UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MED-EL Elektromedizinische Geräte Ges.m.b.H.,

Petitioner

v.

Advanced Bionics AG

Patent Owner

_____

U.S. Patent No. 8,155,747

Issue Date: April 10, 2012

Title: Electric and Acoustic Stimulation Fitting Systems and Methods

Inter Partes Review No. IPR2020-00190

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PETITION FOR INTER PARTES REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.*

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Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,155,747

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1002	Declaration of Douglas Paul Sladen, Ph.D.
1003	U.S. Patent No. 5,721,783 to Anderson ("Anderson")
1004	U.S. Publication No. 2001/0031996 to Leysieffer ("Leysieffer")
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I. BACKGROUND

MED-EL Elektromedizinische Geräte Ges.m.b.H. ("Petitioner" or "MED-EL") respectfully petitions for *inter partes* review and cancellation of claims 1-8 of U.S. Patent No. 8,155,747 (the "'747 patent") (Ex. 1001). As the evidence shows, the challenged claims were taught by the prior art and should have been rejected on the basis of anticipation and/or obviousness.

Broadly, the '747 patent claims a system comprising a computer with access to software which can be used for modifying the parameters of acoustic and electric stimulation hearing devices when such devices are located in the same ear.

Petitioner presents for the first time U.S. Patent No. 5,721,783 ("Anderson") (Ex. 1003), which discloses a system for modifying the parameters of both acoustic and electric stimulation hearing devices that includes a computer with software that is configured to communicate with and modify parameters of the acoustic and electric elements of an electric-acoustic processor, wherein the acoustic elements generate acoustic stimulation signals to the acoustic sensing organs of the ear, wherein the electric elements apply electric stimulation signals to the auditory nerve of the ear, and wherein the electric and acoustic elements are situated in the same ear. Additional references that also disclose these same limitations include PCT Publication No. WO 92/08330 ("Dooley") and U.S. Publication No. 2001/0031996 ("Leysieffer").

These references were both cited by Applicant in an Information Disclosure Statement ("IDS") after a Notice of Allowance but were never applied by the Examiner.

The evidence conclusively demonstrates that there is more than a reasonable likelihood that the claims of the '747 patent are unpatentable. Claims 1-8 of the '747 patent add nothing to the prior art and should be found unpatentable for anticipation and/or obviousness. Accordingly, Petitioner respectively requests that the Board institute trial on the grounds set forth herein.

II. NOTICES AND STATEMENTS

A. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner identifies the following related matters. On October 3, 2018, Petitioner, MED-EL Elektromedizinische Geräte Ges.m.b.H., and MED-EL Corporation, USA filed suit against Advanced Bionics, L.L.C. ("Advanced Bionics") in the United States District Court for the District of Delaware seeking damages for infringement of two MED-EL patents by Advanced Bionics' HiRes Ultra 3D products. *See MED-EL Elektromedizinische Geräte Ges.m.b.H. et al. v. Advanced Bionics et al.*, No. 1:18-cv-01530 (D. Del.). On November 28, 2018, Advanced Bionics, L.L.C., Sonova AG, and Advanced

Bionics AG brought a counterclaim against MED-EL and its subsidiary for infringement of various patents, including the '747 patent.

B. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

Petitioner, MED-EL Elektromedizinische Geräte Ges.m.b.H., and its subsidiary, MED-EL Corporation, USA, are the real parties-in-interest.

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

MED-EL identifies as lead counsel Lawrence M. Green, Reg. No. 29,384, and backup counsel as Kathryn E. Noll, Reg. No. 48,811, Lisa M. Tittemore (*pro hac vice* to be filed), and Kerry L. Timbers (*pro hac vice* to be filed), all with Sunstein Kann Murphy and Timbers LLP.

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

MED-EL may be served through its counsel, Sunstein Kann Murphy & Timbers LLP, via email to sunsteinip@sunsteinlaw.com, lgreen@sunsteinlaw.com, knoll@sunsteinlaw.com, ltittemore@sunsteinlaw.com, and ktimbers@sunsteinlaw.com, or otherwise to:

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

Petitioner certifies that the '747 patent is available for *inter partes* review and that is the real parties-in-interest are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

F. Fees (37 C.F.R. § 42.15(a))

The required fee is paid via Deposit Account No. 19-4972. The Office is authorized to charge fee deficiencies and credit overpayments to the same Deposit Account.

III. STATEMENT OF PRECISE RELIEF REQUESTED

MED-EL respectfully requests cancellation of claims 1-8 of U.S. Patent No. 8,155,747 (the "'747 patent") (Ex. 1001) based on the following grounds of unpatentability, explained in detail in section VIII.

Ground	35 U.S.C.	Claims	References
1	102(b)	1, 3, 4, 5, 6, and 7	U.S. Patent No. 5,721,783 to Anderson ("Anderson") (Ex. 1003)
2	102(b)	1, 2, 4, and 5	U.S. Publication No. 2001/0031996 to Leysieffer ("Leysieffer") (Ex. 1004)
3	102(b)	1, 2, 4, 5, 6, and 7	PCT Publication No. WO 92/08330 to Dooley ("Dooley") (Ex. 1005)
4	103(a)	1, 2, 4, 5, 6, and 7	PCT Publication No. WO 92/08330 to Dooley ("Dooley") (Ex. 1005) and von Ilberg, C., Kiefer, J., Tillein, J., Pfenningdorff, T., Hartmann, R., Stürzebecher, E., & Klinke, R., *Electric-Acoustic Stimulation of the*

Ground	35 U.S.C.	Claims	References
			Auditory System, ORL: Journal for Oto-Rhino-Laryngology and Its Related Specialties, 61:334-340, 1999 ("von Ilberg 1999") (Ex. 1006)
5	103(a)	1, 2, 4, and 5	U.S. Publication No. 2001/0031996 to Leysieffer ("Leysieffer") (Ex. 1004) and PCT Publication No. WO 00/69512 to Harrison et al. ("Harrison") (Ex. 1007)
6	103(a)	8	U.S. Publication No. 2001/0031996 to Leysieffer ("Leysieffer") (Ex. 1004) and U.S. Patent No. 6,231,604 to von Ilberg ("von Ilberg '604") (Ex. 1008) or U.S. Publication No. 2001/0031996 to Leysieffer ("Leysieffer") (Ex. 1004), PCT Publication No. WO 00/69512 to Harrison ("Harrison") (Ex. 1007), and U.S. Patent No. 6,231,604 to von Ilberg ("von Ilberg '604") (Ex. 1008)

IV. THE '747 PATENT

A. Prosecution History

Application No. 12/495,620 (the "'620 Application") leading to the '747 patent was filed with 9 claims on June 30, 2009. Ex. 1009. The '620 application was a division of Application No. 11/097,611, filed March 31, 2005, and claimed the benefit under 35 U.S.C. § 119(e) of Provisional Application Number 60/559,297, filed April 2, 2004. Ex. 1009, p. 1.

A first office action, dated August 20, 2010, rejected original claims 1-9 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,289,247 ("Faltys et al."). Ex. 1009, p. 55-59.

In Applicant's response, dated November 22, 2010, Applicant argued that Faltys et al. taught a multichannel cochlear prosthesis that applies a pattern of electrical stimulation to the cochlea but that Faltys et al. did not disclose or suggest a device that is capable of providing acoustic stimulation signals to the acoustic sensing organs of the ear or a computer provided with access to software that is configured to communicate with and modify parameters of a hearing aid, an electric-acoustic processor, or any other device that provides (or is capable of providing) acoustic stimulation to the acoustic sensing organs of the ear. Ex. 1009, p. 65-72. Applicant argued, "In contrast, Applicant describes and claims **a system for modifying the parameters of both acoustic and electric stimulation hearing devices**." Ex. 1009, p. 68 (emphasis in original).

A final office action, dated January 28, 2011, maintained the rejection of original claims 1-9 under 35 U.S.C. § 102(b) as being anticipated by Faltys et al. Ex. 1009, p. 76-82. The Examiner found Applicant's arguments in the November 22, 2010 response to be "not persuasive," noting that the "features upon which applicant relies (i.e., acoustic stimulation) are not recited in the rejected

claims(s)…limitations from the specification are not read into the claims." Ex. 1009, p. 78.

In Applicant's response, dated April 21, 2011, Applicant amended independent claim 1, adding "wherein the hearing aid and the acoustic elements of an electric-acoustic processor are devices that provide acoustic stimulation signals to the acoustic sensing organs of the ear." Ex. 1009, p. 87-94. Additionally, Applicant argued that Faltys et al. did not expressly or inherently describe "**a computer provided with access to software that is configured to communicate with and modify parameters of *at least one of* a hearing aid *and* the acoustic elements of an electric-acoustic processor** and at least one of a cochlear implant speech processor and the electric elements of an electric-acoustic processor; **wherein the hearing aid and the acoustic elements of an electric-acoustic processor are devices that provide acoustic stimulation signals to the acoustic sensing organs of the ear**" or "**software [] scripted to provide a suggested assessment of the proper sequencing of acoustic and electric events *for at least one of* the hearing aid *and* the acoustic elements of the electric-acoustic processor and *at least one of* the cochlear implant speech processor and the electric elements of the electric-acoustic processor**." Ex. 1009, p. 92-93 (emphasis in original).

The Office issued an advisory action on May 20, 2011, finding that the proposed amendments to claim 1 "do not provide a substantive change that would distinguish the invention from the art of record." Ex. 1009, p. 98-100.

In Applicant's response, dated May 28, 2011, Applicant further amended claim 1, as follows:

> A system for modifying the parameters of acoustic and electric stimulation hearing devices, comprising: a computer provided with access to software that is configured to communicate with and modify parameters of at least one of (a) a hearing aid and a cochlear implant speech processor and (b) the acoustic and electric elements of an electric-acoustic processor ~~and at least one of a cochlear implant speech processor and the electric elements of an electric-acoustic processor~~;
>
> wherein the hearing aid and the acoustic elements of an electric-acoustic processor are devices that provide acoustic stimulation signals to the acoustic sensing organs of the ear, the acoustic stimulation signals being sound waves directed into the ear canal;
>
> wherein the cochlear implant speech processor and the electric elements of an electric-acoustic processor are devices that provide electric stimulation signals to the auditory nerve of the ear, the electric stimulation signals being stimulation current applied to electrodes implanted within the cochlea of the ear;
>
> wherein the hearing aid and the cochlear implant speech processor, or the acoustic and electric elements of the electric-acoustic processor, are situated in the same ear providing both acoustic

stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear.

Ex. 1009, p. 101-111.

Applicant explained that claim 1 "has been amended to expressly recite what is meant by the terms **'acoustic stimulation signals'** and **'electric stimulation signals,'**" as well as narrowed "to recite **a system for modifying the parameters of acoustic and electric stimulation hearing devices** in which the devices 'are situated in the same ear providing both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear.'" Ex. 1010, p. 106 (emphasis in original).

The Office issued an advisory action on June 17, 2011, noting that the proposed amendments filed after the final rejection raised new issues that would require further consideration and/or search. Ex. 1009, p. 117-119.

