Paper No. 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.
Patent Owner.

IPR No. IPR2017-01812

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,895,280

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 6,895,280
1002	U.S. Patent No. 6,895,280 File History
1003	Declaration of Mark W. Kroll, PhD
1004	U.S. Patent No. 5,501,703 ("Holsheimer")
1005	U.S. Patent No. 5,411,537 ("Munshi")
1006	U.S. Patent No. 6,609,031 ("Law")
1007	U.S. Patent No. 5,330,515 ("Rutecki")
1008	U.S. Patent No. 5,733,313 ("Barreras '313")
1009	"Computer Assisted and Patient Interactive Programming of Dual Octrode Spinal Cord Stimulation in the Treatment of Chronic Pain" by Kenneth M. Alo et al. ("Alo")
1010	U.S. Patent No. 5,948,007 ("Starkebaum")
1011	U.S. Patent No. 5,948,006 ("Mann '006")
1012	U.S. Patent No. 6,185,452 ("Schulman '452")
1013	U.S. Patent No. 4,082,097 ("Mann")
1014	U.S. Patent No. 3,942,535 ("Schulman '535")
1015	"Spinal cord stimulation for chronic, intractable pain: superiority of 'multi-channel' devices," by Richard B. North et al. ("North")
1016	U.S. Patent No. 5,121,754 ("Mullett")
1017	U.S. Patent No. 5,324,310 ("Hunter")
1018	U.S. Patent No. 5,702,431 ("Wang")
1019	U.S. Patent No. 5,024,224 ("Engebretson")
1020	U.S. Patent No. 7,319,901 ("Dublin")

Nevro Corp. ("Petitioner") submits this petition for *inter partes* review ("IPR") of claims 22-24 and 26-30 (the "Challenged Claims" or "Claims") of U.S. Patent 6,895,280 (the "'280 patent" or "'280") (Ex.1001), assigned to Boston Scientific Neuromodulation Corporation ("PO"). As explained below, there is a reasonable likelihood that at least one of the Claims is unpatentable over the presented prior art—which includes art not previously considered by the Office—and accordingly, the Board should institute trial and cancel the Claims as obvious under §103[1].

I. INTRODUCTION AND BACKGROUND IN THE ART

A. The '280 Patent

The '280 patent is generally directed to a spinal cord stimulation ("SCS") system. Ex.1001, 1:10-11. An SCS system is a medical device that can be implanted into a human, and is used to deliver electrical stimulus to portions of a person's spinal cord to control chronic pain and symptoms associated with other ailments. SCS was first performed in 1967, and SCS systems have existed since at least the 1970s. Ex.1009, 30-31. Ex.1003¶¶21-22.

By the late 1990s, many SCS systems were commercially available. *See*

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[1] Section cites are to 35 U.S.C. or 37 C.F.R. as the context indicates. All emphasis/annotations added, unless otherwise noted.

Ex.1009, 31-32. As the '280 observes, by 1999, SCS was already "a well accepted clinical method for reducing pain in certain populations of patients." Ex.1001, 1:10-11, 23-24. There were two types of SCS systems. The first included a fully "implantable pulse generator" (IPG) with an internal power source and lead wires with connected electrodes, all of which would be implanted into a patient.[2] Ex.1001, 1:25-30; Ex.1006, 1:36-39. The IPG was configured to generate electrical pulses that would be delivered to the electrodes placed along the patient's spinal cord. Ex.1001, 1:25-30. The second type also delivered electrical stimulation through implanted leads but using radio frequency ("RF") signals between an implanted, passive receiver and an externally worn transmitter placed over the site of the receiver. Ex.1006, 1:55-57; Ex.1003¶23.

Most SCS patients experience pain distributed across the spine, with multiple and variable foci. Ex.1009, 31. By the late 1990s, it was well-known that, to provide adequate pain relief, SCS systems could include multiple current sources, multiple electrodes, and interactive programming to adjust the parameters

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[2] Other analogous stimulation systems including IPGs, such as cardiac pacemakers, were similarly structured. *E.g.*, Ex.1005, 1:29-31. *See also* Ex.1009, 31 (describing SCS as a "nerve pacemaker").

of the stimulation delivered to different pain areas. Ex.1009, 31; Ex.1003¶24. As the '280 admits, by 1999, there were commercially available SCS products that addressed these needs. Ex.1001, 2:1-9. The '280 states that available SCS devices possessed one or two of the following features: "(1) providing multiple stimulation channels to address variable stimulation parameter requirements and multiple sites of electrical stimulation signal delivery; (2) allowing modest to high stimulation currents…; and (3) incorporating an internal power source with sufficient… capacity to provide years of reliable service to the patient." Ex.1001, 2:1-9.

The '280 purports to improve known SCS systems by combining various known features into one system. Ex.1001, 2:25-42. According to the '280, the claimed SCS system has "***independently programmable***, stimulation channels within an…IPG…which channels can provide ***concurrent, but unique stimulation fields***." Ex.1001, Abstract; *id.*, 3:3-5 ("[T]he SCS system provides the ability to ***stimulate simultaneously*** on all available electrodes"). While prior art devices had "***only a single voltage source, and hence only a single stimulation channel, which must be multiplexed***" to deliver stimulation to multiple electrodes (Ex.1001, 2:11-14; *id.*, 2:18-21), the '280's system has "a multiplicity of independent bidirectional output current sources…wherein each output current source is connected to an electrode node" (Ex.1001, 4:29-31). Therefore, unlike prior art

SCS systems (characterized by the '280 as "multi-channel"), the '280 patent purports to be a true multi-channel system with the ability to simultaneously provide "unique" stimulation fields on multiple channels:

> ***[T]he SCS system*** provides the ability to ***stimulate simultaneously*** on all available electrodes…. This advantageous feature thus allows the clinician to ***provide unique electrical stimulation fields for each current channel***, ***heretofore unavailable with other 'multichannel' stimulation systems (which 'multichannel' stimulation systems are really multiplexed single channel stimulation systems)***.

Ex.1001, 3:3-21.

The specification explains that the purported invention is a multi-channel SCS system (*i.e.*, one that can simultaneously provide stimulation to two or more channels with different stimulation parameters) that includes a rechargeable battery. Ex.1001, 2:47-3:35. The '280 claims are directed toward this purported inventive combination, reciting an SCS system that includes "a multi-channel implantable pulse generator (IPG) having a replenishable power source" along with a number of other well-known features. *See* Ex.1003¶¶32-35.

B. Overview of the Prosecution History

The application that led to the '280 patent was filed on November 27, 2002 and claims priority to U.S. Application 09/626,010 (issued as U.S. Patent 5,416,227), which was filed July 28, 2000 and claims priority to U.S. Provisional

Application 60/145,829 filed July 27, 1999. Ex.1001, 1:4-9. For purposes of this proceeding, Petitioner assumes the '280's priority date is July 27, 1999.

While the '280 describes the purported invention as the addition of a rechargeable battery to a multi-channel SCS system, the Examiner found such features in the prior art during the prosecution of the '280. Ex.1002, 280-81. For example, in a Non-Final Rejection rejecting pending prosecution claims on various §§102 and 103 grounds—including based on a combination of U.S. Patents 5,501,703 ("Holsheimer") and 5,769,877 ("Barreras '877")—the Examiner found Holsheimer "describes an implantable epidural spinal cord stimulator…***having applicant's claimed multi-channel pulse generator***…whose outputs can be changed independently of one another." *See* Ex.1002, 278-83. The Examiner further found that while it was unclear whether Holsheimer's IPG had a replenishable power source, it would have been obvious in view of Barreras '877, which discloses an implantable medical device with a replenishable power source. Ex.1002, 280-81.

In that Office Action, the Examiner also objected to a number of non-rejected claims for depending from a rejected base claim, but noted those 25 claims would be allowable if rewritten in independent form. Ex.1002, 283. The Examiner also allowed five pending claims. As the reasons for allowance, the Examiner stated the art did not disclose: (1) "connecting an external trial stimulator

(ETS)," (2) "charging a rechargeable battery in the external battery charger using an external power source," or (3) stopping charging of the IPG battery when the charging current or voltage reaches a "prescribed level." Ex.1002, 283-84.

The applicant then canceled the rejected claims without disputing the Examiner's findings as to those claims and rewrote most of the objected-to dependent claims in independent form (Ex.1002, 305-06), and the Examiner allowed those claims (Ex.1002, 323-330).[3] In the Notice of Allowance, the Examiner noted that unlike the claimed IPG, prior art IPGs "do[] not show a separate 'control logic circuit' or 'timer logic circuit'"—a feature not required by the Claims here. Ex.1002, 329. *See* Ex.1003¶¶36-40.

C. Known Technologies

As the Examiner found, by July 1999, both multi-channel SCS systems and IPGs that employ a replenishable power source were well-known. Numerous references—in addition to those cited by the Examiner—disclose these features. *See, e.g.*, Ex.1010, 4:60-65 (describing SCS system with multiple channels that can "***simultaneously*** provide ***different amplitudes, frequencies, repetition rates, and pulse widths***" to electrodes); Ex.1011, 4:56-62 ("[T]he implanted device…may also contain a battery…preferably of the rechargeable type…."); Ex.1008, 4:7-20

[3] As a result of this re-writing, the '280 contains 20 independent claims.

("an implantable, electrically operated medical device…incorporating a rechargeable back-up power source"); Ex.1005, 4:3-10 ("bioimplantable battery-powered device incorporating…a single rechargeable power source"); Ex.1012, 1:37-40, 1:66-2:9; Ex.1003¶¶25-31.

Even the ancillary features the Examiner found distinguished the '280 claims over the prior art were well-known by July 1999. For example, although the Examiner found the prior art did not disclose an SCS system with "a rechargeable battery in the external battery charger" that would be recharged "using an external power source" (Ex.1002, 283), using a rechargeable-battery-powered external charger to recharge an implanted battery was well-known for over 20 years before the '280 patent was filed. *E.g.*, Ex.1013, 14:37-42 ("numeral 62 [in external unit 20] designates the rechange [*sic*] power source which applies the power to transmitting coil 19"), Fig.4 (element 62), 1:44-49, 1:55-58, 4:17-27; Ex.1014, 11:10-13 ("The power source 37 utilizes its own rechargeable battery 53 which is connected to an induction coil located in the charging head 42…."), 7:17-18, Fig.4 (element 53), 3:31-32, 11:22-26.

The Examiner also noted additional claimed features in the reasons for allowance. The claimed features relevant to the Claims are: (i) connecting an "external trial stimulator" to the SCS system (Ex.1002, 283) and (ii) stopping the charging of the IPG battery when the charging current or voltage reaches a

"prescribed level" (Ex.1002, 284). But all of these features were similarly well-known before July 1999, for example:

(i) U.S. Patent No. 5,330,515—issued July 1994—teaches use of "***an external stimulus generator***" to conduct stimulation testing before permanent implantation. Ex.1007, 14:3-18; *see also* Ex.1009, 33 (disclosing a "trial stimulator").

