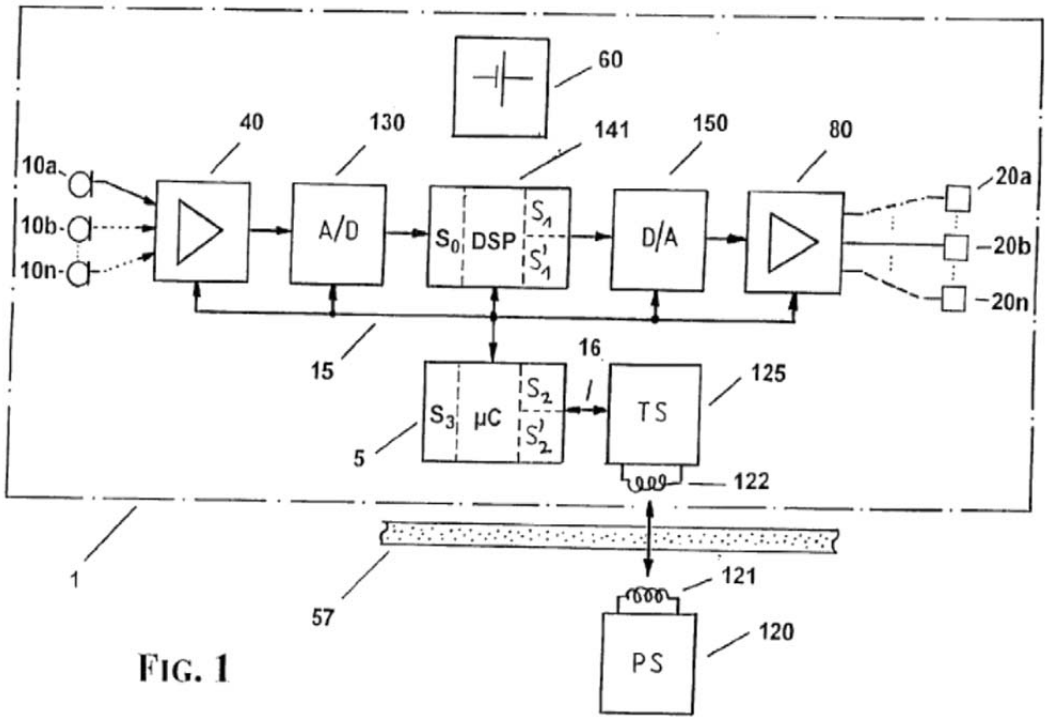


FIG. 1

B. *KSR* Rationale to Combine

To the extent not disclosed in either Vaneecloo or Carlsson, a POSA would have found it obvious to modify the BAHA apparatus of the Vaneecloo-Carlsson combination (Section VI. above) to include an analog-to-digital converter, a digital signal processor, and acoustic feedback suppression as recited in claims 6, 7 and 9 of the ‘040 Patent.

As explained in section VII.(A.)(1.) above, Leysieffer discloses among other features, a microphone, an analog to digital converter, a digital signal processor, and using certain signal processing algorithms for feedback suppression or reduction. Ex. 1009, p. 11, lines 9-23, Fig. 1, p. 12, first ¶, p. 8, first ¶. The above-identified features were well known in the art of hearing aid devices prior to the critical date. Ex. 1002 at ¶¶ 152-160.

With respect to claims 6 and 7 of the '040 Patent, to the extent Patent Owner may argue that the Vaneecloo-Carlsson combination does not include electronic circuitry for converting a signal from a microphone of the hearing aid from an analog signal to a digital signal or a digital signal processor, Leysieffer clearly teaches such electronic circuitry. See the configuration in Fig. 1 including microphones 10a-10n and A/D converter 130. Ex. 1009, p. 11, lines 9-13, 15-23; Ex. 1002 at ¶ 156. A POSA would have found it obvious to modify the BAHA apparatus of the Vaneecloo-Carlsson combination (Section VI. above) to include an analog-to-digital converter and a digital signal processor to enable digital processing of sound picked up by the hearing aid microphone(s). Doing so would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, and/or would have involved satisfying a demand for improving known medical devices, to attain predictable, beneficial results. *See KSR*, 550 U.S. at 416; Ex. 1002 at ¶¶ 152-157, 161-164. A