After filing a Request for Continued Examination on June 27, 2011, Applicant submitted an information disclosure statement on July 16, 2011. Ex. 1009, p. 125, 131-138.

The Office issued a Notice of Allowance on August 15, 2011, allowing amended claim 1 and the original claims 2-9, noting that an Examiner's amendment to the record was made to replace "provide" in the wherein clauses of claim 1 with "are configured to generate or apply." Ex. 1009, p. 140-147.

On October 29, 2011, Applicant filed a Request for Continued Examination and submitted two more information disclosure statements on October 29, 2011, and on November 15, 2011. Ex. 1009, p. 157, 158-160, 541, 611-612.

On November 16, 2011, the Office issued a Notice of Allowance. Ex. 1009, p. 613-619. On January 31, 2012, Applicant filed a Request for Continued Examination and submitted a further information disclosure statement. Ex. 1009, p. 629, 636-640.

On February 9, 2012, the Office issued a Notice of Allowance, and the '747 patent issued April 10, 2012. Ex. 1009, 745-751, 768.

B. '747 Fitting Systems and Methods

The '747 patent claims a system comprising a computer with access to software which can be used for modifying the parameters of acoustic and electric stimulation hearing devices when such devices are located in the same ear. The system claimed in the patent requires software configured to communicate with and modify parameters of either (a) a hearing aid or a cochlear implant speech processor or (b) the acoustic and electric elements of an electric-acoustic processor. In either case, i.e., whether (a) or (b), the devices are situated in the same ear and are configured to generate or apply acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear. Other than the general idea that the software is configured to

"communicate with and modify parameters" of these devices, the claims do not recite any method steps implemented in software. The system claimed in the patent does not include any hardware other than hardware that was admitted to be well-known and conventional at the time the '620 application was filed. Claim 1 reads:

> A system for modifying the parameters of acoustic and electric stimulation hearing devices, comprising [the "Preamble"]:
>
> a computer provided with access to software that is configured to communicate with and modify parameters of at least one of (a) a hearing aid and a cochlear implant speech processor and (b) the acoustic and electric elements of an electric-acoustic processor; ["Paragraph One"]
>
> wherein the hearing aid and the acoustic elements of an electric-acoustic processor are devices that are configured to generate or apply acoustic stimulation signals to the acoustic sensing organs of the ear, the acoustic stimulation signals being sound waves directed into the ear canal; ["Paragraph Two"]
>
> wherein the cochlear implant speech processor and the electric elements of an electric-acoustic processor are devices that are configured to generate or apply electric stimulation signals to the auditory nerve of the ear, the electric stimulation signals being stimulation current applied to electrodes implanted within the cochlea of the ear; ["Paragraph Three"]
>
> wherein the hearing aid and the cochlear implant speech processor, or the acoustic and electric elements of the electric-acoustic processor, are situated in the same ear and are configured to generate or apply both

> acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear." ["Paragraph Four"].

Ex. 1001, C15:L31-57.

Claims 2-8 of the '747 patent all depend from Claim 1 and add additional limitations. Claim 2 recites a programming interface unit which is configured to exchange information between the computer and at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor. Ex. 1001, C16:L1-6.

Claim 3 recites that the computer is configured to communicate directly with at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor through wireless communications. Ex. 1001, C16:L7-12.

Claim 4 recites that the computer is configured to communicate directly with at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processer, and the acoustic elements of the electric-acoustic processor through wired communications. Ex. 1001, C16:L13-18.

Claim 5 recites that the computer is configured to display data used to at least one of map, evaluate, and modify the parameters of at least one of the hearing

aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processer. Ex. 1001, C16:L19-25.

Claim 6 recites that the software is scripted to evaluate data relevant to operational parameters of at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L26-31.

Claim 7 recites that the software is configured to map parameter levels and ranges and is configured to map responses of a patient wearing at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L32-38.

Claim 8 recites that the computer is configured to simultaneously and sequentially output instructions capable of modifying acoustic and electric stimulation parameters to determine interaction between multiple channels in at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L39-47.

V. STATE OF THE ART AT THE CLAIMED PRIORITY DATE

The ’747 patent concedes that both cochlear implants and hearing aids were well known in the prior art. The patent further explains that it was well known in that prior art that when these types of prosthesis are provided to a patient, “it is necessary to ‘fit’ or ‘adjust’ the prosthesis.” Ex. 1001, C2:L43-44. As used in the ’747 patent, “the terms ‘fit’, ‘adjust’, ‘fitting’, ‘adjusting’, ‘program’, or ‘programming’, relate to making electronic or software programming changes to the prosthetic, as opposed to making physical or hardware changes. Proper fitting allows the prosthesis to better perform its intended function of helping the patient sense sound.” Ex. 1001, C2:L44-49.

The ’747 patent also discloses that it was known in the prior art that “[a]coustic transducers, such as earphone hearing instruments or hearing aids, can be used by patients with residual hearing in conjunction with a cochlear prosthesis in either the same ear (ipsilater [sic] ear) as the cochlear implant or the opposite ear (contralateral ear).” Ex. 1001, C3:L28-32.

A. U.S. Patent No. 5,721,783 (“Anderson”)

U.S. Patent No. 5,721,783 (“Anderson”) (Ex. 1003) issued on February 24, 1998, more than a year before than the earliest claimed priority date for the ’747 patent, and thus, Anderson is prior art under 35 U.S.C. § 102(b).

Anderson discloses a hearing aid system which includes an acoustic hearing aid with an earpiece 10 (*see* Ex. 1003, FIG. 1) and a cochlear implant. The "user 100 is equipped with a pair of CIC wireless hearing aid earpieces (left 10' and right 10"), and RPU 16 and wireless BTE implant electrode driver unit 104." Ex. 1003, C27:L41-44; FIG. 10. Digital signal processor 948 in remote processor unit 16 (RPU) operates both the earpieces 10 and the cochlear implant. DSP 948 contains software for modifying the parameters of both the cochlear implant and the acoustic earpiece 10. Ex. 1003, C28:L42-57; C3:L3-34. Anderson was not cited by either Applicant or the Examiner during prosecution of the '620 Application. Ex. 1009.

B. U.S. Publication No. 2001/0031996 ("Leysieffer")

U.S. Publication No. 2001/0031996 ("Leysieffer") (Ex. 1004) was published on October 18, 2001, more than a year before the '747 patent's earliest claimed priority date, and thus, Leysieffer is prior art under 35 U.S.C. § 102(b).

Leysieffer discloses an "at least partially implantable system for rehabilitation of a hearing disorder." Ex. 1004, Abstract. Leysieffer further discloses an "electromechanical transducer for mechanical stimulation of the middle ear or inner ear, and an intracochlear, electrically acting stimulation electrode array" for stimulation of the same inner ear. Ex. 1004, Paragraph [0020]. Leysieffer teaches that hearing aids with an output-side acoustic stimulus were

conventional as of the filing date of the application and that the requirements for signal processing are fundamentally similar to or the same as those for an electromechanical transducer for mechanical stimulation of the middle ear or inner ear. Ex. 1004, Paragraph [0014]. Leysieffer also discloses use of software for communicating with and modifying the parameters of such devices, including when the devices are situated ipsilaterally, e.g., for addressing hearing loss in the same ear. Leysieffer discloses that the software is used to fit an implantable hearing aid configured to capture acoustic sounds and deliver them to the acoustic sensing organs of the ear and a cochlear implant speech processor configured to generate or apply electric stimulation signals to the auditory nerve (i.e., stimulation current applied to electrodes implanted within the cochlea of the ear), e.g., to address hearing loss in the same ear. Ex. 1004, Paragraphs [0087]-[0090]. Leysieffer was first cited in an IDS filed by Applicant on October 29, 2011, after the first Notice of Allowance, but was never applied by the Examiner. Ex. 1009.

C. PCT Publication No. WO 92/08330 ("Dooley")

PCT Publication No. WO 92/08330 ("Dooley") (Ex. 1005) was published on May 14, 1992, making it prior art against the '747 patent under 35 U.S.C. § 102(b).

Dooley discloses a bimodal aid, including an acoustic aid 14 and implant aid 15 (a cochlear implant), and a "bimodal speech processor" consisting of a "speech processor" linked to an "acoustic aid processor." Ex. 1005, Abstract; Ex. 1005,

P10:L25-P11:L4. Dooley explains that the bimodal speech processor processes audio information in accordance with patient-specific settings. Ex. 1005, P10:L25-P11:L4. Dooley describes fitting hardware and techniques for fitting the implant aids to the patient. Ex.1005, p. 29-39. Dooley was first cited in an IDS filed by Applicant on October 29, 2011, after the first Notice of Allowance, but was never applied by the Examiner. Ex. 1009.

D. von Ilberg, C., Kiefer, J., Tillein, J., Pfenningdorff, T., Hartmann, R., Stürzebecher, E., & Klinke, R., *Electric-Acoustic Stimulation of the Auditory System*, ORL: Journal for Oto-Rhino-Laryngology and Its Related Specialties, 61:334-340, 1999 ("von Ilberg 1999")

Electric-Acoustic Stimulation of the Auditory System ("von Ilberg 1999") (Ex. 1006) was published in 1999, making it prior art against the '747 patent under 35 U.S.C. § 102(b). von Ilberg 1999 discloses the use of both acoustic stimulation and electrical stimulation simultaneously in the same ear, nearly without interference, in response to hearing loss. Ex. 1006, Abstract. von Ilberg 1999 further explains the fitting of hearing devices for optimized outputs. Von Ilberg 1999 was not cited by either Applicant or the Examiner during prosecution of the '620 Application. Ex. 1009.

E. PCT Publication No. WO 00/69512 ("Harrison")

PCT Publication No. WO 00/69512 ("Harrison") (Ex. 1007) was published on November 23, 2000, more than a year before the earliest claimed priority date for the '747 patent, making it prior art against the '747 patent under 35 U.S.C.

§ 102(b). Harrison discloses a "hybrid cochlear implant hearing aid" system. Ex. 1007, Abstract. The hybrid cochlear implant hearing aid system includes implantable cochlear stimulation and an in-the-canal hearing aid in the same ear. Ex. 1007, C4:L12-18; C5:L55-60. Harrison was first cited in an IDS filed by Applicant on October 29, 2011, after the first Notice of Allowance, but was never applied by the Examiner. Ex. 1009.

F. U.S. Patent No. 6,231,604 ("von Ilberg '604")

U.S. Patent No. 6,231,604 ("von Ilberg '604") (Ex. 1008) issued on May 15, 2001, more than a year before the earliest claimed priority date for the '747 patent, and thus, von Ilberg '604 is prior art under 35 U.S.C. § 102(b). von Ilberg '604 discloses a hearing prosthesis, which includes an electrical stimulation module, an acoustic stimulation module, and a stimulation amplifier, for a user in an acoustic environment having a range of audio frequencies. Ex. 1008, Abstract. von Ilberg '604 discloses the use of a cochlear implant and an acoustic hearing device in a single ear and the fitting of a cochlear implant, including adjustment strategies for calibrating the stimulation signals for the cochlear implant. Applicant first cited von Ilberg '604 in IDS filed on October 29, 2011, after the first Notice of Allowance, but the Examiner never applied von Ilberg '604. Ex. 1009.