(ii) U.S. Patent No. 5,411,537—issued May 1995—discloses stopping charging of the implanted battery when its voltage "is greater than or equal to V_{max}." Ex.1005, 11:51-60; *see also* Ex.1008, 9:7-16 (disclosing "monitor[ing] the voltage level of the [implanted] power source" and sending a "'stop' recharging command" when fully charged).

Thus, the Claims are, at most, obvious implementations of an SCS system that recite various well-known features, functioning in predictable combinations, as a person of ordinary skill in the art ("POSA") would have expected at the '280 patent's priority date. Ex.1003¶¶170-71.

II. IDENTIFICATION OF CHALLENGED CLAIMS AND GROUNDS OF UNPATENTABILITY

Petitioner challenges claims 22-24 and 26-30. These claims are unpatentable based on the following §103 grounds—none of which is redundant:

Ground 1: Barreras in view of a POSA's knowledge renders obvious claim 27;

Ground 2: Barreras in view of Wang renders obvious claim 27;

Ground 3: Barreras, with or without Wang, in view of Engebretson renders obvious claims 28-30[4];

Ground 4: Holsheimer in view of Alo renders obvious claim 26; and

Ground 5: Holsheimer in view of Munshi and Wang renders obvious claims 22-24.

In support of the proposed grounds of rejection, the Declaration of technical expert Dr. Mark Kroll is attached as Ex.1003. Dr. Kroll is a professor of biomedical engineering, and has over 25 years of experience researching or developing implantable medical devices and systems. Ex.1003¶¶1-20.

III. PERSON OF ORDINARY SKILL IN THE ART

The applicable POSA would have at least (1) a bachelor's degree in electrical or biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices. Ex Ex.1003¶¶12-18.

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[4] Petitioner challenges claim 27, from which claims 28-30 depend, based on Barreras alone (Ground 1) and Barreras in view of Wang (Ground 2). Ground 3 applies to claims 28-30 and adds Engebretson as a secondary reference. Thus, Ground 3 is based on Barreras, with or without Wang, in view of Engebretson.

IV. CLAIM CONSTRUCTION UNDER §42.104(b)(3)

For purposes of IPR, "[a] claim in an unexpired patent…shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." §42.300(b). Claim terms are generally given their ordinary and customary meaning as understood by a POSA at the time of the invention ***in light of the intrinsic evidence*** unless a patentee acts as his own lexicographer or disavows the full scope of the claim term. *See Info-Hold, Inc. v. Applied Media Techs.*, 783 F.3d 1262, 1265-66 (Fed. Cir. 2015); *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1320 (Fed. Cir. 2011) ("The specification is 'the single best guide to the meaning of a disputed claim term,' and, usually, the specification's use of a claim term is dispositive."). The proper constructions of the Claims include the constructions of certain claim terms noted below. For terms not specifically construed, Petitioner interprets them for purposes of this review in accordance with their plain and ordinary meaning under the broadest reasonable interpretation ("BRI") standard applicable here. Because the standard for claim construction at the PTO is different than that used in litigation, *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016); MPEP §2111, Petitioner expressly reserves the right to argue in litigation different constructions for any term, as appropriate to that proceeding.

1. "multi-channel implantable pulse generator (IPG)" (Claims 22, 26)

In light of the intrinsic evidence, the term "multi-channel IPG" must be interpreted to be: "an IPG that can simultaneously provide stimulation to two or more channels with different stimulation parameters."[5]

In the "Background of the Invention," the '280 criticizes prior art systems having only one voltage source, and describes them as having only a single stimulation channel:

> Even then, such device still has only one voltage source, and ***hence only a single stimulation channel, for delivery of the current stimulus to multiple electrodes through a multiplexer***.

Ex.1001, 2:18-21; *see also id*., 2:11-15. At the time, such multiplexed single

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[5] Petitioner has mapped the prior art to this construction. However, the prior art discloses and/or renders obvious the Challenged Claims even if "multi-channel IPG" were construed more broadly. Ex.1003¶41n.1. For example, as explained below (§V.D.4.i), Holsheimer discloses a multi-channel IPG that can stimulate on multiple channels having different stimulation parameters and that the channels can selectively stimulate simultaneously or shifted in time. Thus, Holsheimer discloses "multi-channel IPG" even if it were construed more broadly and did not require simultaneous stimulation on multiple channels.

stimulation channel systems were often improperly described as "multi-channel." *See, e.g.*, Ex.1015, 119 ("***Although technically single-channel systems gated to multiple contacts, and incapable of simultaneously delivering different signals to separate channels, these devices commonly are described as 'multi-channel.'***"); Ex.1003¶¶28-31. Given the ambiguity surrounding the use of the term multi-channel in the field, the patentee clarified how the '280 uses the term by expressly defining the claimed invention and disclaiming multiplexed single-channel stimulation systems:

> ***[T]he SCS system*** provides the ability to ***stimulate simultaneously*** on all available electrodes…. This advantageous feature thus allows the clinician to provide ***unique electrical stimulation fields for each current channel***, ***heretofore unavailable with other 'multichannel' stimulation systems (which 'multichannel' stimulation systems are really multiplexed single channel stimulation systems)***. Moreover, this feature…allows "virtual electrodes" to be realized, where a "virtual" electrode… results from the vector combination of electrical fields from two or more electrodes that are activated ***simultaneously***.

Ex.1001, 3:3-29 (Summary of the Invention). "Where the general summary or description of the invention describes a feature of the invention…and criticizes other products…that lack that same feature, ***this operates as a clear disavowal of these other products***…." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1332-33 (Fed. Cir. 2009); *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357

F.3d 1340, 1347 (Fed. Cir. 2004) ("When the specification 'makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent…."). The '280 describes its invention similarly in the Abstract:

> A spinal cord stimulation (SCS) system includes multiple electrodes, ***multiple, independently programmable, stimulation channels*** within an implantable pulse generator (IPG) which ***channels can provide concurrent, but unique stimulation fields***….

Ex.1001, Abstract. These statements describe the invention as a whole and put the public on notice that the '280's SCS system must be able to stimulate simultaneously on multiple stimulation channels and, therefore, is not a multiplexed single-channel system. *See Eon-Net*, 653 F.3d at 1322 (limiting construction where "statements about the invention are not limited to specific embodiments or examples but describe and define the invention overall"); *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) ("Statements that describe the invention as a whole are more likely to be found in…[*e.g.*,] Summary of the Invention."); *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

Consistent with these statements, the '280 specification repeatedly and consistently describes the claimed system as capable of ***simultaneously*** providing stimulation to two or more channels with ***different parameters***. *See Am.*

Piledriving Equip. v. Geoquip, Inc., 637 F.3d 1324, 1334 (Fed. Cir. 2011) ("[A] statement in a specification that describes the invention as a whole can support a limiting construction of a claim term….***That is especially true where, as here, other statements and illustrations in the patent are consistent with the limiting description***."); *Nystrom v. TREX Co, Inc.*, 424 F.3d 1136, 1144-45 (Fed. Cir. 2005) (affirming construction based on consistent meaning applied throughout specification). For example, the '280 explains "***each channel may be programmed to provide its own specified pattern or sequence of stimulus pulses***" and "any of the channels" can be "***simultaneous[ly] activat[ed]***." Ex.1001, 10:30-34, 26:65-67; *see also id.*, 10:39-42 ("[L]eft and right sides, or upper and lower extremities, may require ***different stimulus parameter settings***.…), 14:42-44 ("If two non-overlapping channels are scheduled to start ***simultaneously***, the lower number channel takes priority and starts first….").

The claims themselves also demonstrate the multiple channels must be able to simultaneously provide stimulation. For example, claims 4 and 19 each claim a SCS system including a "multi-channel IPG" with "arbitration means for ***selectively preventing overlap of current pulses amongst the m stimulation channels***." Ex.1001, claims 4, 19; *see also id.*, 14:21-26 (arbitration circuit "***prevent[s] more than one channel from producing a stimulus current at the same time***, i.e., to prevent current pulses from different channels that overlap"). If

the claimed "multi-channel IPG" did not have the ability to provide simultaneous stimulation on multiple channels, there would be no occasion to "***selectively prevent[] overlap*** of current pulses" among the channels.

Accordingly, "multi-channel IPG" must be construed as "an IPG that can simultaneously provide stimulation to two or more channels with different stimulation parameters."

2. "sunning[6] [*sic*] the change in rectification in the IPG using circuitry means located in the external battery charger" (Claim 28)

For purposes of this review, Petitioner construes this term as a means-plus-function limitation under §112, ¶6. *E.g., Advanced Ground Info. Sys. v. Life360*, 830 F.3d 1341, 1347 (Fed. Cir. 2016); §42.104(b)(3).

The claimed function is "sensing the change in rectification in the IPG" and the corresponding structure is a charge-complete detection circuit in the external charger that senses the reflected impedance through the external coil caused by a change in the implanted device's rectifier circuit from full-wave to half-wave. Ex.1001, 44:35-48 ("A fully charged condition is also ***sensed by monitoring the***

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[6] Under the BRI standard applicable here, Petitioner assumes that "sunning" is a typo and should be read to encompass "sensing" based on dependent claim 29's reference to "sensing the change in rectification in step (h)."

reflected impedance through the coil 279…[A] fully charged condition is signaled from the IPG ***by switching the rectifier circuit 682 within the IPG from a full-wave rectifier circuit to a half-wave rectifier circuit***. When such rectifier switching occurs, the voltage V1 suddenly increases (e.g., a transient or pulsed component appears in the voltage V1) because the amount of reflected energy suddenly increases. This sudden increase in V1 is ***detected by the charge complete detection circuit 697***…[and] signal[s]…the implant battery 180 is fully charged."), Fig. 9C (element 697).

V. THE CHALLENGED CLAIMS ARE OBVIOUS

A. Ground 1: Barreras and a POSA's Knowledge Render Obvious Claim 27

1. Overview of Barreras

U.S. Patent No. 5,733,313 to Barreras[7] issued in March 1998 and is prior art under §102(b). Ex.1003¶44. Barreras is directed to an "implantable, electrically operated medical device system" that includes "an implanted radio frequency (RF) receiving unit (receiver) incorporating a back-up rechargeable power supply and an implanted, electrically operated device, and an external RF transmitting unit (transmitter)." Ex.1008, Abstract. The transmitter, which can itself be powered by

[7] This Barreras patent is different from Barreras '877 that was cited by the Examiner during prosecution. Barreras '313 was not cited during prosecution.

a rechargeable battery, transmits RF energy to the receiver to power the implanted medical device and/or recharge its back-up power supply. *Id*. The receiver "incorporates all the elements required to autonomously generate and regulate…stimulation pulses." Ex.1008, 3:40-46. Upon sensing that the implanted battery is fully charged, Barreras' receiver telemeters a termination command to the transmitter to stop RF energy transmission thereby preventing the implanted battery from overcharging and preserving the transmitter's battery supply. Ex.1008, 6:15-20. Barreras' system also alerts the patient when the implanted power source is nearing depletion and needs to be recharged by an audible tone generated within the receiver or by the transmitter. Ex.1008, 4:55-61. *See also* Ex.1003¶¶58-62.