POSA would have recognized prior to the critical date that this modification would have allowed the BAHA apparatus of the Vaneecloo-Carlsson combination to realize one or more advantages of digital signal processing in a hearing aid device. Various advantages of digital signal processing in hearing aids were known before the critical date, and included, for example: real time audio signal processing capability; multi-channel audio signal processing for different frequency bands; more closely matching signal processing to listening needs of the individual patient; processing that is adapted to differences in listening environments; noise and feedback reduction; and programmability. Ex. 1002 at ¶¶ 155, 156, 162.

With respect to claim 9, to the extent it could further be argued that the Vaneecloo-Carlsson combination lacks digital signal processing circuitry that suppresses acoustic feedback, Leysieffer teaches digital signal processing circuitry that implements acoustic feed-back suppression algorithms. Ex. 1009, p. 8, first ¶. It would have been obvious to the POSA to incorporate acoustic feed-back suppression in the BAHA device of the Vaneecloo-Carlsson combination. Ex. 1002 at ¶¶ 158-163. Doing so would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, and/or would have involved satisfying a demand for improving known medical devices, to attain predictable, beneficial results (effective acoustic feedback suppression). *See KSR*, 550 U.S. at 416; Ex. 1002, ¶¶ 161-164. As Dr.

Popelka explains, a POSA would have recognized, prior to the critical date, that bone conduction devices are susceptible to acoustic feedback, for example because a bone conduction signal can create vibrations at the microphone directly, thus creating undesirable acoustic feedback, or the bone conducted signal itself can have an acoustic component that feeds back to the microphone. Ex. 1002, ¶¶ 158-160.

C. Claims Chart for Ground 2

The following claims chart further details how the obvious modification of Vaneecloo, Carlsson and Leysieffer teaches all features recited in claims 6, 7 and 9 of the '040 Patent.

U.S. Patent No. 7,043,040 - Claims 6, 7 and 9	**Exemplary Citations in Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007) and Leysieffer (Ex. 1009)**
Claim 6. "The hearing aid apparatus according to claim 1, further comprising: electronic circuitry operative to convert a signal from a microphone of the hearing aid to the vibratory generating part from an analog signal to a digital signal."	[For features of base claim 1, see **Ground 1** above (Section VI.).] Analog to digital (A/D) converters were well known in the art of hearing aid systems. Ex. 1002, ¶¶ 152-155. Leysieffer teaches electronic circuitry with signal conversion with specific components in Fig. 1 including microphones 10a-10n and A/D converter 130. Ex. 1009, p. 11, lines 9-13; Ex. 1002, ¶ 156.

U.S. Patent No. 7,043,040 - Claims 6, 7 and 9	**Exemplary Citations in Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007) and Leysieffer (Ex. 1009)**
Claim 7. "The hearing aid apparatus according to claim 6, wherein the electronic circuitry comprises digital signal processing means."	Digital signal processors were also well known in the art of hearing aid systems. Ex. 1002, ¶¶ 152-155. Specifically, Leysieffer teaches electronic circuitry with digital signal processing means in Fig. 1 including module 40 for signal preprocessing, A/D converter 130, and DSP 141 that receives and processes digitized sensor signals. Ex. 1009, p. 11, lines 15-23; Ex. 1002, ¶¶ 156, 157.
Claim 9. "The hearing aid apparatus according to claim 6, wherein the electronic circuitry comprises signal processing means for actively counteracting acoustic feed-back problems in the apparatus."	Leysieffer teaches such electronic circuitry implementing algorithms to address acoustic feed-back problems. Ex. 1009, p. 8, first ¶; Ex. 1002, ¶¶ 156, 158-160.

VIII. Ground 3: Claim 8 is unpatentable under 35 U.S.C. § 103(a) as being obvious over Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007), Leysieffer (Ex. 1009) and Schaefer (Ex. 1019).