VI. PERSON OF ORDINARY SKILL IN THE ART ("POSITA")

A person of ordinary skill in the art ("POSITA") is a hypothetical person who is presumed to know the relevant prior art. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In this case, the art relevant to the '747 patent is the fields of acoustic and electric stimulation hearing devices and fitting methods and systems, including software to modify the various parameters for acoustic, electric and electric-acoustic stimulation of hearing devices for patients with residual hearing. A POSITA in this field would have had the equivalent of a Master of Science degree in audiology or a related discipline and two or three years' experience designing, developing, programming, evaluating, or fitting acoustic, electric or electric-acoustic stimulation systems for diagnostic and rehabilitative use in patients' auditory systems.

VII. CLAIM CONSTRUCTION

Petitioner notes that a claim "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b).

The term "electric-acoustic processor" occurs in all of the claims of the '747 patent. The '747 patent specification defines "electric-acoustic processor" to mean:

> An electric-acoustic processor system, as with the example embodiment shown in FIG. 4C, can include any combination of the elements of cochlear implant systems and hearing aid systems, as needed, to facilitate a device capable of providing both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear.

Ex. 1001, C11:L1-7. The '747 patent specification further provides that an "electric-acoustic processor" can be "in addition to, or as an alternative to, the cochlear implant systems and hearing aids." Ex. 1001, C10:L65-67.

VIII. EXPLANATION OF GROUNDS FOR UNPATENTABILITY

The showing in the following subsections establishes a reasonable likelihood of prevailing as to each ground of invalidity with respect to the challenged claims as to that ground. The showing, accompanied by the Declaration of Douglas Paul Sladen, Ph.D. (Ex. 1002), establishes why the challenged claims of the '747 patent are unpatentable under the statutory grounds raised, including claim charts specifying where each element of a challenged claim is met by the prior art (Ex. 1010). 37 C.F.R. § 42.104(b)(4).

A. Ground 1 – Anticipation of Claims 1 and 3-7 by Anderson

Claim 1

Claim 1 of the'747 patent is the only independent claim. The preamble of claim 1 recites, "A system for modifying the parameters of acoustic and electric stimulation hearing devices." Ex. 1001, C15:L31-32. Anderson discloses the use of both an acoustic stimulation hearing device or element (*see, e.g.*, Ex. 1003, FIG. 1 (earpiece 10), FIG. 2 (earpiece 22); *see also* Ex. 1003, C27:L4-24) and an electric stimulation hearing device or element, a cochlear implant as shown, for example, in Figure 10 and Figure 11. Ex. 1003, FIGS. 10, 11; *see* Ex. 1003, C27:L25-29. Figure 10 of Anderson, below, shows implant electrode driver unit 104 and CIC wireless hearing aid and earpieces 10' and 10".

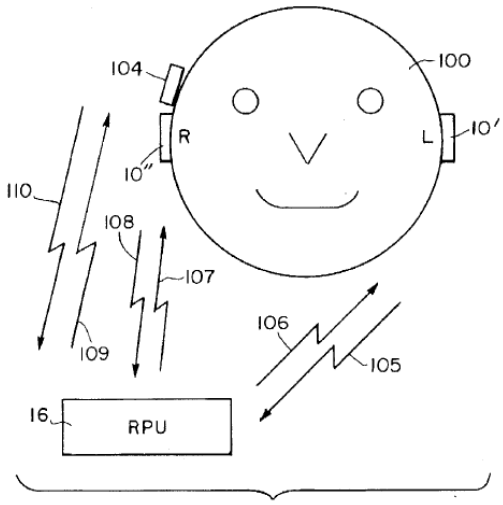


FIG. 10

Anderson discloses that "a user is equipped with a pair of CIC wireless hearing aid earpieces (left 10' and right 10"), an RPU 16 and wireless BTE implant electrode driver unit 104…" Ex. 1003, C27:L41-44.

Paragraph One of claim 1 of the '747 patent recites a computer provided with access to software. Anderson discloses a remote processor unit (RPU) 16, which is illustrated in block diagram format in Figure 9. Ex. 1003, FIG. 9; Ex. 1003 C2:L46-47 ("The RPU (which contains a digital signal processor or other computer)…"). Anderson discloses that "[t]he combination of an ear-piece 10 with an RPU 16 can be used in lieu of a laptop computer" and that "[w]hen manual command of RPU functions (e.g., control of parameter settings or data entry) is desired, a keyboard attached to or built into the RPU housing can be used." Ex. 1003, C26:L24-26, C20:L52-55. Anderson teaches that audio signals are enhanced and signal processing is performed in the RPU. Ex. 1003, C1:L61-64. Furthermore, in discussing the performance of a hearing test, Anderson discloses that RPU 16 has access to software and that it determines parameters that are stored in RPU 16:

> The present invention allows hearing tests to be performed via the earpiece normally worn by the user, without the need for additional expensive test equipment. All signal generation capabilities necessary to perform hearing tests are available in the hearing aid system comprising an earpiece 10 and RPU 16. Specifically, the RPU DSP 948 can be used to generate tones of varying frequencies and amplitudes, as well as other signals known to be useful for hearing

> test purposes (e.g., nonsense syllables) that are converted to acoustic waves by the earpiece. Such tones are used to perform a hearing test that determines appropriate gain vs. frequency parameters for a program stored in the RPU DSP 948 that performs signal enhancement to compensate for the user's hearing loss. Note that the hearing test program that controls the RPU DSP 948 during the hearing test can be temporarily stored in the RPU DSP 948 for the duration of the test, then deleted upon completion of the test to allow re-use of RPU DSP 948 memory resources during normal operation. The hearing test program may be loaded into the RPU DSP 948 through the secondary wireless link 944 or a wired peripheral link 950.

Ex. 1003, C27:L4-24. Accordingly, RPU DSP 948 has access to software.

Paragraph One further recites that the software "is configured to communicate with and modify parameters of at least one of (a) a hearing aid and a cochlear implant speech processor and (b) the acoustic and electric elements of an electric-acoustic processor." Ex. 1001, C15:L33-37. This limitation of Paragraph One of claim 1 is interpreted to mean that the software is configured to communicate with and modify parameters of either a hearing aid and a cochlear implant speech processor or the acoustic and electric elements of an electric-acoustic processor.

The '747 patent does not specifically define the term "speech processor," and, therefore, the term is understood by a POSITA to have its ordinary meaning.

Ex. 1002, ¶49. The ’747 patent identifies a speech processor 16 for the cochlear implant in Figure 2A, as well a speech processor 72 for the electric-acoustic processor system, e.g., in Figure 4C, as shown below. Ex. 1001, FIGS. 2A, 4C.

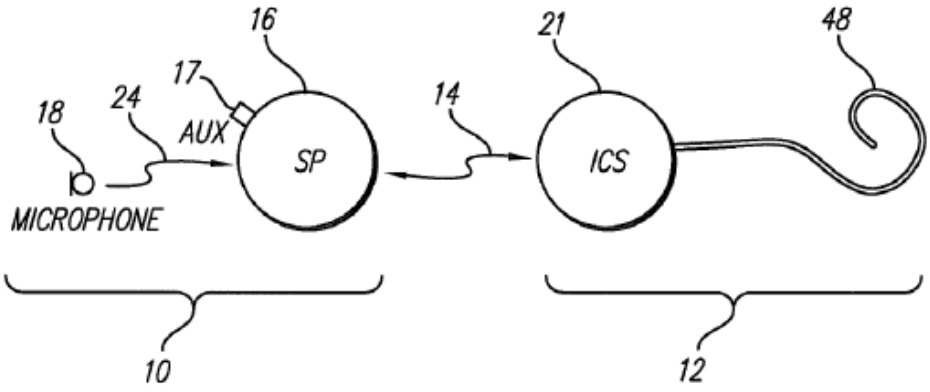


FIG. 2A

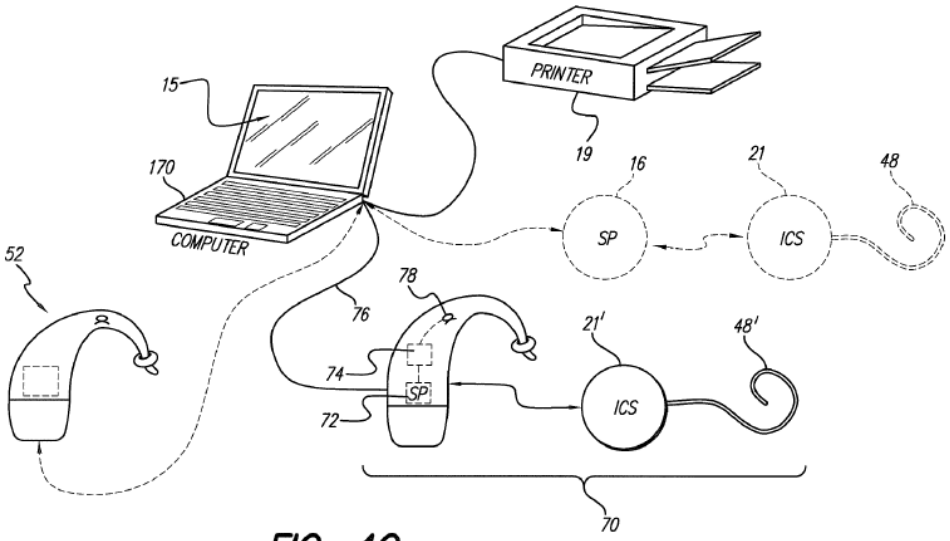


FIG. 4C

An electric-acoustic processor is defined in the '747 patent as "a device capable of providing both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear." Ex. 1001, C11:L1-7. The '747 patent further states that an "electric-acoustic processor" can be in addition to or as an alternative to the cochlear implant systems and hearing aids. Ex. 1001, C10:L65-C11:L1. This electric-acoustic processor system "can include any combination of the elements of cochlear implant systems and hearing aid systems, as needed." Ex. 1001, C11:L1-4.

Anderson discloses digital signal processor (DSP) 948 which is part of RPU 16, "where the audio signals are enhanced according to the user's needs." These audio signals are "transmitted from the RPU 16 over the primary wireless link 17 to the earpiece 10 where they are converted by a speaker 15 to sounds that can only be heard by the user 11." Ex. 1003, C23:L4-14. DSP 948 is taught by Anderson to convert audio signals from the earpiece microphone to a single radio output signal. DSP 948 also achieves cancellation of background noise and competing talkers using any number of techniques or circuits well known in the art (Ex. 1003, C27:L35-47) such as by "the equivalent function implemented in a program executed by the RPU DSP 948. The noise-canceled signal is then further processed by, e.g., a normalization program implemented in the RPU DSP 948 that reduces talker variability with regard to volume level, average pitch, pitch range and tone.