2. Claim 27

a) [27.preamble]: "A method of charging a rechargeable battery contained within an implantable pulse generator (IPG), which IPG is connected to an implanted, secondary coil antenna, the method employing an external battery charger, which charger contains a rechargeable battery electrically connected to an external, primary antenna coil"

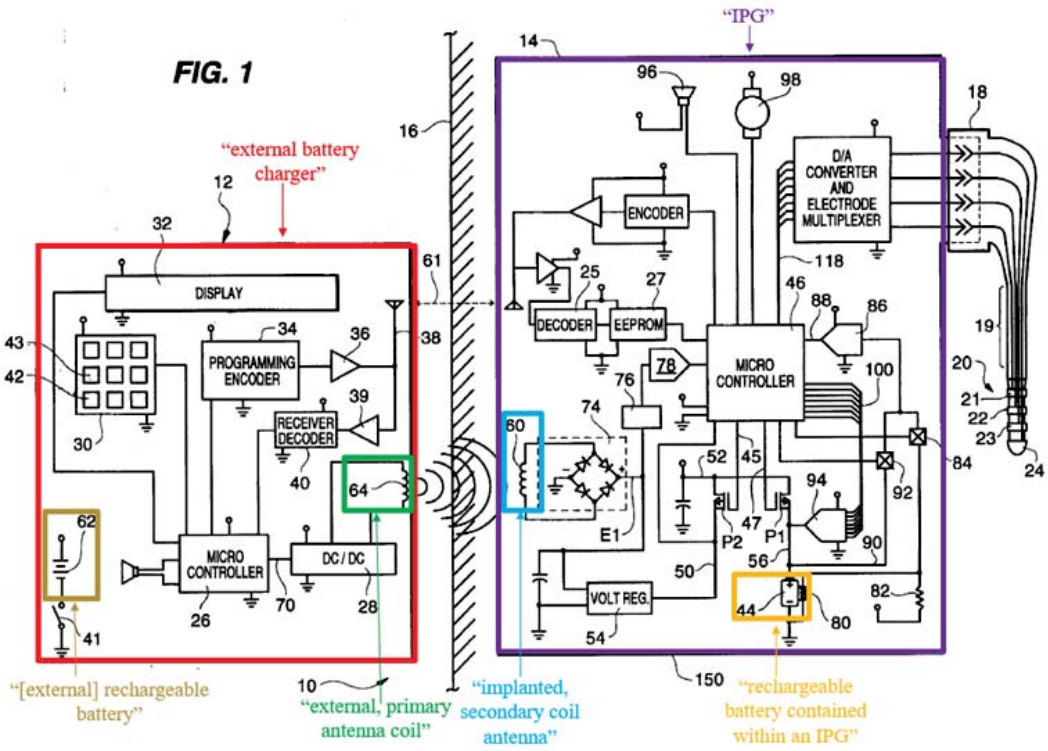
Barreras discloses "a method for non-invasively ***recharging the power source within the receiver***, whereby the electrical energy contained in the battery powering the ***external transmitter*** is transferred into the ***rechargeable power source within the receiver*** utilizing an inductive RF power link between the

external transmitter (recharging unit) and the ***implanted receiver (unit being recharged)***." Ex.1008, 5:34-41; *see also id.*, Abstract, 1:8-11, 4:8-15, 4:17-18. Therefore, Barreras discloses "charging a rechargeable battery" (*e.g.*, charging rechargeable power source 44) "contained within an implantable pulse generator" (*e.g.*, within implanted receiver 14) "employing an external battery charger" (*e.g.*, via external transmitter 12). Ex.1003¶¶71-72; *see also* Ex.1008, Fig. 1 (annotated below).

Barreras also discloses "***inductor 60***" is "***contained within the receiver 14***," as depicted in Figure 1 below. Ex.1008, 8:35-43; *see also id.*, 9:19-23. Therefore, Barreras discloses the "IPG" (*e.g.*, receiver 14) "is connected" (*e.g.*, contains) to "an implanted, secondary coil antenna" (*e.g.*, inductor 60).

Barreras further discloses the "***transmitter*** can be powered by…a ***rechargeable***…***battery***." Ex.1008, Abstract; *see also id.*, 4:19-21. Moreover, Barreras discloses an "***output inductor 64***" in the "***transmitter 12***" through which the RF waves generated by the transmitter are transmitted to the "receiver 14." Ex.1008, 8:39-43; *see also id.*, Fig. 1 (annotated below).

Therefore, Barreras discloses "an external battery charger" (*e.g.*, transmitter 12) that "contains a rechargeable battery" (*e.g.*, rechargeable battery 62) "electrically connected to an external, primary antenna coil" (*e.g.*, connected to output inductor 64). Ex.1003¶¶71-72.



b) [27.a]: "charging the rechargeable battery in the external battery charger using an external power source"

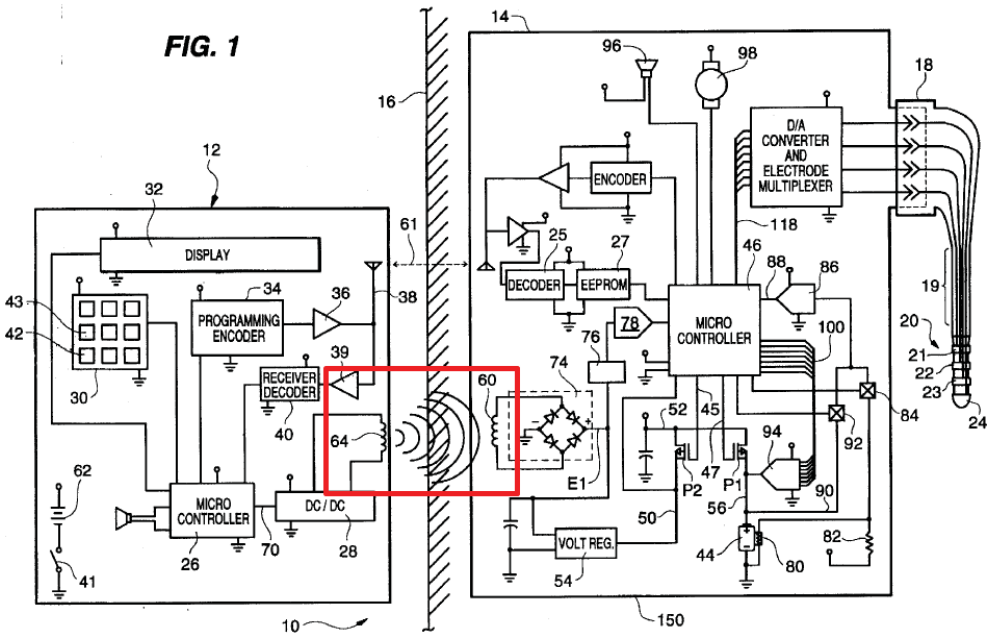
Barreras discloses that the "transmitter can be powered by…a rechargeable…battery." Ex.1008, Abstract; *see also id*., 4:18-20. Therefore, the transmitter's rechargeable battery must be charged before the transmitter can be used to transfer energy to the receiver. Ex.1003¶73. And the power to recharge the transmitter's rechargeable battery must come from "an external power source," such as a standard AC power line. *Id*. Therefore, Barreras discloses this limitation.

c) [27.b]: "aligning the primary antenna coil with the implanted secondary coil"

Barreras discloses using a "primary antenna coil" (*e.g.*, transmitter's inductor 64) and "implanted secondary coil" (*e.g.*, receiver's inductor 60) to

transfer energy from the transmitter to the receiver. *E.g.*, Ex.1008, 8:39-43 ("This will cause the transmitter 12 to generate, via the battery 62, the DC/DC converter 28 and an ***output inductor 64***, high energy RF waves which are coupled into the ***inductor 60 contained within the receiver 14***."); *see also id*., 8:26-32, Fig. 1. Moreover, Barreras discloses that the "distance between the inductors 64 and 60" affects "the RF energy required to quickly recharge the rechargeable power source 44. A ***close proximity requires much less RF energy to recharge the rechargeable power source 44 than a longer distance would, in the same time***." Ex.1008, 8:49-55; *see also id*., 5:51-55, 8:26-32, 9:31-38.

Barreras thus expressly discloses that some form of alignment between transmitter's inductor 64 and receiver's inductor 60 is necessary to recharge the rechargeable battery in the implant. Figure 1 (below) shows coils 60 and 64 are aligned and transferring energy:



In light of Barreras' disclosure and a POSA's knowledge, it would have, at a minimum, been obvious to align Barreras' transmitter and receiver coils because better alignment between the transmitter's and receiver's inductors would conserve the transmitter's battery power by more efficiently recharging the implanted battery. Ex.1003¶¶74-75; Ex.1008, 8:49-53. Therefore, Barreras discloses and/or renders obvious this limitation.

d) [27.c]: "broadcasting electromagnetic energy through the primary antenna coil"

Barreras discloses "a method for ***non-invasively recharging*** the power source within the receiver, whereby the ***electrical energy contained in the battery powering the external transmitter is transferred into the rechargeable power source within the receiver utilizing an inductive RF power link*** between the external transmitter (recharging unit) and the implanted receiver (unit being

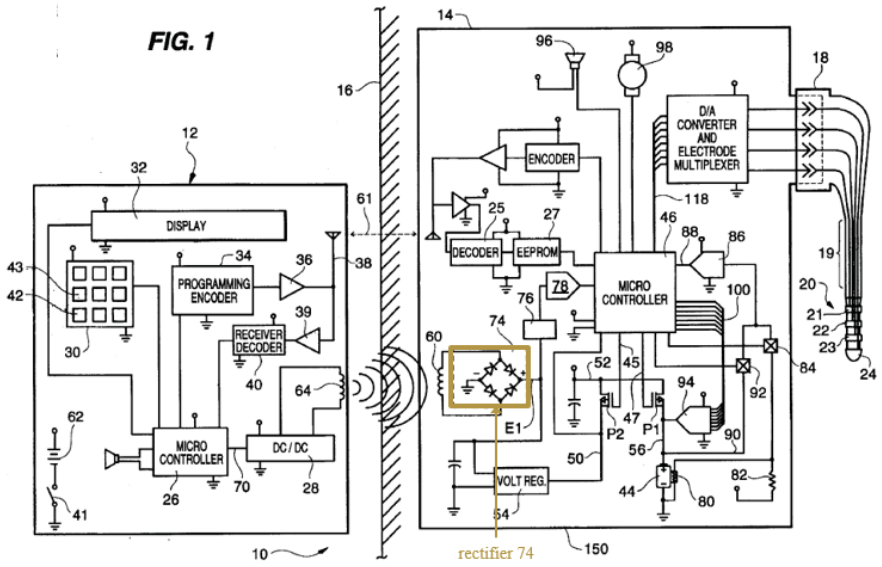
recharged)." Ex.1008, 5:34-41; *see also id*., 4:62-64, 6:28-31, 7:50-52, 8:1-5. The recharge process includes "caus[ing] the transmitter 12 to generate, via…***output inductor 64***, ***high energy RF waves*** which are coupled into the inductor 60 contained within the receiver 14." Ex.1008, 8:39-43. Therefore, Barreras discloses "broadcasting" (*e.g.*, transferring inductively) "electromagnetic energy" (*e.g.*, RF waves) "through the primary antenna coil" (*e.g.*, via output conductor 64). Ex.1003¶78.

e) [27.d]: "receiving the broadcast electromagnetic energy through the secondary antenna coil, whereby an alternating current is produced in the secondary coil"

Again, Barreras' discloses "caus[ing] the transmitter 12 to generate, via…an output inductor 64, ***high energy RF waves*** which are ***coupled into the inductor 60*** contained within the receiver 14." Ex.1008, 8:39-43; *see also id*., 4:62-64, 8:26-32 ("RF energy is being coupled into an inductor 60" when "the transmitter 12 is proximal to the receiver 14."). Thus, Barreras discloses "receiving…through the secondary antenna coil" (*e.g.*, via inductively coupling with inductor 60) "broadcast electromagnetic energy" (*e.g.*, RF waves). Ex.1003¶79.