A. Vaneecloo, Carlsson, Leysieffer and Schaefer teach all claim features of Claim 8

Claim 8 depends from claim 7. Claim 8 recites "The hearing aid apparatus according to claim 7, wherein the signal processing means adapts frequency characteristics to individual differences in an acoustic head shadow effect, to a sound environment, to a resonance of the patient's skull, or to a hearing capacity of a functioning ear of the patient."

As stated in Ground 2 (Section VII.), the obvious combination of Vaneecloo, Carlsson and Leysieffer discloses all features of claim 7. To the extent Patent Owner may argue that this combination does not satisfy additional features recited in dependent claim 8, Schaefer discloses these features.

1. Teachings of Schaefer (Ex. 1019)

Schaefer describes implantable hearing aids in which signal processing means adapt frequency characteristics to hearing capacity of the individual patient. For instance, as described at col. 5, lines 43-58, Schaefer teaches: "The frequency response of the amplifier circuit is shaped, as is well known in the art, to compensate for frequency sensitivity deficiencies of the subject. The magnitude of the output signals from amplifier **20** is also limited to a predetermined maximum value to prevent possible injury (acoustic trauma) to the inner ear." Petitioner notes that Leysieffer (Ex. 1009) refers to the Schaefer patent at p. 3, line 12 as an example of a hearing aid device that can benefit from the Leysieffer embodiment.

B. *KSR* Rationale to Combine

To the extent not disclosed in Vaneecloo, Carlsson or Leysieffer, a POSA would have found it obvious to modify the BAHA apparatus of the Vaneecloo-Carlsson-Leysieffer combination (Sections VI., VII. above) to implement signal processing that adapts frequency characteristics to individual differences and/or to

the hearing capacity of the functioning ear, such as compensating for "frequency sensitivity deficiencies of the subject". Such processing is taught by Schaefer. Ex. 1019, col. 5, lines 52-55; Ex. 1002, ¶ 168. This modification would have involved nothing more than combining known prior art elements in known ways, with no change to their respective functions, and/or would have satisfied a demand for improving known medical devices, to attain predictable, beneficial results. *See KSR*, 550 U.S. at 416; Ex. 1002, ¶¶ 169-171.

As explained by Dr. Popelka, a POSA would have recognized, before the critical date, that it is desirable to process signals of the BAHA device to account for frequency sensitivity deficiencies that affect the hearing capacity of the patient. Ex. 1002, ¶¶ 169-171.

C. Claim Chart for Ground 3

The following claim chart further details how the obvious modification of Vaneecloo in view of Carlsson, Leysieffer and Schaefer satisfies all features recited in claim 8 of the '040 Patent.

U.S. Patent No. 7,043,040 – Claim 8	**Exemplary Citations in Vaneecloo (Ex. 1003) in view Carlsson (Ex. 1007), Leysieffer (Ex. 1009) and Schaefer (Ex. 1019)**
Claim 8. "The hearing aid apparatus according to claim 7, wherein the signal processing means adapts frequency characteristics to	[For features of base claim 1, see **Claims Chart for Ground 1** above. For features of claim 7, see **Claims Chart for Ground 2** above.]

U.S. Patent No. 7,043,040 – Claim 8	**Exemplary Citations in Vaneecloo (Ex. 1003) in view Carlsson (Ex. 1007), Leysieffer (Ex. 1009) and Schaefer (Ex. 1019)**
individual differences in an acoustic head shadow effect, to a sound environment, to a resonance of the patient's skull, or to a hearing capacity of a functioning ear of the patient."	Schaefer describes implantable hearing aids where the signal processing means adapts frequency characteristics to individual differences. Specifically, Schaefer teaches: "The frequency response of the amplifier circuit is shaped, as is well known in the art, to compensate for frequency sensitivity deficiencies of the subject. The magnitude of the output signals from amplifier **20** is also limited to a predetermined maximum value to prevent possible injury (acoustic trauma) to the inner ear." Ex. 1019, col. 5, lines 52-58. Ex. 1002, ¶¶ 168.

IX. <u>Ground 4</u>: Claim 10 is unpatentable under pre-AIA 35 U.S.C. § 103(a) as being obvious over Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007), Leysieffer (Ex. 1009) and Lesinski (Ex. 1018).