The resulting noise-canceled and normalized signal is then processed, e.g., by a program implemented in the RPU DSP 948 to create appropriate signals that will subsequently drive the individual electrodes of a cochlear implant via the implant driver 104." Ex. 1003, C28:L42-58. Also, during hearing tests, as discussed above, the RPU DSP 948 generates tones of varying frequencies and amplitudes that are used to perform hearing tests that determine appropriate gain versus frequency parameters for a program stored in the RPU DSP 948 that performs signal enhancement and communicates with the hearing aid. Ex. 1003, C27:L4-24. It is apparent from the foregoing disclosure that RPU DSP 948 is an electric-acoustic processor based upon the definition in the '747 patent and that software run on the DSP 948 is configured to communicate with and modify parameters of the acoustic and electric elements. A POSITA would have understood the electric element of the electric-acoustic processor to include the cochlear implant of Anderson and the acoustic element to include earpiece 10 or 22 of Anderson. Ex. 1002, ¶52. Thus, Anderson discloses the limitations of Paragraph One.

The limitation of Paragraph Two of claim 1 recites that the hearing aid and the acoustic elements of an electric-acoustic processor are devices that are configured to generate or apply acoustic stimulation signals to the acoustic sensing organs of the ear, the acoustic stimulation signals being sound waves directed into the ear canal. This limitation is disclosed in Anderson:

> During normal operation, speech signals from a nearby talker (and other signals in the ambient audio environment) are picked up by the earpiece wireless microphone 20 and transmitted to the RPU FM receiver 24. The RPU FM receiver 24 output level may be adjusted using the RPU FM receiver 24 volume control. The resulting electrical waveform representing signals from the nearby talker travels through the DPDT switch 25, which is set to the lower position as show in FIG. 2, to the signal enhancer 26. The signal enhancer 26 may be, for example, a voice changer device that varies the pitch of a received speech signal according to the settings of pushbutton controls located on the RPU signal enhancer 26. The speech signal's pitch can then be raised or lowered as desired to help compensate for a user's hearing loss relative to a particular talker's voice characteristics. The modified speech signal travels from the RPU signal enhancer 26 to the RPU FM transmitter 27, and finally to the earpiece headset 21 receiver where the signal is converted to acoustic waves heard by the user.

Ex. 1003, C5:L3-21.

The limitation of Paragraph Three recites that the cochlear implant speech processor and the electric elements of an acoustic-electric processor are devices that are configured to generate or apply electric stimulation signals to the auditory nerve of the ear, the electric stimulation signals being stimulation current applied to electrodes implanted within the cochlea of the ear. This limitation is disclosed in Anderson:

> The noise-canceled signal is then further processed by, e.g., a normalization program implemented in the RPU DSP 948 that reduces talker variability with regard to volume level, average pitch, pitch range and tone. The resulting noise-canceled and normalized signal is then processed, e.g., by a program implemented in the RPU DSP 948 to create appropriate signals that will subsequently drive the individual electrodes of a cochlear implant via the implant driver 104. The number of electrode driver signals depends upon the type of implant as well as the number of functional electrodes in a given patient. The appropriate signals are transmitted in the audio data field of RPU interrogations from the RPU 16 to the implant driver 104 via path 109. The implant driver 104 then receives data in the interrogation audio data field and converts the data in the ASIC 111 to signals supplied to the electrode drivers 112 used to stimulate the cochlear implant electrodes 113 by means well known in the prior art.

Ex. 1003, C28:L50-67. As previously noted, DPU RSP 948 is an electric-acoustic processor.

Paragraph Four, the final limitation of claim 1, recites that the hearing aid and the cochlear implant speech processor, or the acoustic and electric elements of the electric-acoustic processor, are situated in the same ear and are configured to generate or apply both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear. This limitation is disclosed in Figure 10 of Anderson, shown above, in which implant electrode driver unit 104, CIC wireless hearing aid, and earpiece 10" are

disposed in the same ear. Ex. 1003, FIG. 10. More particularly, Anderson discloses:

> To combat these problems, a user 100 is equipped with a pair of CIC wireless hearing aid earpieces (left 10' and right 10"), an RPU 16 and wireless BTE implant electrode driver unit 104… Note that a system using only one earpiece is also possible, but a more generally applicable system that uses two earpieces is described here. The driver unit 104 contains transceiver circuitry similar to that used in an earpiece 10 transponder (see FIG. 11), with differences as noted in the following, and electrode driver circuitry 112 well known in the prior art for driving the cochlear implant electrodes 113…. An interrogation RF signal travels on a path 106 from the RPU 16 to the left earpiece 10', and the same interrogation RF signal travels via another path 109 from the RPU to the driver unit 104. The left earpiece 10' is responsive to a specific address bit pattern contained in the interrogation, as explained earlier, and the driver unit 104 is also responsive to the same address. Audio and auxiliary data bits in the interrogation are received simultaneously by both the left earpiece 10' and driver unit 104. The left earpiece 10' uses the received interrogation data bits to compute a parity bit for the subsequent reply, while the driver unit 104 uses the interrogation audio data bits to drive the cochlear implant electrodes…

Ex. 1003, C27:L41-67. Figure 11 is shown below.

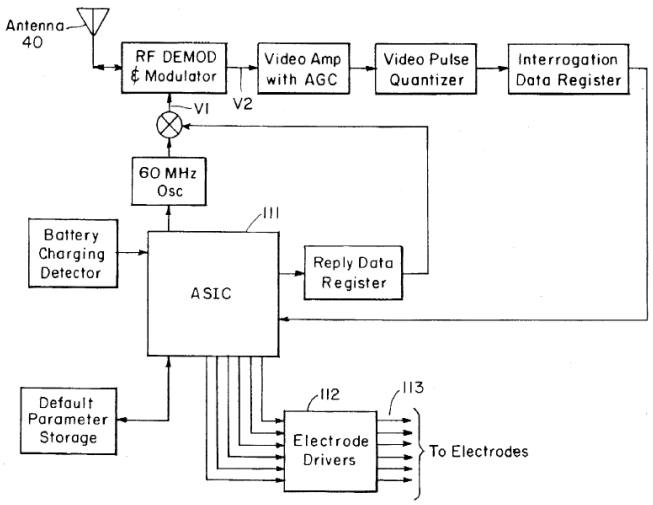


FIG. 11

Accordingly, Anderson fully discloses each and every limitation of claim 1 and thus, anticipates claim 1.

Claim 3

Claim 3 recites that the computer is configured to communicate directly with at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor through wireless communications. Ex. 1001, C16:L7-12. This limitation requires only communication with at least one of the foregoing, and therefore, it is fully disclosed at least by the foregoing language of Anderson, which states that audio signals are transmitted from the RPU 16 over wireless link 17 to earpiece 10 (the hearing aid). Ex. 1003, C23:L8-12. Anderson fully discloses the limitations of claim 3 and thus, anticipates claim 3.

Claim 4

Claim 4 recites that the computer is configured to communicate directly with at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor through wired communications. Ex. 1001, C16:L13-18. Anderson discloses that one of the purposes of its wireless invention is "to provide profoundly deaf cochlear implant patients with a wireless system allowing improved freedom of movement compared to existing wire-connected systems." Ex. 1003, C2:L65-C3:L5. Additionally, Anderson discloses, "Profoundly deaf cochlear implant patients can be provided with a wireless system having improved performance, appearance and freedom of movement compared to existing wire-connected systems." Ex. 1003, C27:L30-33. Anderson teaches that prior art systems were wired systems, i.e., systems that communicated over wires. Anderson fully discloses the limitations of claim 4 and thus, anticipates claim 4, or at least renders claim 4 obvious.

Claim 5

Claim 5 recites that the computer is configured to display data used to at least one of map, evaluate, and modify the parameters of at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor. Ex.

1001, C16:L19-25. Anderson discloses the performance of hearing tests with respect to hearing aids in which parameters of the hearing aids are evaluated or modified. Ex. 1003, C27:L4-24. In reference to Figure 7, Anderson also discloses various embodiments of an RPU, one of which has an alphanumeric liquid crystal display 71. Ex. 1003, C20:L64-65. Further, with reference to Figure 9, as one example of DSP 948, Anderson discloses Motorola DSP56L002, which includes a display 954 and a keyboard 946. Ex. 1003, C21:L25-30. Figures 7 and 9 are shown below.

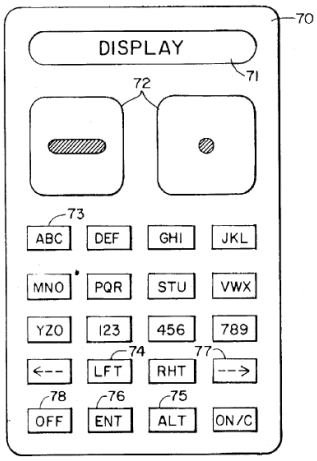


FIG. 7

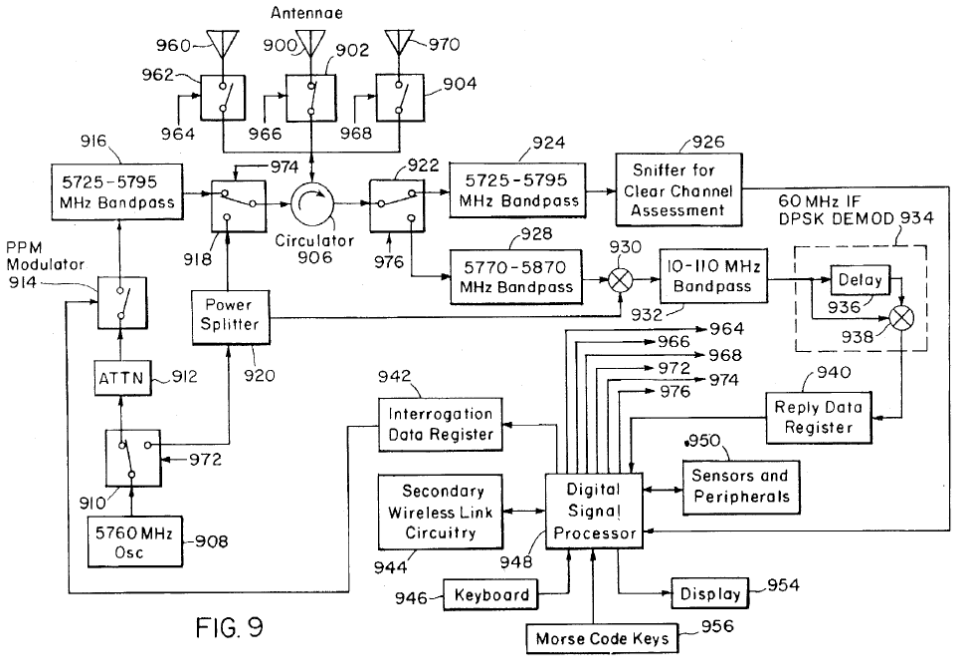


FIG. 9

Accordingly, Anderson fully discloses that RPU 16 may be a computer that has a display and therefore is configured to display data which is used to map, evaluate, and/or modify the parameters. Since, as discussed above, RPU 16 is used to at least evaluate and/or modify the parameters of at least the hearing aid, Anderson discloses and anticipates claim 5.