Barreras also discloses "an alternating current is produced in the secondary coil" through its disclosure that the RF power coupled into the implanted receiver's inductor "is alternating current or AC in nature." Ex.1008, 4:62-67. Further, Figure 1 of Barreras shows a "rectifier 74" in "receiver 14" connected to the output

of inductor 60. Ex.1008, 8:26-32, 8:39-43, 8:43-47, Fig. 1, claim 7 ("receiving unit includes…means for rectifying said RF energy into a relatively high D.C. voltage"). Because the output from inductor 60 is sent to the rectifier 74—an electrical device that converts (or rectifies) an alternating current ("AC") into a direct current ("DC")—the output from inductor 60 is necessarily AC. Ex.1003¶¶80-83.



f) [27.e]: "rectifying the induced, alternating current received by the secondary coil"

As discussed (§V.A.2.e), Barreras expressly discloses that the RF power coupled into the implanted receiver's inductor "is ***alternating current***…[that] ***is rectified***, filtered and converted into a high DC voltage within the receiver." Ex.1008, 4:64-67. Therefore, Barreras discloses this limitation. Ex.1003¶84.

g) [27.f]: "charging the rechargeable battery carried within the IPG, while monitoring the charging current or voltage across the battery as the battery is being charged to prevent overcharging"

Barreras discloses that "***during recharging of the power source 44***, the micro controller 46 will ***monitor the voltage level of the power source 44***" so that the "***power source 44 cannot be overcharged***." Ex.1008, 9:7-17; *see also id*., 9:44-53. Therefore, Barreras discloses "charging the rechargeable battery carried within the IPG" (*e.g.*, recharging power source 44 in receiver 14) "while monitoring the charging current or voltage across the battery as the battery is being charged" (*e.g.*, monitoring voltage level of power source 44 during recharging) "to prevent overcharging" (*e.g.*, so power source 44 cannot be overcharged). Ex.1003¶85.

h) [27.g]: "stopping the charging at the battery charger when the current or voltage at the battery in the IPG reaches a prescribed level"

Barreras discloses that "during recharging of the power source 44" its system "monitor[s] the voltage level of the power source 44" and "***[u]pon sensing a fully charged state, the microcontroller 46 will telemeter to transmitter 12, via the RF communications link 61, a 'stop' recharging command***." Ex.1008, 9:7-17; *see also id*., 9:44-53. And upon receiving this "termination command," the transmitter "will terminate RF transmission" to the receiver. Ex.1008, 4:34-39 ("***[T]ransmitter*** will transmit high energy RF waves in order to recharge the back-

up power source at a faster rate and ***will terminate the RF transmission upon receiving from the receiver a 'termination command' which indicates that the back-up power source is fully charged***."). Therefore, Barreras discloses "stopping the charging at the battery charger" (*e.g.*, terminating RF transmission at the transmitter) "when the current or voltage at the battery in the IPG reaches a prescribed level" (*e.g.*, voltage level reaches fully charged state). Ex.1003¶86.

B. Ground 2: Barreras and Wang Render Obvious Claim 27

As discussed with respect to Ground 1 (§V.A.2), Barreras discloses and/or renders obvious every limitation of claim 27. However, to the extent further disclosure is required for claim element [27.b], it would have been obvious in further view of Wang, as detailed below.

1. Overview of Wang

U.S. Patent No. 5,702,431 to Wang issued in December 1997 and is prior art under §102(b). Ex.1003¶46. Wang is directed to "[a]n improved transcutaneous energy transmission ["TET"] device…for charging rechargeable batteries in an implanted medical device and to minimize peak temperature rises in the implanted device." Ex.1018, Abstract; *see also id*., 1:16-22. Wang teaches "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." Ex.1018, 5:13-15. Therefore, Wang's system includes "an alignment circuit and indicator…to indicate whether

the coils are properly aligned." Ex.1018, 5:15-17. *See also* Ex.1003¶¶63-68.

2. Motivation to Combine

Barreras teaches that the distance between external and implanted coils affects the amount of energy needed to recharge the implanted battery, but does not provide details of the circuitry that will ensure the coils are properly aligned for maximum charging efficiency. Ex.1008, 8:49-55. A POSA considering Barreras would have therefore looked to related references to solve this problem. Ex.1003¶¶69-70. Wang addresses this problem and provides a mechanism for detecting and alerting the patient of proper alignment between the coils for efficient energy transmission. *E.g.*, Ex.1018, 5:13-17. A POSA would not only have been motivated to incorporate Wang's alignment circuitry in Barreras' recharging system to ensure charging efficiency is maximized, but also because Wang's implementation did not require any additional components in the implanted device. Ex.1018, 4:20-24; Ex.1003¶¶69-70. It was well-known that because these stimulation systems are implanted, it was desirable and beneficial to minimize the size and, therefore, footprint of implanted devices. Ex.1003¶70. Because Barreras and Wang describe analogous systems for non-invasively recharging batteries in an implantable medical device, a POSA would have found it obvious to use Wang's alignment circuitry in Barreras' system and would have known that the combination would work as expected. Ex.1003¶70.

3. Claim 27

a) [27.b] "aligning the primary antenna coil with the implanted secondary coil"

Wang teaches the "***coils of the external energy transmission device and the implanted medical device must be properly aligned*** for efficient energy transmission." Ex.1018, 5:13-15. Accordingly, Wang provides "an ***alignment circuit and indicator***…***to indicate whether the coils are properly aligned***." Ex.1018, 5:15-17; *see also id*. 11:41-46 ("[T]he alignment indicator 40…uses the correlation between the input current and ***alignment*** to provide an output signal which indicates when the energy transmission device 50 is sufficiently ***aligned with the receiving coil 10*** of the implanted device 14."), Figs.1, 5. Therefore, Wang discloses "aligning the primary antenna coil with the implanted secondary coil" (*e.g.*, aligning coils of the external and implanted devices). Ex.1003¶76.

A POSA would have found it obvious to use Wang's alignment circuitry to determine whether the coils of the external charger and the implanted device are properly aligned in implementing Barreras' system. Ex.1003¶77. Barreras and Wang are analogous systems and concern advantageous ways of noninvasively recharging an implanted battery. *Id*. Moreover, Barreras discloses that the "distance between the inductors 64 and 60" affects "the RF energy required to quickly recharge the rechargeable power source 44" (Ex.1008, 8:49-55) and Wang provides the alignment circuitry that can detect when the coils are properly aligned

(*see, e.g.*, Ex.1018, 11:13-17). Accordingly, a POSA would have been motivated to incorporate Wang's beneficial alignment detection circuitry in Barreras' external charger to provide a mechanism that indicates to the patient when the coils are properly aligned and charging efficiency is maximized. Ex.1003¶77; §V.B.2.

C. Ground 3: Barreras, with or without Wang, and Engebretson Render Obvious Claims 28-30

1. Overview of Engebretson

U.S. Patent No. 5,024,224 to Engebretson issued in June 1991 and is prior art under §102(b). Ex.1003¶47. Engebretson is directed to "the conveying of signals from a device implanted beneath the surface of the skin to a second device located external to [the] skin." Ex.1019, 1:9-12. To accomplish this, Engebretson proposes using "a rectification circuit" in the implanted device "which can be switched between modes of half wave and full wave rectification in response to the signal to be conveyed." Ex.1019, 1:53-56. An encoder causes the rectifier to switch between the rectification modes, which "may be considered as different binary states and in this fashion binary messages can be represented as changes in the impedance of the implanted device as a function of time." Ex.1019, 3:3-9. A decoder in the external device then detects the "rectifier mode at any given point in time" to receive the implanted device's binary message. Ex.1019, 3:31-37. "In this fashion the implanted device can convey signals to the external device for providing a readout of the conditions sensed or existing beneath the surface of the

skin." Ex.1019, 3:37-40. *See also* Ex.1003¶¶88-90.

2. Motivation to Combine

Barreras' recharging system includes communicating a termination command from the implanted device to the external device when the implanted battery is fully charged so that the battery is not overcharged. *See* §V.A.2.h). To ensure the implanted battery is not overcharged, the receiver also cuts off the charging current to the battery in case the transmitter does not receive the termination command due to electromagnetic interference. Ex.1008, 9:11-16. A POSA considering Barreras would have looked to related references for other ways to send communications (*e.g.*, termination command) from the implanted device to the external device. Ex.1003¶¶91-92. One such reference is Engebretson, which describes a low-power, low-cost communications method between implanted and external devices in an analogous implantable medical device system. Ex.1003¶92. Because of the similarities among Barreras, Wang, and Engebretson, a POSA would have known that features from Engebretson could be predictably combined with Barreras (with or without Wang). Ex.1003¶92.

3. Claim 28

Claim 28 depends on claim 27 and further recites "(h) sunning [*sic*] the change in rectification in the IPG using circuitry means located in the external battery charger, to thereby sense when the rechargeable battery in the IPG is fully

charge [*sic*]."

As discussed (§V.A.2.h), Barreras discloses that upon sensing that the rechargeable battery in the receiver is fully charged, the receiver telemeters a "'stop' recharging command" to the transmitter 12 via the RF communications link 61. Ex.1008, 9:7-17; *see also id*., 4:34-39, 9:44-53. Barreras, however, does not disclose "sunning [*sic*] the change in rectification in the IPG using circuitry means located in the external battery charger, to thereby sense when the rechargeable battery in the IPG is fully charge." It would have been obvious to include this feature in implementing Barreras' system in light of Engebretson. Ex.1003¶¶93-97.

Engebretson discloses using "rectification modes" as "different binary states" to convey binary messages from an implanted device. Ex.1019, 3:3-9; *see also id*., 1:53-56, 3:12-22. An "encoder 18" in the implanted device causes a "rectifier 16" to selectively switch between full-wave and half-wave rectification modes, which "may be considered as different binary states and in this fashion binary messages can be ***represented as changes in the impedance of the implanted device as a function of time***." *See* Ex.1019, 3:3-22. A "current sensing resistor 34" and "decoder circuit 36" in the external device sense the energy delivered through amplifier 28 and can detect at any given time what mode the rectifier is in. Ex.1019, 3:23-34, 3:17-21 (in full-wave mode, "the current flowing

through resistor 34 comprises two current pulses per cycle and comprises one pulse per cycle when half wave rectification is in effect."); *see also id*., 1:62-67, 2:52-57, Fig. 1. "In this fashion the implanted device can convey signals to the external device for providing a readout of the conditions sensed or existing beneath the surface of the skin," such as the implanted device's parameter settings. Ex.1019, 3:37-40, 4:3-7, 4:64-68; *see also id*., 1:43-47.