A. Vaneecloo, Carlsson, Leysieffer and Lesinski teach all claim features of Claim 10

Claim 10 depends from claim 6. Claim 10 recites: "The hearing aid apparatus according to claim 6, further comprising: directivity means comprising at least one directivity dependent microphone and/or signal processing means in the electronic circuitry." As stated in Ground 2 (section VII.), the obvious combination

of Vaneecloo, Carlsson and Leysieffer discloses all features of claim 6. To the extent Patent Owner may argue that this combination does not satisfy additional features recited in dependent claim 10, Lesinski discloses these features.

1. Teachings of Lesinski (Ex. 1018)

Lesinski describes microphones used in implantable hearing aids, including advantages of using an array of microphones. Ex. 1018, col. 1, lines 12-17; col. 8, lines 44-52; Fig. 4; col. 7, lines 19-39; Fig. 6; Ex. 1002, ¶ 175. In reference to Fig. 6, an array of individual microphones 50 can be used in electronics module 100. Ex. 1018, col. 7, lines 19-23; Ex. 1002, ¶ 175. The signal-processing amplifier 30 sums the independently generated signal from microphones 50 to produce a desirable characteristic sensitivity pattern from the array 128, thus providing the subject with perceived directivity of sound. Ex. 1018, col. 7, lines 23-39; Ex. 1002, ¶¶ 175, 177.

B. *KSR* Rationale to Combine

To the extent not disclosed in Vaneecloo, Carlsson or Leysieffer, a POSA would have found it obvious to modify the BAHA apparatus of the Vaneecloo-Carlsson-Leysieffer combination (Sections VI., VII. above) to include directional microphone functionality, such as taught by Lesinski. Ex. 1018, col. 7, lines 19-23. Ex. 1002, ¶¶ 176-182. This modification would have involved nothing more than

combining known prior art elements in known ways, with no change to their respective functions, and/or would have satisfied a demand for improving known medical devices, to attain predictable, beneficial results. *See KSR*, 550 U.S. at 416; Ex. 1002 at ¶¶ 176-182.

As explained by Dr. Popelka, a POSA would have recognized Lesinski as just one example of what was well-known feature before the critical date - the use of microphones for purposes of directivity of sound in hearing aid. Ex. 1002, ¶¶ 177-180. Dr. Popelka further explains advantages of microphone directionality, known before the critical date, including improved signal-to-noise ratio and improved speech recognition in noisy environments. Ex. 1002, ¶ 177-180.

C. Claim Chart for Ground 4

The following claim chart further details how the obvious modification of Vaneecloo in view of Carlsson, Leysieffer and Lesinski satisfies all features recited in claim 10 of the '040 Patent.

U.S. Patent No. 7,043,040 – Claim 10	**Exemplary Citations in Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007), Leysieffer (Ex. 1009) and Lesinski (Ex. 1018)**
Claim 10. "The hearing aid apparatus according to claim 6, further comprising: directivity means comprising at least one directivity	[For features of base claim 1, see **Claims Chart for Ground 1** above. Section VI.(C.). For features of claim 6, see **Claims Chart for Ground 2** above.

U.S. Patent No. 7,043,040 – Claim 10	**Exemplary Citations in Vaneecloo (Ex. 1003) in view of Carlsson (Ex. 1007), Leysieffer (Ex. 1009) and Lesinski (Ex. 1018)**
dependent microphone and/or signal processing means in the electronic circuitry."	Section VII.(C.)] *Lesinski* teaches that an array of individual microphones **50** can be used in electronics module **100** as shown in **Fig. 6**. Ex. 1018, col. 7, lines 19-23. The signal-processing amplifier **30** sums the independently generated signals from microphones **50** to produce a desirable characteristic sensitivity pattern from the array **128**, thus providing the subject with directivity of sound. Ex. 1018, col. 7, lines 23-39; Ex. 1002, ¶ 175, 177.

X. CONCLUSION

Petitioner has demonstrated a reasonable likelihood that Petitioner will prevail in demonstrating that claims 1-10 and 13 of the '040 Patent are unpatentable as being obvious over the art discussed above. 35 U.S.C. § 314(a). Petitioner requests that the PTAB institute an *inter partes* review proceeding and cancel claims 1-10 and 13 of the '040 Patent.