Claim 6

Claim 6 recites that the software is scripted to evaluate data relevant to the operational parameters of at least the hearing aid. As discussed, Anderson discloses the use of software to perform a hearing test with regard at least to the hearing aid system comprising earpiece 10 that evaluates data relevant to operational parameters of at least the hearing aid comprising earpiece 10. Ex. 1003, C27:L4-

24. Accordingly, Anderson fully discloses the limitations of claim 6 and thus, anticipates claim 6.

Claim 7

Claim 7 recites that the software is configured to map parameter levels and ranges and is configured to map responses of a patient wearing at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L32-38. In discussing a hearing test, Anderson discloses software that generates tones that perform a hearing test that determines gain versus frequency parameters for a program stored in the RPU DSP 948 that performs signal enhancement with respect to earpiece 10. Ex. 1003, C27:L7-24. A POSITA would have understood that such signal enhancement was associated with mapping parameter ranges and levels and mapping responses of a patient. Ex. 1002, ¶69. That patient would be wearing a hearing aid, which is one of the devices listed in the claim. Thus, since claim 7 only requires wearing at least one of the listed devices, Anderson discloses the limitations of claim 7 and thus, anticipates claim 7.

B. Ground 2 – Anticipation of Claims 1, 2, 4, and 5 by Leysieffer

Claim 1

Leysieffer discloses each and every element of Claim 1 of the '747 patent. As discussed further below, Leysieffer discloses a system including acoustic elements (e.g., an electromechanical transducer or a conventional hearing aid device) and electric elements (i.e., an intracochlear stimulation electrode array) of an electric-acoustic speech processor that generate or apply stimulation signals in the same ear, and a computer provided with access to software that is configured to communicate with and modify the parameters of those devices.

The preamble of claim 1 recites "[a] system for modifying the parameters of the acoustic and electric stimulation hearing devices." Ex. 1001, C15:L31-32. Leysieffer describes a system with both acoustic and electric stimulation hearing devices. Specifically, Leysieffer includes an "electromechanical transducer" coupled to a bone in the middle ear (acoustic element) and an "electrical intracochlear array 10 having several stimulation electrodes 11" (electric element). Ex. 1004, Paragraph [0071]; *see also* Ex. 1004, Paragraph [0005] ("In these so-called cochlear implants (CI) an array of stimulation electrodes which is controlled by an electronic system (electronic module) is inserted into the cochlea."). Leysieffer also discloses that its system modifies, for example, audiological

adaption parameters. Ex. 1004, Paragraph [0088]. Thus, Leysieffer discloses the Preamble of claim 1.

Paragraph One of claim 1 of the '747 patent recites "a computer provided with access to software that is configured to communicate with and modify parameters of at least one of (a) a hearing aid and a cochlear implant speech processor and (b) the acoustic and electric elements of an electric-acoustic processor." Ex. 1001, C15:L33-37. Leysieffer describes an external programming system 48 which "can be a PC-based system with corresponding programming, processing, display and administration software." Ex. 1004, Paragraph [0089]. Leysieffer also discloses a computer microcontroller 44 that has access to software in storages (S3, S4 and S5) for communicating and modifying parameters. Ex. 1004, Paragraph [0088]. The microcontroller 44 in Leysieffer "communicates via a bidirectional data bus 45 and a telemetry system (TS) 46 wirelessly (for example, via inductive coupling) through the closed skin indicated at 47 with an external programming system (PS) 48." Ex. 1004, Paragraph [0089]. Leysieffer further explains that "operating parameters, i.e., patient-specific data, for example, audiological adaption data, or variable implant system parameters (for example, a variable in a software program for control of battery recharging), can be transmitted transcutaneously, i.e. wirelessly through the closed skin, to the implant

and can thus be changed." Ex. 1004, Paragraph [0032]. Figure 2 of Leysieffer, below, illustrates these elements.

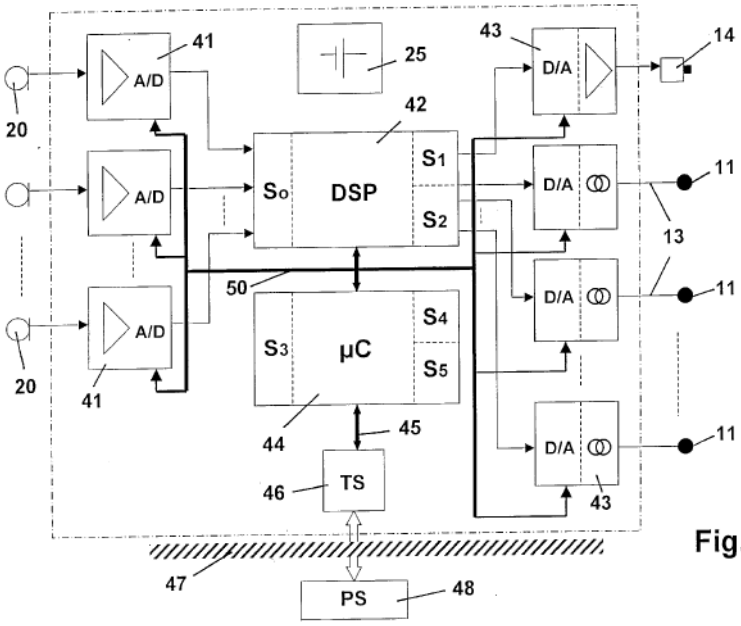
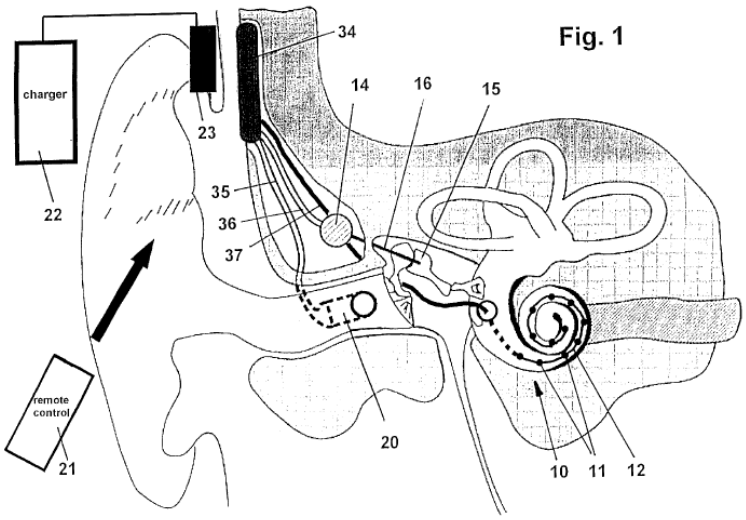


Fig. 2

Leysieffer does not specifically use the term "electric-acoustic processor." As discussed above with respect to Anderson, the '747 patent defines such a processor as "a device capable of providing both acoustic stimulation signals to the acoustic sensing organs of the ear, and electric stimulation signals to the auditory nerve of the same ear." Ex. 1001, C10:L65 – C11:L7. Leysieffer discloses such a device, electronic module 34, which contains digital signal processor 42. Digital signal processor 42 "contains software modules which provide for dual control of the stimulating electrode array 10 and the electromechanical transducer 14 in such a manner that the spectral, time, amplitude- and phase-referenced transducers or stimulating electrode signal properties are configured such that optimum hearing

success is achieved for the pertinent patent." Ex. 1004, Paragraph [0087]. In accordance with the foregoing definition in the '747 patent, a POSITA would understand that digital signal processor 42 is an electric-acoustic processor. Ex. 1002, ¶76. Leysieffer also discloses an electromechanical transducer 14 which corresponds to the acoustic elements recited in claim 1. Programming system 48 (the "the computer") communicates with microcontroller 44 (Ex. 1004, Paragraph [0089]), and microcontroller 44 communicates with the digital signal processor 42 via data bus 50 (Ex. 1004, Paragraph [0090]) to alter audiological adaptation parameters (Ex. 1004, Paragraph [0088]). Thus, Leysieffer fully discloses Paragraph One of claim 1.

The limitation of Paragraph Two of claim 1 recites that the hearing aid and the acoustic elements of an electro-acoustic processor are devices that are configured to generate or apply acoustic stimulation signals to the acoustic sensing organs of the ear, the acoustic stimulation signals being sound waves directed into the ear canal. Ex. 1001, C15:L38-43. With respect to Paragraph Two of claim 1, the acoustic element of Leysieffer illustrated in Figure 1 includes an electromechanical transducer 14. Ex. 1004, FIG. 1. Figure 1 is shown below.



In the embodiment disclosed in Figure 1, Leysieffer describes transducer 14 as "an electromechanically active heteromorph composite element, the mechanical vibrations of which are transmitted to the ossicular chain via a coupling rod 16 …" Ex. 1004, Paragraph [0073]. Leysieffer also discloses the use of an acoustic element with an acoustic output of sound waves directed into the ear canal. In particular, Leysieffer states that:

> The above described, at least partially implantable hearing systems for rehabilitation of a [sic] inner ear damage which are based on an output-side electromechanical transducer differ from conventional hearing aids essentially only in that the out-put side acoustic stimulus (i.e. an amplified acoustic signal in front of the eardrum) is replaced by an amplified mechanical stimulus of the middle ear or inner ear. The acoustic stimulus of a conventional hearing aid ultimately leads to vibratory, i.e. mechanical stimulation of the inner ear, via mechanical stimulation of the eardrum and the subsequent middle ear. The

> requirements for effective audio signal preprocessing are fundamentally similar or the same.

Ex. 1004, Paragraph [0014]. Thus, Leysieffer discloses both an electromechanical transducer for mechanical stimulation of the middle ear or inner ear and a conventional hearing aid that generates sounds waves directed into the ear canal. Given this disclosure, a POSITA would understand that an acoustic element that generates or applies sound waves directed into the ear canal, such as a conventional hearing aid, also would be used in the apparatus of Leysieffer. Ex. 1002, ¶ 81. As noted above, digital signal processor 42 contains software modules which provide for control of transducer 14. Thus, Leysieffer fully discloses Paragraph Two of claim 1 or at least renders obvious the limitations of Paragraph Two of claim 1.

Leysieffer also discloses Paragraph Three of claim 1. Paragraph Three recites that the cochlear implant speech processor and the electric elements of an electric-acoustic processor are devices that are configured to generate or apply electric stimulation signals to the auditory nerve of the ear, the electric stimulation signals being stimulation current applied to electrodes implanted within the cochlea of the ear. Ex. 1001, C15:L44-50. Leysieffer discloses an intracochlear stimulation electrode array 10 which "comprises an electrode carrier 12 of electrically insulating, flexible material along which the stimulation electrodes 11

connected to feed lines 13 are distributed at a distance to each other. The stimulation electrodes 11 are embedded in the carrier 12 or fixed on the carrier 12 such that a portion of the surface per stimulation electrode is in direct galvanic contact with the lymphatic fluid of the inner ear or directly with one of the neural structures to be stimulated." Ex. 1004, Paragraph [0072]. As noted previously, digital signal processor 42 contains software modules which provide for control of the stimulating electrode array 10. Ex. 1004, Paragraph [0087]. Thus, Leysieffer fully discloses Paragraph Three of claim 1.