Therefore, Engebretson discloses the claimed function of "sensing" (*e.g.*, monitoring) "the change in rectification in the IPG" (*e.g.*, switch between half-wave and full-wave rectification modes by the rectification circuit in the implanted device). Ex.1003¶95.

As discussed (§IV.2), the structure disclosed in the '280 corresponding to the claimed function is a charge-complete detection circuit in the external charger that senses the reflected impedance through the external coil caused by a change in the implanted device's rectifier circuit from full-wave to half-wave. Engebretson modulates the impedance of the implanted device by switching the rectifier 16 in the implanted device between half-wave and full-wave modes. Ex.1019, 3:3-9 ("The rectification modes may be considered as different binary states and in this fashion binary messages can be ***represented as changes in the impedance of the implanted device*** as a function of time."). Because of mutual induction through the external and implanted coils, a change in the implanted device's impedance is

necessarily sensed by the external coil. Ex.1003¶97.

As explained above, Engebretson discloses circuitry in the external device (*e.g.*, decoder circuit 36, resistor 34, and/or amplifier 28 in the external device 12) that is able to decipher at any given time whether the implanted device's rectifier 16 is in full-wave or half-wave mode by monitoring the energy (or reflected impedance) delivered through amplifier 28. Ex.1019, 3:23-34. That circuitry (*e.g.*, decoder circuit 36, resistor 34, and/or amplifier 28 in the external device 12), which can be incorporated into Barreras' external charger, is equivalent to the charge-complete detection circuit disclosed in the '280 patent. Ex.1003¶97.

A POSA would have found it obvious to use Engebretson's advantageous communication method to "sens[e] when the rechargeable battery in the IPG is fully charge[d]" in Barreras' system. Ex.1003¶96. As discussed (§V.C.2), Barreras teaches that it is desirable to prevent overcharging of an implanted battery and to enhance the service life of the transmitter's battery by using RF telemetry to send a "'stop' recharging command" from the receiver to the external transmitter. Ex.1008, 6:15-20, 9:7-17; *see also id.*, 4:34-39, 9:44-53. However, recognizing that electromagnetic interference could prevent the transmitter from receiving the "stop" command, Barreras also cuts off the current needed to charge the implanted battery at the receiver as a back-up measure so that the battery will not overcharge even if the transmitter does not receive the "stop" command. Ex.1008, 9:11-17,

9:46-53.

Engebretson provides an advantageous low-power, low-cost method of communicating between implanted and external devices through the use of inductive data transmission, which—compared to Barreras' RF transmissions—is much less susceptible to the types of electromagnetic interference Barreras acknowledges can hinder RF communications. Ex.1003¶96. Moreover, Engebretson expressly contemplates using a rechargeable battery in the implanted device of its disclosed system. *E.g.*, Ex.1019, 2:28-32, 3:67-4:7. A POSA would have therefore found it obvious to use Engebretson's rectification modes as a way to communicate between an implanted device and external device to convey the "stop" recharge command from the receiver to the transmitter in Barreras' recharge system. Ex.1003¶96. Therefore, Barreras and Engebretson render obvious this limitation.

4. Claim 29

Claim 29 depends on claim 28 and further recites "wherein sensing the change in rectification in step (h) comprises: switching from a full-wave to a half-wave rectifier circuit when the battery in the IPG is fully charged, which decreases or stops charging to the IPG battery" and "sensing the reflected impedance change at the primary coil caused by a change from switching from the full-wave rectifier circuit to the half-wave rectifier circuit, the change indicating that the IPG battery

is fully charged."

Barreras and Engebretson render obvious these limitations for the same reasons discussed for claim 28. *See* §V.C.3. For example, it would have been obvious to send Barreras' "stop" recharge command when the implanted battery is fully charged (Ex.1008, 4:34-39, 9:7-17, 9:44-53) using Engebretson's method of communicating signals from the implanted device to the external device by switching the implanted device's rectification circuit between half-wave and full-wave rectification modes (Ex.1019, 1:53-56, 3:3-9, 3:12-22). Ex.1003¶¶95-96, 98-99.

In addition, Engebretson discloses "a signal is conveyed from the implanted device to the external device by modulating the impedance of the implanted device" by switching rectifier 16 between half-wave and full-wave modes. Ex.1019, 1:38-41, 3:3-9. Because of mutual induction through the external and implanted coils, a change in the implanted device's impedance is necessarily sensed by the external coil. Ex.1003¶97. Thus, "[b]y monitoring the energy delivered, the external device ascertains the modulated impedance of the internal device and thereby ascertains the signal being conveyed." Ex.1019, 1:44-47.

Therefore, Engebretson discloses "sensing the reflected impedance change at the primary coil" (*e.g.*, monitoring energy delivered through primary coil that reflects the internal device's impedance) "caused by a change from switching from

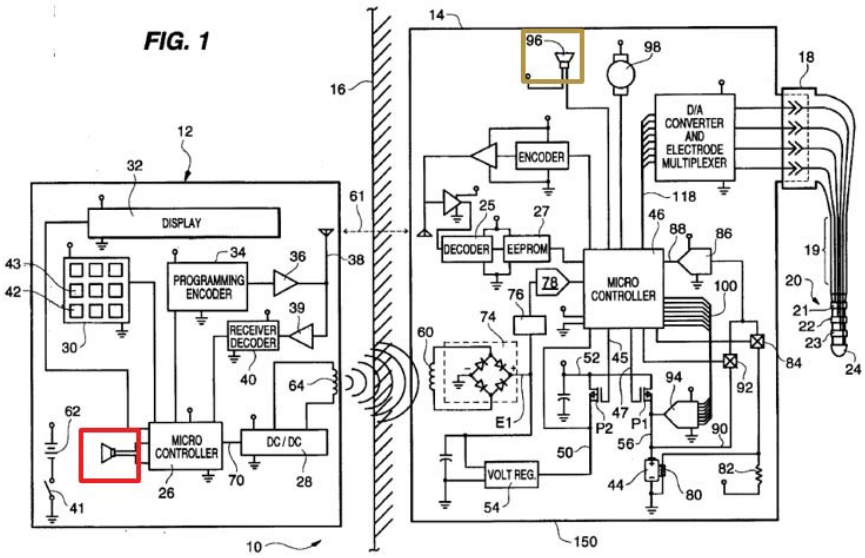
the full-wave rectifier circuit to the half-wave rectifier circuit" (*e.g.*, changes in impedance caused by switching from full-wave to half-wave modes of rectification). Ex.1003¶¶98-99.

5. Claim 30

Claim 30 depends on claim 29 and further recites "(i) providing an alarm signal employing circuitry located external to the IPG, upon sensing a change in rectification in step (h), thereby indicating the battery is fully charged."

Barreras discloses that its "receiver includes a mechanism for alerting the patient when the back-up power source is nearing depletion and needs to be recharged," including "an audible tone generating device within the receiver" or "a specific message shown in the transmitter's display combined with a specific audible tone generated by the transmitter." Ex.1008, 4:55-61; *see also id*., 9:63-67, 11:35-39, 12:1-5, Figs. 1, 4, 5. For example, Figure 1 below shows an "audible alarm 96" in receiver 14. In addition, Figure 1 shows a similar audible alarm in the transmitter (shown in red).[8]

[8] Although the red-outlined element in Figure 1 is not numbered, a POSA would have understood it to be an audible alarm in the transmitter at least because (1) the same symbol depicts audible alarm 96, and (2) Barreras expressly discloses the



It would have been an obvious design choice to use Barreras' audible alarm in the transmitter to alert the patient that the implanted battery is fully charged. Ex.1003¶102. A POSA would have found it obvious and straightforward to modify Barreras' system to trigger the transmitter's audible alarm once the transmitter senses the change in the receiver's rectifier mode—using Engebretson's communication method of determining rectification modes—that conveys Barreras' "stop" recharging command indicating the battery is fully charged. Ex.1003¶102. A POSA would have recognized that it was advantageous to implement an audible alarm to alert the patient that the battery is fully charged, so

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patient can be alerted the battery needs recharging "with a specific audible tone generated by the transmitter." Ex.1008, 4:55-61; Ex.1003¶101.

that the patient is aware of the charge level of the implanted battery and the patient knows the transmitter no longer needs to be in close proximity to the receiver for recharging. Ex.1003¶103.

D. Ground 4: Holsheimer and Alo Render Obvious Claim 26

1. Overview of Holsheimer

Holsheimer issued in March 1996 and is prior art under §102(b). Ex.1003¶42. Holsheimer describes a multi-channel IPG for an SCS system that can deliver pulses on multiple channels that are "selectably simultaneous or alternate in time, are selectably equal or different in amplitude, or both." Ex.1004, 2:30-33. Holsheimer teaches the IPG can include multiple current sources, each capable of delivering different pulse parameters to a channel: "This invention relates to…changing the intensity and location of resulting spinal cord stimulation by changing the pulse parameters of at least two separate voltage or current controlled sources." Ex.1004, 1:8-13; *see also id.*, 1:41-52, 2:24-26 ("The apparatus uses a multi-channel neurological pulse generator which provides independently controlled voltage or current pulses."). The "use of multiple, superimposed potential [electrical] fields…results in different and variable stimulated spinal cord areas as compared to a single field, and thus provides a better controllable paresthesia effect." Ex.1004, 2:35-39. *See also* Ex.1003¶¶104-07.

During prosecution of the '280, the Examiner rejected certain pending claims on §103 grounds over the combination of Holsheimer and Barreras '877. The Examiner explained that Holsheimer "describes an implantable epidural spinal cord stimulator (Figs. 1 and 20) ***having applicant's claimed multi-channel pulse generator*** 14 comprising an electrode array (Fig.19 – 38A-38E and Fig.20 --39A-39G) whose outputs can be changed independently of one another (col.7, lines 20-22)." Ex.1002, 280. The applicants did not dispute the Examiner's finding that Holsheimer taught a multi-channel pulse generator and cancelled the rejected claims.

While Petitioner relies on the same Holsheimer patent, Petitioner relies on Holsheimer in combination with prior art references (*e.g.*, Munshi, Wang, and Alo) that were not previously before the Office. Moreover, three of the presented grounds of unpatentability (Grounds 1-3) do not rely on Holsheimer at all, and instead rely on new references not previously before the Office (*e.g.*, Barreras '313, Wang, and Engebretson). And, as described below, these new and unconsidered references teach the very limitations the Examiner noted were the reasons for allowance. For example, as relevant to the Claims, Barreras '313 discloses stopping the charging of the IPG battery when the charging current or voltage reaches a "prescribed level" (Ex.1002, 284). Ex.1008, 9:7-16. Alo discloses connecting an "external trial stimulator" to the SCS system (Ex.1002,

283). Ex.1009, 33. And Barreras '313 teaches charging a rechargeable battery in the external battery charger (Ex.1002, 283). Ex.1008, Abstract, 4:18-20. In addition, this Petition is supported by the testimony of Dr. Kroll, which presents knowledge of a POSA not before the Examiner. Accordingly, this Petition does not involve "the same or substantially the same prior art or arguments previously [] presented" during prosecution. §325(d).