Respectfully submitted,

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Appendix – Exhibits List

APPENDIX – LIST OF EXHIBITS

Ex. No.	Description
1001	U.S. Patent No. 7,043,040 (P. Westerkull)
1002	Expert Declaration by Dr. Gerald R. Popelka, Ph.D.
1003	Verified English language translation of "Baha prosthetic rehabilitation of unilateral anacusis," *Ann. Otolaryngol Chir. Cervicofac.*, Vol. 117, No. 6, pp. 410-417 (2000) (F.M. Vaneecloo et al.)
1004	F.M. Vaneecloo et al., "Réhabilitation prothétique B.A.H.A. des cophoses unilatérales: Etude par la stéréaudiométrie," *Ann. Otolaryngol. Chir. Cervicofac.*, Vol. 117, No. 6, pp. 410-417 (2000)
1005	M. Chasin, "Update on implants: Bone-anchored devices and middle ear implants," *The Hearing Journal*, Vol. 52, No. 7, pp. 10-16, July 1999
1006	J.J. Wazen et al., "Long-Term Results With the Titanium Bone-Anchored Hearing Aid: The U.S. Experience," *The American Journal of Otology*, Vol. 19, pp. 737-741 (1998)
1007	Peder U. Carlsson, "On Direct Bone Conduction Hearing Devices: advances in transducer technology and measurement methods," Technical Report No. 195, (1990), pages 1-183
1008	M. Chasin et al., "Current Trends in Implantable Hearing Aids," *Trends in Amplification*, Vol. 2, No. 3, pp. 84-107 (1997)
1009	CA 2 301 437 A1 (H. Leysieffer)
1010	Prosecution history of U.S. Patent No. 7,043,040 B2 (146 pages)
1011	D.A. Hough et al., "The Surgical Technique for Implantation of the Temporal Bone Stimulator (Audiant ABC)," *The American Journal of Otology*, Vol. 7, Issue No. 5, pp. 315-321 (Sept. 1986)
1012	J.V.D. Hough et al., "Long-Term Results for the Xomed Bone Conductor," *Otolaryngologic Clinics of North America*, Vol. 28, No. 1, pp. 43-52 (Feb. 1995)
1013	EP 0 421 338 A1 to B. Farinella et al.
1014	B.A. Weber et al., "Application of an Implantable Bone Conduction Hearing Device to Patients with Unilateral Sensorineural Hearing Loss," *Laryngoscope*, Vol. 102, pp. 538-542 (May 1992)
1015	E.P. Fowler, "Bilateral Hearing Aids for Monaural Total Deafness: A Suggestion for Better Hearing," *Arch Otolaryngol*, Vol. 72, pp. 57/41-58/42 (1960)
1016	A. Tjellström et al., "Bone-Anchored Hearing Aids: Current Status in Adults and Children," *Otolaryngologic Clinics of North America*, Vol. 34, No. 2, pp. 337-355 (April 2001)

Ex. No.	Description
1017	U.S. Patent No. 6,697,674 (Leysieffer et al.)
1018	U.S. Patent No. 5,881,158 (Lesinski et al.)
1019	U.S. Patent No. 4,729,366 (Schaefer)
1020	U.S. Patent No. 4,548,082 (Engebretson)
1021	D.P. Egolf et al., "The hearing aid feedback path: mathematical simulations and experimental verification," *J Acoust Soc Am*, 78(5), pp.1578-1587 (1985)
1022	Hawkins, D. B. and W. S. Yacullo, "Signal-to-noise ratio advantage of binaural hearing aids and directional microphones under different levels of reverberation," *J Speech Hear Disord*, 49(3): 278-286 (1984)
1023	Dempsey, J. J., "A functional measure of front-to-back ratio," *J Aud Res*, 25(2): 91-100 (1985)

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 12,140, which is 14,000 words or less as required by 37 C.F.R. § 42.24(a)(1)(i). This word count excludes the table of contents, table of authorities, certificate of word count, certificate of service, and exhibit list.

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CERTIFICATE OF SERVICE

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

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