Paragraph Four of claim 1 recites that the hearing aid and the cochlear implant speech processor or the acoustic and electric elements of the electric-acoustic processor are situated in the same ear. This paragraph is illustrated in Figure 1 of Leysieffer, as shown above, which discloses that electrode array 10, transducer 14, and module 34 are in the same ear. Ex. 1004, FIG. 1; Ex. 1004, [0062], [0064], [0071], [0087]. Module 34 includes digital signal processor 42.

Paragraph Four of claim 1 also recites that the hearing aid and the cochlear implant speech processor or the acoustic and electric elements of the electric-acoustic processor are configured to generate or apply both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear. Leysieffer also discloses that electric stimulation signals from the digital signal processor 42 are supplied to the

stimulating electrodes 11 and acoustic stimulation signals are supplied to the output-side electromechanical transducer 14. Ex. 1004, Paragraph [0086]. Thus, digital signal processor 42 applies both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to auditory nerve of the same ear. Thus, Leysieffer fully discloses Paragraph Four of claim 1.

Accordingly, Leysieffer fully discloses each and every limitation of claim 1 and thus, anticipates claim 1.

Claim 2

Claim 2 depends from claim 1 and adds the requirement of a programming interface unit configured to exchange information between the computer and at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor. Ex. 1001, C16:L1-6. Leysieffer teaches this limitation.

Leysieffer discloses that the "the microcontroller 44 communicates via a bidirectional data bus 45 and a telemetry system (TS) 46 wirelessly (for example, via inductive coupling) through the closed skin indicated at 47 with an external programming system (PS) 48. The programming system 48 can be a PC-based system with corresponding programming, processing, display and administration software. Via this telemetry interface, the operating software of the implant system which is to be changed or completely replaced is transmitted and at first buffered

in the storage area S4 and/or S5 of the microcontroller 44." Ex. 1004, Paragraph [0089]. Leysieffer further states that "corresponding signal processing portions of this software are transmitted into the program storage areas S1 and S2 of the digital signal processor 42 via a data bus 50." Ex. 1004, Paragraph [0089]. Data bus 50 corresponds to the recited interface unit. Since the digital signal processor 42 corresponds to the electric-acoustic processor, and programing system 48 and microcontroller 44 correspond to the computer recited in claim 1, Leysieffer fully discloses the limitations of claim 2 and thus, anticipates claim 2.

Claim 4

Claim 4 recites that the computer is configured to communicate directly with at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor through wired communications. Ex. 1001, C16:L 13-18. Figure 1 of Leysieffer, which is set forth above, discloses wired communications between electronic module 34 by means of a transducer feed line 36, a wire, to electromechanical transducer 14 and, via an array feed line 37, to the intracochlear stimulation electrode array 10. Ex. 1004, FIG. 1; Paragraph [0083]. Module 34 of Figure 2 includes signal processor 42 and microcontroller 44. Ex. 1004, Paragraph [0084] ("Figure 2 shows the possible structure of the signal processing electronic module 34 of an at least partially implantable hearing system."). Also, as discussed

above, Figure 2 of Leysieffer discloses wired communication between microcontroller 44 and signal processor 42 via data bus 50. Ex. 1004, [0089]. Thus, the computer 44 of Leysieffer is directly connected through wired communications to the transducer 14 (the hearing aid), the intracochlear array 10 (the electric elements), and signal processor 42 (the electric-acoustic processor). Accordingly, Leysieffer fully discloses the limitations of claim 4 and thus, anticipates claim 4.

Claim 5

Claim 5 depends from claim 1 and adds the requirement that the computer is configured to display data used to at least one of map, evaluate, and modify the parameters of at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor. Ex. 1001, C16:L19-25. As noted above, in Leysieffer, the audiological parameters can be altered from the outside, i.e., by external programming system 48, which includes a display. Ex. 1004, Paragraphs [0088], [0089]. Such a display is configured to display data used to at least modify the parameters of at least the hearing aid. Leysieffer fully discloses the limitations of claim 5 and thus, anticipates claim 5.

C. Ground 3 – Anticipation of Claims 1, 2, and 4-7 by Dooley

Claim 1

Dooley discloses every limitation of claim 1. With respect to the Preamble, Dooley discloses a system for modifying the parameters of acoustic and electric stimulation hearing devices, as shown in Figure 2, below. Ex. 1005, Fig. 2. Dooley discloses a bimodal device that includes an acoustic element, i.e., acoustic hearing aid 14, together with an electric element, i.e., implant aid 15. The implant aid 15 comprises an electrode array 16. Ex. 1005, P10:L28 – P11:L2. Dooley also discloses a programming unit 21 "to test for and control device parameters of operation for the speech processor 11 and/or acoustic aid processor 12 which optimise hearing performance for a patient…" Ex. 1005, P11:L11-16.

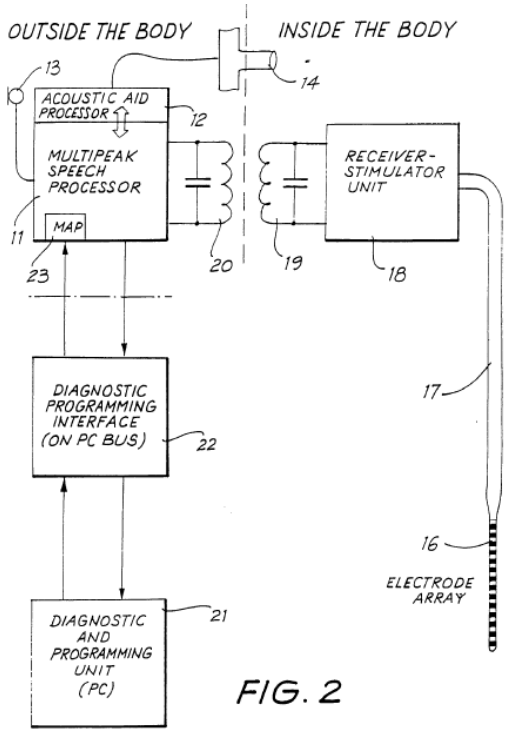


FIG. 2

Regarding Paragraph One of claim 1, Dooley discloses a computer provided with access to software. The diagnostic and programming unit 21 "is implemented as a program running on a personal computer." Ex. 1005, P11:L8-9. In Dooley, both the cochlear implant aid 15 and the acoustic aid 14 are controlled by the same speech processor, processor 11. Ex. 1005, P7:L28-P8:L2; *see* Figs. 1 and 2. Based upon the definition of "electric-acoustic processor" in the '747 patent, this speech processor 11 thus corresponds to the electric-acoustic processor recited in claim 1. The computer in Dooley (diagnostic and programming unit 21) is "utilised in a clinical situation to test for and control device parameters of operation for the speech processor 11 and/or acoustic aid processor 12 which optimise hearing performance for a patient according to defined criteria." Ex. 1005, P11:L11-16. Thus, programming unit 21 communicates with and modifies parameters of at least the acoustic and electric elements of an electric-acoustic processor. The operation of speech processor 11 is described at length on pages 12-20 of Dooley (Ex. 1005). Accordingly, Dooley discloses all of the limitations recited in Paragraph One of claim 1.

The acoustic elements of an electric-acoustic processor in Paragraph Two of claim 1 are disclosed in Dooley. Dooley discloses acoustic aid 14, which is described as follows: "reference to an acoustic hearing aid is reference to an aid of the type adapted to fit in or adjacent an ear of a patient and which provides an

acoustic output suitable to at least partially compensate for hearing deficiencies of the patient." Ex. 1005, P1:L7-11. Accordingly, a POSITA would have understood that the hearing aid disclosed in Dooley is a prior art device configured to generate or apply acoustic stimulation signals to the acoustic sensing organs of the ear which are sound waves directed into the ear canal. Ex. 1002, ¶ 100. Features extracted by speech processor 11 "can also be used as a basis for modification of the speech waveform following which it is then amplified and presented to the acoustic aid." Ex. 1005, P8:L7-10. Accordingly, Dooley discloses all of the elements of Paragraph Two of claim 1.

Dooley also discloses the electric elements of an electric-acoustic processor of Paragraph Three of claim 1, e.g., a cochlear implant aid 15 that comprises an electrode array 16. Ex. 1005, P10:L28-P11:L1. With respect to implant aid 15, Dooley states, "Throughout this specification a cochlear implant aid will refer to a device which includes components which are fitted within the body of a patient and which are adapted to electrically stimulate the nervous system of a patient in order to at least partially compensate for usually profound hearing loss of the patient." Ex. 1005, P1:L11-16. Dooley further discloses that "[t]he speech processor [11] extracts certain parameters from the incoming acoustic waveform that are relevant to the perception of speech sounds. Some of the speech parameters extracted by the speech processor are translated into an electrical signal

and delivered to a cochlear implant." Ex. 1005, P8:L3-7. Accordingly, Dooley discloses all the limitations of the Paragraph Three of claim 1.

Paragraph Four of claim 1 recites that the hearing aid and the cochlear implant speech processor or the acoustic and electric elements of the electric-acoustic processor are situated in the same ear and are configured to generate or apply both acoustic stimulation signals to the acoustic sensing organs of the ear and electric stimulation signals to the auditory nerve of the same ear. This limitation constitutes nothing more than a statement of how the previously recited apparatus is intended to be used and is not a structural limitation. Ex. 1005, P1:L7-16, P8:L3-10, P10:L28-P11:L1.

Dooley discloses a contralateral arrangement in which a hearing aid is disposed in one ear while the cochlear implant is disposed in the opposite ear. The '747 patent discloses both the ipsilateral (same ear) arrangement recited in claim 1, as well as the contralateral arrangement disclosed by Dooley. The '747 patent does not describe any structural differences between the apparatus for the ipsilateral arrangement and the apparatus for the contralateral arrangement. In fact, the '747 patent explicitly states that "the ICS 21 and the hearing aid 52 of Figs. 4A and Fig.4B are suitable for being situated in the same ear (ipsilateral) or contralateral ears of a patient (e.g., with residual hearing)." Ex. 1001, C13:L15-16. The '747 patent further notes that "Fig. 4C further illustrates alternative embodiments where

the speech processor 16 and the ICS 21 of a cochlear implant system and/or a hearing aid can be simultaneously situated in a patient's ear contralateral to the electric-acoustic system 70." Ex. 1001, C13:L49-53. There is no indication in the '747 patent that the structure or operation of the cochlear implant system or the hearing aid is different in any way when placed in the same ear or in different ears. In fact, the foregoing quoted sections of the '747 patent indicate that the same apparatus is used for both ipsilateral and contralateral arrangements. A POSITA would have understood the structure and/or operation of the cochlear implant system and/or the hearing aid to remain the same, regardless of whether the apparatus was used in an ipsilateral arrangement or in a contralateral arrangement. Ex. 1002, ¶ 107.