2. Overview of Alo

"Computer Assisted and Patient Interactive Programming of Dual Octrode Spinal Cord Stimulation in the Treatment of Chronic Pain" by Kenneth M. Alo et al. was published in the Winter 1998 edition of Neuromodulation: Journal of the International Neuromodulation Society—a reputable well-known publisher of academic articles in the neuromodulation field. Ex.1009, cover-1, cover-3 (showing copyright 1998); *see Ericsson, Inc. v. Intellectual Ventures I LLC*, IPR2014-00527, Paper 41 at 11 (May 18, 2015) (relying on document's statements regarding its publication, where document was published by a well-known, reputable organization). Thus, Alo is prior art under at least §102(a). Ex.1003¶45.

Additional evidence confirming Alo's publication date includes a sticker in the middle of Alo's cover page that states "Property of the National Library of Medicine" and a sticker on the upper left-hand side that includes a date—"4/12/99"—indicating the date on which the National Library of Medicine added

the issue of the Neuromodulation journal containing Alo to its collection. Ex.1009, cover-1. The date stamp further corroborates the public availability of the Neuromodulation journal prior to the '280's July 1999 priority date.

Alo describes a study that "evaluate[s] the effectiveness of spinal cord stimulation using multiple independent programmable electrode selections compared to simple continuous stimulation." Ex.1009, 30. According to Alo, it was known that "effectiveness of SCS therapy would be improved by using multiple electrodes in multiple programs" and the authors hypothesized that "active patient participation can improve the program selection process." Ex.1009, 32. During the study, two leads were implanted into each patient and those leads were "externalized" to connect them to a "trial stimulator" for a "trial period [of] 5 to 7 days." Ex.1009, 33. During this trial period, the patients were allowed to activate and individually test out up to 24 different programs that were loaded into the "trial stimulator" or "transmitter." Ex.1009, 34. After the trial period, the patients and clinician "[p]rogramm[ed] for the Permanent SCS Implant" by selecting an "optimal set" of programs and deleting programs that did not provide effective paresthesias. Ex.1009, 34. "Subsequent permanent implantation was performed 3 or 4 weeks later…." Ex.1009, 33. *See also* Ex.1003¶¶108-09.

3. Motivation to Combine

A POSA would have found it obvious to employ Alo's method of implanting an SCS system in implementing Holsheimer's system. Holsheimer and Alo both describe SCS systems and describe the use of analogous SCS devices. Ex.1003¶110. And, as taught by Alo, it was an industry standard at the time to test the efficacy of SCS therapy through the use of an external stimulator prior to permanent IPG implantation to ensure effective treatment and avoid unnecessary medical costs and trauma to the patient. Ex.1003¶111; *see, e.g.*, Ex.1007, 14:3-10 ("[T]he pain suffered by the particular patient should be found to respond to….stimulation by tests conducted before a permanent implant is performed.").

A POSA would have found it obvious to use this implantation method for Holsheimer's system even though Alo's system includes an external transmitter coupled with an implanted receiver (Ex.1009, 34-35) and Holsheimer's system includes a fully implantable IPG. Ex.1003¶112. Holsheimer teaches "[w]hile the preferred system employs fully implanted elements, systems employing partially implanted generators and radio-frequency coupling may also practice the present invention." Ex.1004, 4:2-5. And, a POSA would have known the benefits of conducting a trial prior to permanent implantation would be the same whether the device being permanently implanted is a fully implantable IPG, as taught by Holsheimer, or a receiver, as used in Alo. Ex.1003¶112.

4. Claim 26

a) [26.preamble]: "A method for implanting a spinal cord stimulator system into a patient for stimulation therapy"

Holsheimer discloses an "***implantable*** pulse generator" in a "***neurological stimulation system***…***to stimulate spinal cord 12 of the patient***." Ex.1004, 3:53-56. And Holsheimer's preferred system "employs ***fully implanted elements***." Ex.1004, 4:2-3. Therefore, to the extent the preamble is limiting, Holsheimer discloses it. Ex.1003¶113.

b) [26.a]: "implanting a nerve stimulation lead with a distally located, multi-electrode array placed near target tissue, said lead having a lead connector on the proximal end"

Holsheimer discloses its SCS system includes "a ***lead*** connected to the pulse generator [that] has ***electrodes at the distal end***" and that the "***lead is implanted a few mm apart from the spinal cord*** with the ***electrode array*** transverse and facing the spinal cord." Ex.1004, 2:25-29, Abstract. Therefore, Holsheimer discloses "implanting a nerve stimulation lead" (*e.g.*, lead is implanted) "with a distally located, multi-electrode array" (*e.g.*, electrode array at the distal end) "placed near target tissue" (*e.g.*, a few mm from the spinal cord).

Holsheimer's IPG 14 in Figure 1 (below) shows a standard connector notch commonly used to depict lead connectors. *See, e.g.*, Ex.1020, Figs. 1, 3-4.

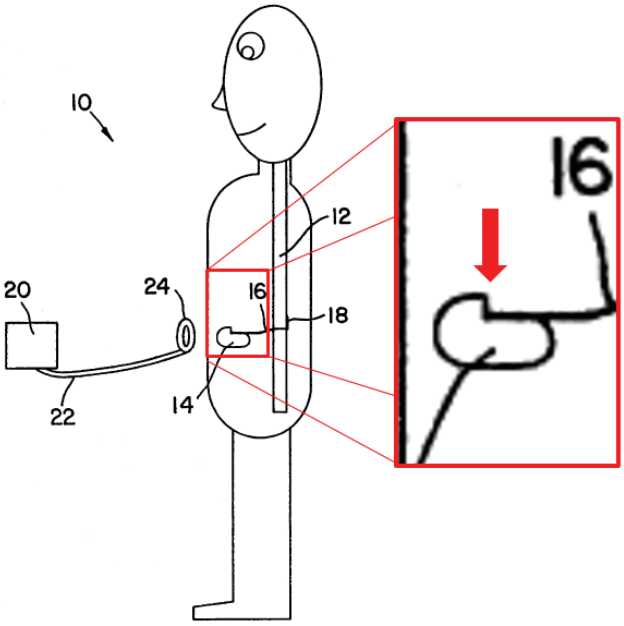


FIG. 1

Moreover, a POSA would have understood Holsheimer's leads detachably connect to the IPG and have lead connectors on their proximal ends because—as the '280 admits—it was well-known lead connectors are necessary to establish an electrical connection between the electrodes on the leads and the IPG. *E.g.*, Ex.1001, 8:46-52 ("***connector may be of the type described in…Pat. No. 6,198,969*** or any other suitable design"), 1:38-39 (citing U.S. Patent 5,121,754, describing a lead with a proximal end that has a "***connector***" to the IPG (Ex.1016, 2:66-3:2)); Ex.1008, 7:38-41 ("The receiver 14 is connected, via ***lead connector 18***, to…an implanted lead 19…."); Ex.1003¶¶114-16.

c) [26.b]: "connecting the lead connector to a percutaneous extension"

Holsheimer does not expressly disclose "connecting the lead connector to a

percutaneous extension," but it would have been obvious to do so in light of Alo.

Alo discloses that "[f]or trial stimulation, the transmitter is ***connected directly to the leads by a percutaneous extension wire.***" Ex.1009, 34. Therefore, Alo also discloses "*connecting the lead connector*" (*e.g.*, connector on leads) to a "*percutaneous extension*" (*e.g.*, percutaneous extension wire). Ex.1003¶117. And, as discussed (§V.D.3), a POSA would have been motivated to employ Alo's implantation method because it was well-known that it was beneficial to test stimulation therapy before committing the patient to permanent implantation. Ex.1003¶117.

d) [26.c]: "externalizing the percutaneous extension through the skin"

Alo further discloses that for trial stimulation the "***trial leads were externalized*** through a short subcutaneous tunnel and connected to the trial stimulator." Ex.1009, 33. Read together with Alo's explanation that, for trial stimulation, the leads are connected to the transmitter by a "***percutaneous extension wire***" (Ex.1009, 34), a POSA would have understood that Alo's trial leads were "externalized" through the skin via the "percutaneous extension wire." Ex.1003¶118. Therefore, Alo discloses "externalizing the percutaneous extension through the skin." *Id.*

e) [26.d]: "connecting an external trial stimulator (ETS) to the externalized lead extension"

Alo discloses that "***for trial stimulation***, the ***transmitter is connected directly to the leads by a percutaneous extension wire***" and the "***trial leads were externalized*** through a short subcutaneous tunnel [to be] ***connected to the trial stimulator*** (MNT9OT-TR16, Quest-ANS, Inc.)." Ex.1009, 33, 34. Therefore, Alo discloses "connecting an external trial stimulator" (*e.g.*, trial stimulator) to the "externalized lead extension" (*e.g.*, percutaneous extension wire). Ex.1003¶119.

f) [26.e]: "programming the stimulation parameters at first optimal values"

Under the heading "***Programming*** for Trial SCS," Alo explains the trial stimulators were programmed with "C-stim" and "PC-stim" programs. Ex.1009, 34 ("The patient was sent home for the first 24 hours of the trial with a simple C-stim ***program***….The next day the patient was given up to 24 ***programs*** to choose from (PC-stim)."), 32 ("***selected programs are downloaded into the transmitter***"), 36 ("Up to 24 ***programs can be loaded into the transmitter***…."). Alo explains "C-stim mode is a conventional, simple continuous stimulation using ***one program***," while in "PC-stim" (or patient-controlled stimulation) mode, "the patient is allowed to manually turn on or off ***predefined programs***" that each "ha[ve] its own preprogrammed specific electrode arrays, amplitude, frequency, and pulse width." Ex.1009, 36. According to Alo, a "program" is "***a combination of settings that***

determine electrode activation including the number of electrodes activated, the polarity of electrodes, frequency, pulse width, and amplitude." Ex.1009, 36. Alo teaches that "with the aid of patient feedback, the physician selects the optimal electrodes for each program" and subsequently downloads the programs into the transmitter. Ex.1009, 32.