There is no question that Dooley discloses both the acoustic elements (hearing aid device) and electric elements (cochlear implant device) of an electric-acoustic processor, as defined in the '747 patent. Whether those devices are disposed in the same ear or in a contralateral arrangement relates to the manner in which the claimed apparatus is intended to be employed and not to its structure, and therefore, the limitations of claim 1 do not distinguish over Dooley. According to well-settled precedent, a recitation which states how an apparatus is intended to be employed does not differentiate a claimed apparatus from a prior art apparatus, if the prior art apparatus teaches all of the structural limitations of the claim. *See In*

re Schreiber, 128 F.3d 1473 (Fed. Cir. 1990) (citing *In re Sinex*, 309 F.2d 448, 492 (CCPA 1969) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus)); *see Ex. Parte Ling*, No. 10/802, 2010 WL 4219754 (B.P.A.I. Oct. 22, 2010) ("Put simply, how an apparatus invention is used is not germane to whether it is anticipated by the prior art."); *see also* MPEP §2114(II). Thus, the final limitation of claim 1 is entitled to no patentable weight and does not distinguish over Dooley.

Accordingly, Dooley anticipates claim 1 of the '747 patent.

Claim 2

Claim 2 is dependent from claim 1 and adds the limitation of a programming interface unit which is configured to exchange information between the computer and at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor. Ex. 1001, C16:L1-6. As previously noted, speech processor 11 corresponds to the electric-acoustic processor. Dooley discloses a diagnostic programming interface 22, which is a communications card connected to the PC bus. Ex. 1005, P11:L10-11. As shown in Figure 2, which is set forth above, the interface unit 22 exchanges information between programming unit 21 (the computer) and speech processor 11 (the electric-acoustic processor, as well as the cochlear implant speech processor) and acoustic aid processor 12. Ex. 1005,

Fig. 2. Dooley fully discloses the limitations of claim 2 and thus, anticipates claim 2.

Claim 4

Claim 4 recites that the computer is configured to communicate directly with at least one of the hearing aid, the cochlear implant speech processor, the electric elements of the electric-acoustic processor, and the acoustic elements of the electric-acoustic processor through wired communications. Figure 2 of Dooley discloses a wired communication between programming unit 21 and speech processor 11 and acoustic aid processor 12. Ex. 1005, Fig. 2. Accordingly, Dooley fully discloses claim 4 and thus, anticipates claim 4.

Claim 5

Claim 5 recites a computer which is configured to display data that is used to map, evaluate, or modify the parameters of at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L19-25. Dooley discloses that "programming unit 21 is implemented as a program running on a personal computer." Ex. 1005, P11:L8-9. Dooley also discloses that "programming unit 21 is utilised in a clinical situation to test for and control device parameters of operation for the speech processor 11 and/or acoustic

aid processor 12 which optimise hearing performance for a patient according to defined criteria." Ex. 1005, P11:L11-16. Dooley further discloses:

> "The speech-processing hearing aid of the second embodiment (mode 1): the audiologist measures the client's hearing thresholds and any other hearing levels that might be needed for the strategies to be tested, e.g. maximum comfortable level (MCL). The measurements are made using the hearing aid and diagnostic and programming unit with associated configuring software rather than a separate audiometer. These values are then stored in a data file automatically. A strategy is chosen and the aid is configured accordingly taking a maximum of time of about five minutes. Calculation and fitting of ideal gain is done automatically and can be quickly accessed in a graphical form at any time by the audiologist. The configured aid is then presented to the subject for evaluation. Different fittings can be tried in quick succession until an appropriate one is found."

Ex. 1005, P32:L22-P33:L11.

A POSITA also would have understood that a personal computer would have a display. Ex. 1002, ¶ 117. Accordingly, a POSITA would have understood that the Dooley computer is configured to display data used to at least one of map, evaluate and modify parameters. Ex. 1002, ¶ 118. Dooley fully discloses the limitations of claim 5 and thus, anticipates claim 5.

Claim 6

Claim 6 recites that the software is scripted to evaluate the data relevant to operational parameters of the electric-acoustic parameters of at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L26-31. As noted above, programming unit 21 is utilized to test for and control device parameters of operation for the speech processor 11, which is the electric-acoustic processor. Dooley also discloses, "With reference to Fig. 2 the bimodal aid is programmed by use of a diagnostic and programming unit 21 which communicates with the speech processor 11 and, in turn, with the acoustic aid processor 12 by way of a diagnostic programming interface 22. The diagnostic and programming unit 21 is implemented as a program on a personal computer. The interface 22 is a communications card connected on the PC bus. Software has been written to find the optimum filter settings to produce the frequency/gain characteristic specified by the audiologist, for use in the frequency response tailoring mode of operation described above. Software to program the other modes of operation have also been programmed and tested." Ex. 1005, P38:L11-24. Accordingly, Dooley fully discloses the limitations of claim 6 and thus, anticipates claim 6.

Claim 7

Claim 7 recites that the software is configured to map parameter levels and ranges and is configured to map responses of a patient wearing at least one of the hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor and the electric elements of the electric-acoustic processor. Ex. 1001, C16:L32-38. Dooley discloses that the parameters are communicated via interface 22 to map memory storage 23 in the speech processor 11. Ex. 1005, P11:L16-18. This feature is also disclosed in Figure 14 of Dooley, below.

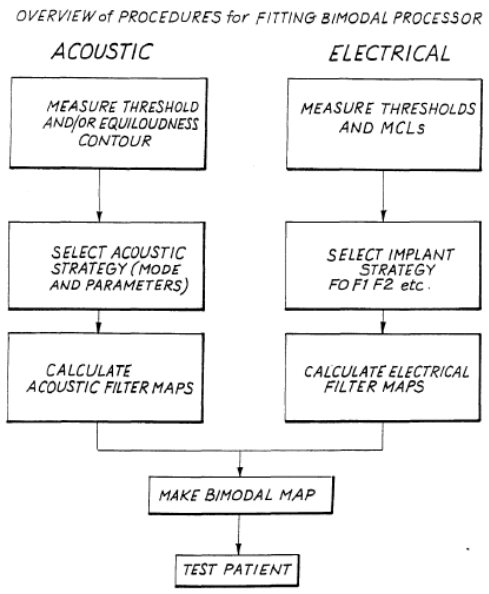


FIG. 14

Figure 14 is described by Dooley as follows: "The bimodal MAP is produced on the personal computer following an iterative testing procedure of the subjective performance of the bimodal aid for a multiplicity of trial settings of the

MAP." Ex. 1005, P39:L2-5; Fig.14. Dooley fully discloses the limitations of claim 7 and thus, anticipates claim 7.

D. Ground 4 – Obviousness of Claims 1, 2, and 4-7 Over a Combination of Dooley and von Ilberg 1999

As noted above, Dooley discloses all of the limitations of claim 1 of the '747 patent. It is also noted, however, that Dooley does not explicitly disclose an ipsilateral arrangement. As argued, this limitation of an ipsilateral arrangement in Paragraph Four of claim 1 is simply a recitation of an intended use which does not further limit the claim or distinguish over the art. If, for some reason, it is determined that this limitation is not an intended use but is a system limitation, use of such an ipsilateral configuration is fully disclosed in the prior art. One example is found in von Ilberg 1999. In particular, von Ilberg 1999 discloses that speech tests were performed with "the HA alone, CI alone and the combination of both (HA + CI) in the implanted ear (without contralateral HA)." Ex. 1006, p. 337; *see also* Ex. 1006, p. 334 (CI refers to cochlear implants and HA refers to conventional or digital hearing aids). The article noted that "a substantial improvement of [the patients'] hearing can be expected" using an ipsilateral configuration. Ex. 1006, p. 340. Therefore, use of an ipsilateral configuration was disclosed in the prior art. Furthermore, von Ilberg 1999 discloses fitting of parameters for both the hearing aid and cochlear implant. Ex. 1006, p. 337.

A POSITA would have combined von Ilberg 1999 with Dooley in the relevant time period. Ex. 1002, ¶125. In 1992, at the time that the Dooley application was published, there was concern that a patient with a cochlear implant could experience loss of residual hearing resulting from the trauma of insertion of the cochlear implant and from the long-term electrical stimulation. Ex. 1002, ¶125. Presumably, this is in part why Dooley proposed a contralateral configuration. However, by the late 1990s and early 2000s, a POSITA would no longer have been concerned about hearing preservation in patients with cochlear implants. Ex. 1002, ¶125.

von Ilberg 1999 demonstrates that the ipsilateral configuration of hearing devices may improve patient performance and discloses, "From our observation, we conclude that the central auditory system is able to combine an acoustic stimulation of the residual hearing with direct electric stimulation of the cochlear nerve without disturbing interferences. On the contrary, the patient observed an additive effect by the simultaneous EAS [electroacoustic stimulation] of her ear. Subjectively, EAS was perceived to sound more natural and pleasant than either form of stimulation alone." Ex. 1006, p. 340.

Based upon this finding of von Ilberg 1999, a POSITA would have been motivated to use an ipsilateral configuration and would have combined von Ilberg

1999 with Dooley, particularly with regard to fitting systems and methodology. Ex. 1002, ¶127.

For the reasons disclosed above, Dooley discloses all of the limitations of 1, 2 and 4-7. Since von Ilberg 1999 discloses an ipsilateral arrangement, all of claims 1, 2, and 4-7 would at least be obvious over a combination of Dooley with von Ilberg 1999.

E. Ground 5 – Obviousness of Claims 1, 2, 4, and 5 over a combination of Leysieffer and Harrison

Leysieffer discloses all of the limitations of claim 1 of the '747 patent. If for some reason, it is determined that Leysieffer does not explicitly disclose the limitations in Paragraph Two of claim 1, namely that the hearing aid and the acoustic elements of the electric-acoustic processor are devices that are configured to generate or apply acoustic stimulation signals to the acoustic sensing organs of the ear, the acoustic stimulation being sound waves directed into the ear canal, acoustic hearing aids were well known in the art, and it would have been obvious to have substituted such a hearing aid for the hearing aid shown in Leysieffer. Ex. 1002, ¶129.

As Leysieffer explains, an electromechanical transducer differs from a conventional hearing aid only in that the "acoustic stimulus (i.e., an amplified acoustic signal in front of the eardrum) is replaced by an amplified mechanical stimulus" of the middle or inner ear. Ex. 1004, Paragraph [0014].

One example of such an acoustic hearing aid is found in Harrison. Harrison discloses a hybrid cochlear stimulation system as shown in Figure 2, below. Ex. 1007, FIG. 2.

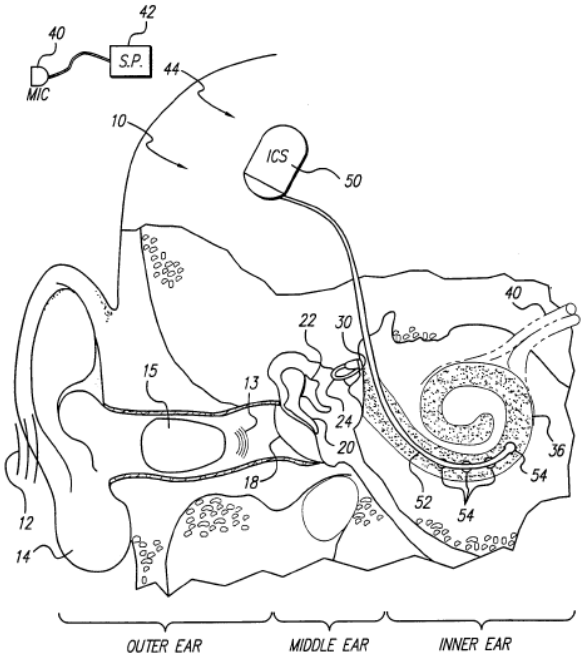


FIG. 2

In the embodiment of Figure 2 of Harrison, the stimulation system includes implantable cochlear stimulation, stimulator (ICS) 50 which provides "direct electrical stimulation of the ganglion cells located at the basal end of the cochlea, to thereby enhance the hearing of high-frequency sounds." Ex. 1007, P5:L30-P6:L3. The embodiment of Figure 2 further discloses an in-the-canal hearing aid 15. "The in-the-canal hearing aid 15, which may be of conventional design, receives the acoustic waves 12 and amplifies them, thereby presenting amplified acoustic waves 13 to the tympanic membrane 18." Ex. 1007, P8:L16-20.

As shown in Figure 1 of Leysieffer, an electromechanical transducer with a coupling rod vibrates the small bones of the middle ear (e.g., incus 15). Ex. 1004, FIG. 1 (electromechanical transducer 14, coupling rod 16, incus 15). In Harrison, a hearing aid presents amplified sound waves to the tympanic membrane 18, creating vibration which vibrates the small bones of the middle ear. Ex. 1007, P8:L16-20. Once a vibration reaches the bones of the middle ear – whether via an electromechanical transducer or via a conventional hearing aid – the bones of the middle ear filter and amplify the perceived acoustic wave 12, causing vibration of the fenestra membrane, which sets up waves of fluid motion within the cochlea, activating hair cells and causing nerve impulses to be transferred to the brain, where they are perceived as sound. Ex. 1007, P6:L4-31. How the vibration is transferred to the middle ear, whether by an electromechanical transducer or by an acoustic transducer, is not important, as the bones are vibrated in substantially the same way with the same result with either device. A POSITA would have understood that for purposes of a system comprising a computer with access to software for modifying the parameters of such devices, as claimed in the '747 patent, the mechanism for vibration of the small bones of the middle ear is entirely interchangeable. Ex. 1002, ¶134. Accordingly, a POSITA would have understood that the electromechanical transducer of Leysieffer and the conventional hearing

aid of Harrison are interchangeable for purposes of the system disclosed in the '747 patent. Ex. 1002, ¶134.

A POSITA also would have combined Leysieffer with Harrison because both teach an ipsilateral arrangement with a hearing aid and a cochlear implant in the same ear. Ex. 1002, ¶135. Based upon the foregoing suggestion in Leysieffer, a POSITA would have understood that because the signal processing is essentially the same for both acoustic and electromechanical transducers, one would have substituted one known hearing aid, the acoustic hearing aid as disclosed in Harrison, for the known electromechanical transducer disclosed in Leysieffer. Ex. 1002, ¶135. The substitution of the acoustic hearing aid of Harrison into the ipsilateral system of Leysieffer would have been simply the substitution of one known and conventional element for another known and conventional element. It would have been straightforward to follow the teachings of Harrison and substitute a known acoustic hearing aid for the known electromechanical hearing aid of Leysieffer. Ex. 1002, ¶136. Accordingly, the combination with Leysieffer and Harrison discloses all of the limitations of claim 1, rendering claim 1 obvious. *KSR International Co. v. Teleflex Inc.*, *et al.*, 550 US 398, 416 (2007) (a combination of familiar elements according to known methods is likely to be obvious as it does no more than yield predictable results.).

Since, as set forth above, Leysieffer discloses all of the limitations of claims 2, 4, and 5, which are dependent from claim 1, claims 2, 4, and 5 also would have been obvious over a combination of Leysieffer and Harrison.

F. Ground 6 – Obviousness of Claim 8 over a Combination of Leysieffer and von Ilberg '604 or over a Combination of Leysieffer, Harrison, and von Ilberg '604

As noted above, Leysieffer discloses all of the limitations of claim 1 of the '747 patent. Claim 8 is dependent from claim 1 and recites that the "computer is configured to simultaneously and sequentially output instructions capable of modifying acoustic and electric stimulation parameters to determine interaction between multiple channels in the at least one of the one hearing aid, the acoustic elements of the electric-acoustic processor, the cochlear implant speech processor, and the electric elements of the electric-acoustic processor." Ex. 1001, C16:L39-47. Claim 8 only requires that the instructions be capable of modifying one of the listed devices. For purposes of this analysis, Petitioner focuses on only the cochlear implant speech processor.

As discussed above, Leysieffer discloses that microcontroller 44 and programming system 48 have access to software for communicating with the devices and modifying parameters. Ex. 1004, Paragraph [0088], Paragraph [0032]. Claim 8 also recites that the computer is configured to simultaneously and sequentially output instructions. As discussed in the '747 patent, this requirement

appears to be simply a matter of combining the screens, templates, and other information found on the computer in a way which permits the individual controlling the fitting process to simultaneously or sequentially view and modify parameters of the device being fitted. Ex. 1001, C12:L51-55. This limitation is directed to the manner in which the computer is intended to be employed, rather than to the structure of the computer or some other apparatus. As previously discussed, such a recitation, which simply sets forth a manner in which a claimed apparatus is intended to be employed, does not distinguish over prior art which discloses all of the limitations of the apparatus. *See In re Schreiber,* 128 F.3d 1473 (Fed. Cir. 1990) (citing *In re Sinex*, 309 F.2d 448, 492 (CCPA 1969) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus)); *see Ex. Parte Ling*, No. 10/802, 2010 WL 4219754 (B.P.A.I. Oct. 22, 2010) ("Put simply, how an apparatus invention is used is not germane to whether it is anticipated by the prior art."); *see also* MPEP §2114(II).

The limitation of claim 8 "to determine interaction between multiple channels" relates to channel-spacing so that the channels of the cochlear implant preferably do not interact or interfere. Ex. 1002, ¶142. A POSITA would have understood the need to minimize channel interaction. Ex. 1002, ¶143. While Leysieffer does not specifically disclose how to deal with channel-spacing, Leysieffer does discuss a fitting process in which operating parameters can be

transmitted transcutaneously to the implant so that they can be changed. Leysieffer also discusses software modules that are designed to be adaptive and states that parameter matching can be done by training by the implant wearer and using other aids. Ex. 1004, Paragraph [0032]. Given this suggestion in Leysieffer to fit the device to a particular implant wearer, a POSITA would be motivated to look to other references that disclose fitting techniques. Ex. 1002, ¶146. One such reference is U.S. Patent. No. 6,231,604 ("von Ilberg '604") (Ex. 1008).

von Ilberg '604 discloses the use of a cochlear implant and an acoustic hearing device in a single ear and the fitting of a cochlear implant. In particular, Figures 3(a)-(c) illustrate adjustment strategies for calibrating the stimulation signals for the cochlear implant. Ex. 1008, C2:L61-62; C5:L4-5. Figure 3(b) of von Ilberg '604 shows an embodiment having acoustic stimulation plus two electrical stimulation channels, and Figure 3(c) shows an embodiment having acoustic stimulation plus multiple channels of electrical stimulation, such as would result from CIS processing. Ex. 1008, C5:L19-25. Figures 3(b) and 3(c) are shown below.

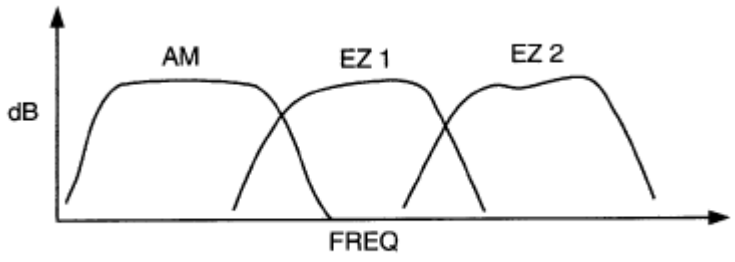


FIG. 3B

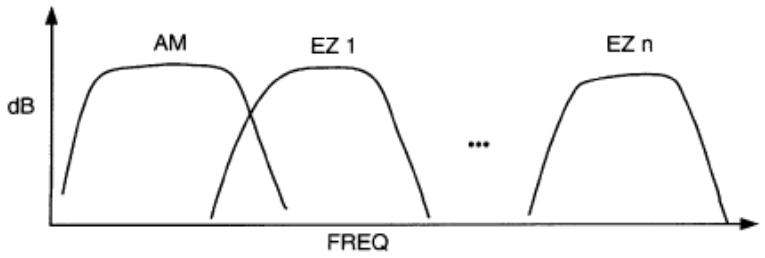


FIG. 3C

As can be seen in Figures 3(b)-(c), the channels are separated so that there is minimal overlap and appropriate channel-spacing. The space between the electric stimulation channels helps to minimize channel interaction and negative interference. Ex. 1002, ¶ 147. A POSITA would have been motivated to combine von Ilberg '604 with Leysieffer or with Leysieffer and Harrison to provide techniques for fitting the device to individual patients based on patient preference to reduce the negative effects of channel interaction on patient performance. Ex. 1002, ¶148. A POSITA would have identified von Ilberg '604 as a solution to fitting, particularly as it addresses channel interaction issues.

Leysieffer discloses that the microcontroller 44 has access to software for communicating with a device and modifying the parameters of the device, and von Ilberg '604 discloses the determination of interaction between acoustic stimulation and multiple channels of the cochlear implant speech processor. All of the limitations of claim 8 are found in a combination of Leysieffer with von Ilberg '604 or in a combination of Leysieffer and Harrison with von Ilberg '604.

IX. CONCLUSION

For the reasons detailed above, there is a reasonable likelihood that the Petitioner would prevail against each of claims 1-8 in the '747 patent. Petitioner respectfully requests that a trial be instituted and that claims 1-8 be canceled as unpatentable.

Dated: November 27, 2019 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This petition complies with the word count limits set forth in 37 C.F.R. § 42.24(a)(i), because this Petition contains 13,030 words, excluding the parts of the petition exempted by 37 C.F.R. § 42.24(a) and determined using the word count provided by Microsoft Word, which was used to prepare this Petition.

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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a) on the Patent Owner by Federal Express of a copy of this Petition for *Inter Partes* Review and supporting materials in its entirety to counsel for Advanced Bionics AG at:

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