Therefore, Alo discloses "programming" (*e.g.*, loading programs into the transmitter) "stimulation parameters" (*e.g.*, electrodes activated, electrode polarity, frequency, pulse width, amplitude) "at first optimal values" (*e.g.*, values of parameters set in the predefined C-stim and PC-stim programs, such as the selection of "optimal electrodes"). Ex.1003¶120.

g) [26.f]: "waiting a specified period of time and re-programming the stimulation parameters to second optimal values"

Alo discloses the "trial period was 5 to 7 days." Ex.1009, 33, 34 ("The patient was allowed to test the system for a total of 5 to 7 days."). And "[a]fter trial stimulation using PC-stim, a number of ***preferred programs are selected*** by the patient and physician." Ex.1009, 36. Under the heading "***Programming*** for the Permanent SCS Implant," Alo further explains that after the patient evaluates the various programs in PC-stim mode, "[p]rograms that did not provide effective paresthesias were deleted" to establish "***a set of optimal programs***" stored in the transmitter to be implemented in a so-called "M-stim mode." Ex.1009, 34. And,

as discussed (§V.D.4.f), "[e]ach program may have its own specified electrodes, amplitude, frequency, and pulse width." Ex.1009, 36. Therefore, Alo discloses "waiting a specified period of time" (*e.g.*, 5 to 7 days) and "reprogramming the stimulation parameters to second optimal values" (*e.g.*, selecting a set of optimal programs to run in "M-stim mode" that each have their own specified electrodes, amplitude, frequency, pulse width). Ex.1003¶121.

h) [26.g]: "disconnecting the percutaneous extension from the lead connector"

Alo explains that the "trial leads" can be used "for permanent implant." Ex.1009, 33 ("Subsequent permanent implantation was performed 3 or 4 weeks later using the same epidural positioning technique. Variations of this technique exist, and other investigators have ***used the trial leads for permanent implant***…."). Thus, to use trial leads for permanent implantation one would have to disconnect the "percutaneous extension wire" used to connect the lead to the transmitter (Ex.1009, 34) to connect the lead to the receiver or IPG that will be implanted (Ex.1009, 35). Ex.1003¶122.

i) [26.h]: "connecting a multi-channel, implantable pulse generator to the lead connector"

Holsheimer discloses "a multi-channel implantable pulse generator (IPG)." *E.g.*, Ex.1004, Title ("***Multichannel*** apparatus for epidural spinal cord stimulator"), Abstract (describing "a ***multi-channel pulse generator*** driving a

plurality of electrodes"). Ex.1003¶123.

Unlike systems the '280 criticizes for having "only a single voltage source, and hence only a single stimulation channel" (Ex.1001, 2:11-14, 2:18-21), Holsheimer's IPG includes multiple voltage sources capable of simultaneously providing different stimulation parameters across multiple stimulation channels. Ex.1004, 1:8-13 ("[T]his invention relates to…changing the intensity and location of resulting spinal cord stimulation by changing the pulse parameters of ***at least two separate voltage or current controlled sources*** applied to in line electrodes transverse to the spinal cord axis."), 5:49-52 ("The circuit of FIG. 4A was used for the two sources stimulation model having electrodes 56, 58 and 60 and ***V1 voltage source 64*** and ***V2 voltage source 66***."), 7:5-14 ("using ***more than one source for stimulation of the spinal cord*** versus Single source stimulation…[T]hese same parameters can also be changed if three, four or more independent sources were employed with analogous results."), 7:17-18 ("FIG. 19 shows pulse generator 14 with positive going ***pulse outputs 72, 74, 76, and 78***…."), 7:44-47, Figs. 4A, 5-6, 19-20.

As discussed (§IV.1), the proper construction of "multi-channel IPG" in the '280 requires the ability to simultaneously deliver stimulation pulses with different stimulation parameters over two or more channels. Holsheimer teaches that its IPG can simultaneously "provide[] ***independently controlled voltage or current***

pulses" with varying parameters on multiple channels. Ex.1004, 2:24-33; *see also id*., 1:45-48 ("This means that post-operative changes in stimulation fields can be obtained by ***selective parametric changes in the pulse generator outputs***."), 1:53-56, 3:56-59 ("The preferred system employs implantable pulse generator 14 to produce a number of ***independent stimulation pulses***…."). Holsheimer emphasizes its IPG's ability to simultaneously deliver pulses to different stimulation channels that have "selectably" different stimulation parameters (*e.g.*, amplitude and pulse width). Ex.1004, 2:30-33; *see also id*., Abstract ("[T]he pulse generator is arranged such that pulses for each channel can ***selectably alternate in time***, can ***selectably be of unequal amplitude***, or both."), 3:60-65 ("Implantable pulse generator 14…with provisions for ***multiple pulse outputs*** which are selectably either ***simultaneous*** or with one shifted in time with respect to the other, and which are selectably of ***independently varying amplitudes***."), 6:1-9, 6:36-38 ("The use of ***simultaneous pulses from two unbalanced sources*** results in a controllable asymmetrical stimulation which is ***impossible to attain with single source stimulation***."), 7:17-23, 7:33-40, 7:44-47, claim 1 ("the source of electrical pulses having means for ***independently changing parameters of the output pulses in each channel***"), claim 15 ("the source of electrical pulses sends electrical pulses of ***variable pulse width*** to the electrodes"); *see also id*., claims 5, 14, 54-56; Figs. 4A, 5-6, 19-20. Therefore, Holsheimer discloses a "multi-channel IPG", as that

term is properly construed in the context of the '280 patent.[9] Ex.1003¶¶124-28.

Alo discloses that a "permanent receiver was placed subcutaneously…under the skin and over the rib cage." Ex.1009, 33-34, 35 ("For permanent stimulation, the transmitter is carried by the patient on a belt and the electrical connection to the receiver is by a transcutaneous interface which consists of a radiofrequency transmitter with antenna…(Fig. 6) and a subcutaneous radiofrequency receiver coil…(Fig.7)."). Alo further discloses that the lead "connect[s] to…an implanted radio frequency receiver." Ex.1009, 35. Therefore, Alo discloses connecting an implantable device (*e.g.*, receiver) "to the lead connector." A POSA would have found it obvious to substitute Holsheimer's implantable IPG in the place of Alo's implantable receiver so that Holsheimer's IPG is connected to the leads. Ex.1003¶¶129-30.

j) [26.i]: "implanting the implantable pulse generator, while programmed to the second, optimal stimulation parameters"

As discussed (§V.D.4.i), Alo discloses permanent implantation of the receiver. *E.g.*, Ex.1009, 33-34 ("permanent receiver was placed subcutaneously…under the skin and over the rib cage"). And, as discussed

[9] And as described above, Holsheimer discloses a "multi-channel IPG," even if that term is given a broader construction than that proposed herein by Petitioner.

(§V.D.4.g), Alo discloses that the transmitter is "[p]rogramm[ed] for the [p]ermanent SCS [i]mplant" by selecting "a set of optimal programs" to be implemented in "M-stim mode." Ex.1009, 34. Therefore, Alo discloses "implanting" an implantable device (*e.g.*, implanted receiver) while the SCS system is "programmed to the second, optimal stimulation parameters" (*e.g.*, transmitter is programmed to include a set of optimal programs to run in "M-stim mode"). Again, it would have been obvious to a POSA to simply substitute Holsheimer's implantable IPG in the place of Alo's receiver and implant Holsheimer's IPG. Ex.1003¶131.

E. Ground 5: Holsheimer, Munshi, and Wang Render Obvious Claims 22-24

1. Overview of Munshi

U.S. Patent No. 5,411,537 to Munshi issued in May 1995 and is prior art under §102(b). Ex.1003¶43. Munshi describes a "bioimplantable device" with a rechargeable power source (*e.g.*, rechargeable battery) as well as techniques for recharging that battery transcutaneously (*i.e.*, through the patient's skin) by electromagnetic induction. Ex.1005, 4:3-10; *see also id*., Abstract, 1:8-17. While Munshi describes its invention primarily in the context of a pacemaker/defibrillator, Munshi teaches that its invention is applicable to "any other bioimplantable device," including "***nerve*** and bone growth ***stimulators***." Ex.1005, Abstract, 1:8-9, 1:20-28, 4:4-5. The implanted device includes a

magnetic coil coupled to the power source that can receive electromagnetic energy from another coil in an external charger that transmits electromagnetic energy to the implanted device by way of induction through the patient's skin. Ex.1005, 10:21-26, 10:32-37. The external charger can be powered by an alternating current source and/or a "rechargeable external battery pack with its own charging system…to allow portability of the external unit." Ex.1005, 10:20-21, 10:43-51. *See also* Ex.1003¶¶132-35.

2. Motivation to Combine

A POSA would have understood that implantable, electrically operated devices—like Holsheimer's IPG—need power to operate, such as from a battery. Ex.1003¶136. A known disadvantage of battery-powered implantable devices, however, was that the service life of the device was limited to the battery's life. *Id*.; *see, e.g.*, Ex.1008, 2:20-22 ("Unfortunately, the service life of these battery powered implantable simulators is limited to the battery life."); Ex.1011, 1:35-38; Ex.1006, 1:44-46. That is, once the battery was depleted, the device would need to be explanted to replace the battery, causing more trauma to the patient and higher medical costs. Ex.1003¶136; *see, e.g.*, Ex.1008, 1:23-30, 2:22-27; Ex.1011, 1:38-41; Ex.1006, 1:46-48. A POSA implementing Holsheimer would have been motivated to address these known concerns. Ex.1003¶¶136-37; MPEP §2143(F).

Munshi addresses this problem, teaching a "rechargeable power source" that

is "recharged through the patient's skin" that can be incorporated into any "bioimplantable battery-powered device." Ex.1005, 4:3-10; Ex.1003¶137. A POSA therefore would have found it obvious to adapt Holsheimer's multi-channel IPG to use a rechargeable battery as taught by Munshi. Ex.1003¶¶137-38. Holsheimer and Munshi describe analogous implantable electrical stimulation systems. Ex.1003¶138; *see also* Ex.1009 at 31 (describing SCS as a "nerve pacemaker"). A POSA would have found it routine to implement Munshi's rechargeable power source in another bioimplantable device, and would have known that the combination would work as expected without undue experimentation. Ex.1003¶138.

In addition, Munshi teaches that in implementing its rechargeable battery system, it is desirable to "find the optimum position of maximum energy transfer [between the two coils]…by noting the position at which the coil current is maximized." Ex.1005, 13:1-5; *see also id*., 12:66-13:1. A POSA implementing Munshi's rechargeable system would have been motivated to address this concern. Ex.1003¶139. Wang—directed to an analogous implantable electrical stimulation system—addresses this problem and teaches "an alignment circuit and indicator…to indicate whether the coils are properly aligned." Ex.1018, 5:15-17; Ex.1003¶139. A POSA would have further been motivated to use Wang's alignment circuitry in Munshi's external charger because Wang uses inductive

methods (*e.g.*, by monitoring reflected impedance) that would "require[] no extra components" in Holsheimer's IPG and "minimizes the size of the receiving coil." Ex.1018, 4:19-26. Because these SCS systems are implanted into a patient's body, it was well-known and desired at the time to minimize the size, and therefore footprint, of the implanted device within the patient's body. Ex.1003¶140.

A POSA therefore would have found it obvious to adapt Holsheimer's SCS system (as modified by Munshi's rechargeable battery) to use alignment circuitry as taught by Wang. Ex.1003¶140. Because of the similarities between Holsheimer as modified by Munshi and Wang, a POSA would have known that features from Wang could be routinely and predictably combined with Holsheimer and Munshi. Ex.1003¶140.

3. Claim 22

a) [22.preamble]: "A spinal cord stimulation system"

Figure 1 of Holsheimer depicts a "***neurological stimulation system***" to "stimulate [a patient's] ***spinal cord***." *E.g.*, Ex.1004, 3:53-55, Fig.1; *see also id.*, Title ("Multichannel apparatus for epidural ***spinal cord stimulator***"), Abstract ("Apparatus for multi-channel transverse epidural ***spinal cord stimulation***…."), 1:7-13, 2:22-24, 2:46-48, claims 13, 22. Therefore, to the extent the preamble is limiting, Holsheimer discloses a "spinal cord stimulation system." Ex.1003¶141.

b) [22.a]: "an implantable, multi-channel implantable pulse generator (IPG) having a replenishable power source"

As discussed (§V.D.4.i), Holsheimer discloses "a multi-channel implantable pulse generator (IPG)." Ex.1003¶142.

Although Holsheimer does not expressly disclose "a replenishable power source," it would have been obvious to include one in Holsheimer's IPG in view of Munshi. Munshi is "directed towards a ***rechargeable battery-powered biomedical device***…." Ex.1005, 1:8-9; *see also id*., Abstract ("bioimplantable device which may be operated on a single rechargeable cell"), 4:3-10, 5:29-33, 7:4-9. Therefore, Munshi discloses "a replenishable power source" (*e.g.*, the rechargeable battery in the implanted device). Ex.1003¶143.

As explained (§V.E.2), a POSA would have been motivated to incorporate Munshi's rechargeable battery into Holsheimer's IPG to improve the service life of the device and minimize the number of surgical procedures required. Ex.1003¶144. Because of the similarities between Holsheimer and Munshi (*e.g.*, implantable electrical stimulation systems), a POSA would have known the combination yielding the structure as claimed would have worked as expected. Ex.1003¶144. And a POSA could have implemented Munshi's rechargeable battery in Holsheimer's IPG with a high degree of predictability. *Id*. Therefore, Holsheimer and Munshi render obvious this limitation.

c) [22.b]: "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

Holsheimer discloses "[a] ***lead connected to the pulse generator has electrodes*** at the distal end corresponding to the number of channels. The ***lead is implanted*** a few mm apart from the spinal cord with the ***electrode array*** transverse and facing the spinal cord." Ex.1004, 2:25-29; *see also id.*, Abstract ("[A] plurality of electrodes [are] mounted near the distal end of a lead."), 2:54-55, 3:56-59, 6:26-31, 6:66-7:1 ("FIG. 17 shows…a symmetrically positioned transverse ***electrode array***…."), 7:22-31, 7:37-62; Figs. 1, 19-20; claim 13 ("an electrode array comprising a first, a second and a third electrode…a source of electrical pulses connected to…the electrodes"); Ex.1002, 280. Therefore, Holsheimer discloses an "implantable electrode array" (*e.g.*, implanted lead with electrode array) "connected to the IPG" (*e.g.*, connected to the pulse generator) and "having a multiplicity of n electrodes (En) thereon" (*e.g.*, plurality of electrodes on the lead). Ex.1003¶¶145-46.

Holsheimer's Figure 1 shows a standard connector notch where the leads would connect to the IPG (*see* §V.D.4.b). In addition, a POSA would have understood Holsheimer's leads, which carry the electrode arrays, would have been detachably connected to the IPG because—as the '280 admits—many different types of leads were known in the art and could be used with the same IPG.

Ex.1001, 9:8-11, 10:19-24. It was well-known at the time that leads can be attached and detached to IPGs, so medical professionals and patients could have the flexibility to select the type of lead that best suits the patient's particular stimulation needs and so malfunctioning leads could be replaced without having to replace the entire IPG. *See, e.g.*, Ex.1016 (prior art cited by Holsheimer), Abstract, 2:66-3:2 (describing a lead with a "connector" to the IPG); Ex.1003¶¶147-48.

d) [22.c]: "a secondary, implanted coil coupled electrically to the replenishable power source"

Munshi discloses "***an input coil 74****….****disposed just under the skin***." Ex.1005, 10:24-26, 10:32-37, 12:54-57. Munshi also discloses a "***rechargeable lithium battery 92***" in the implanted device that is "connected" to the implanted "***receiving coil 74***," as depicted in Figure 2 below. Ex.1005, 10:52-64 ("On the receiving side, the system consists of…receiving coil 74….A rechargeable lithium battery 92 is connected to the above described circuitry.").

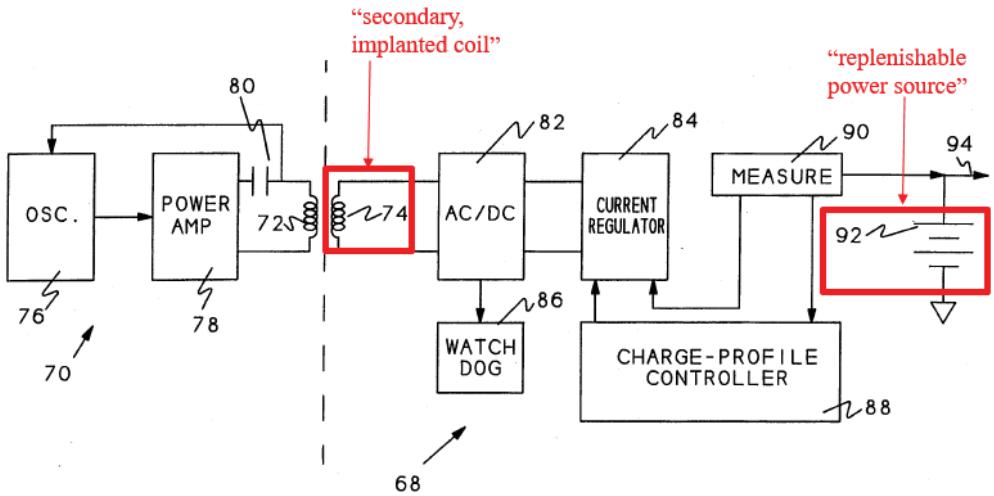


FIG. 2

Therefore, Munshi discloses "a secondary, implanted coil" (*e.g.*, receiving coil 74) "coupled electrically" (*e.g.*, connected) to the "replenishable power source" (*e.g.*, rechargeable battery 92). Ex.1003¶¶149-50.

e) [22.d] "an external battery charger"

Munshi teaches a "user initiates the battery charging operation by placing the energy transmitting coil of the ***external charging unit*** in close proximity to the implanted coil and by turning on the excitation to the transmitting coil." Ex.1005, 12:54-57; *see also id.*, Figure 2 (element 70); 10:20-40, 10:45-47, 10:52-61. Therefore, Munshi discloses "an external battery charger" (*e.g.*, external charging unit 70). Ex.1003¶151.

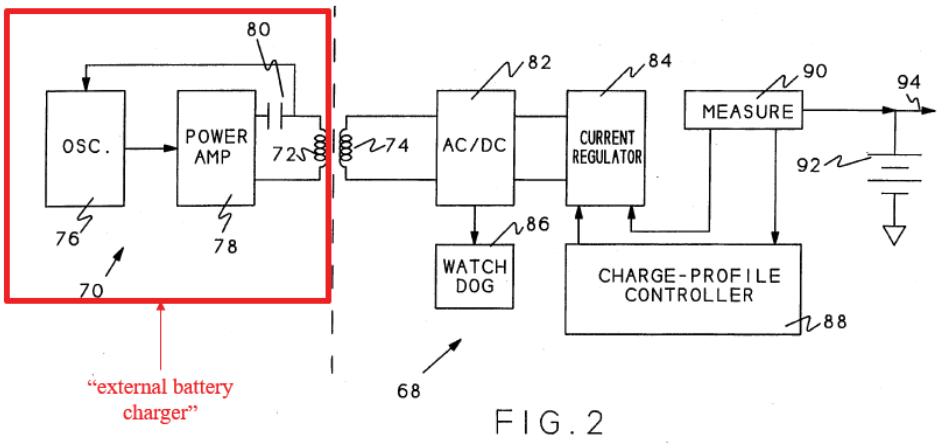


FIG. 2

f) [22.e]: "an external battery charger including: a primary coil"

Munshi teaches the "***external charger 70***" includes "***an external charging coil 72***," as shown in Figure 2 below. Ex.1005, 10:20-26 ("Energy for recharging the battery is coupled through the patient's skin by magnetic induction between an

external charging coil 72 and an input coil 74…."); *see also id.*, 10:32-37, 10:38-40, 12:54-57.

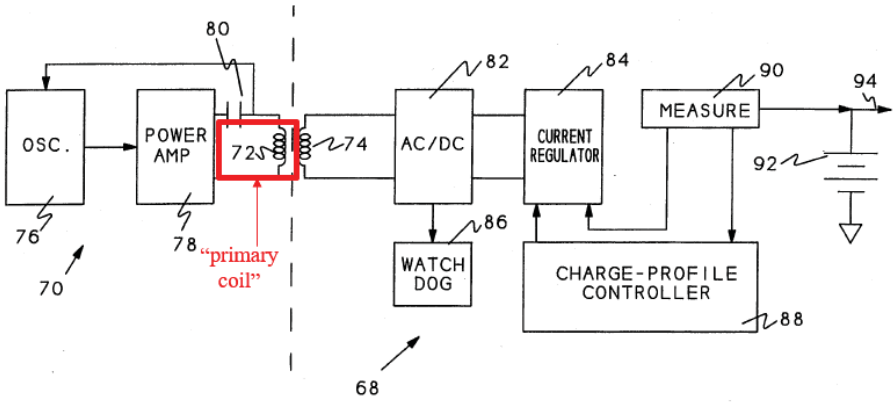


FIG. 2

Therefore, Munshi discloses "an external battery charger" (*e.g.*, external charger 70) "including: a primary coil" (*e.g.*, transmitting coil 72). Ex.1003¶152.

g) [22.f]: "a rechargeable battery contained in the charger, electrically coupled to the primary coil"

Munshi discloses various circuitry in the "***external charger 70***," including the "***transmitting coil 72***," which can obtain power from "any suitable source, such as…battery pack." Ex.1005, 10:38-45. Munshi further teaches a "***rechargeable external battery pack*** with its own charging system could be provided to allow portability of the external unit." Ex.1005, 10:45-47.

To the extent PO argues Munshi does not expressly disclose the rechargeable external battery pack is "contained" in the external charger, it would have been obvious to include the rechargeable external battery pack in the external charger. Ex.1003¶154. Munshi explains the "rechargeable external battery pack"

can be used to improve "portability" of the external unit. Ex.1005, 10:45-47. Including the "rechargeable external battery pack" in the "external charger" would further improve portability because the patient would be required to carry only one device rather than two separate components. Ex.1003¶154.

Therefore, Munshi discloses "an external battery charger" (*e.g.*, external charger 70) "including…a rechargeable battery contained in the charger" (*e.g.*, rechargeable external battery pack) "electrically coupled to the primary coil" (*e.g.*, power supplied to transmitting coil 72 by rechargeable external battery pack). Ex.1003¶¶153-54.

h) [22.g]: "a power amplifier for applying alternating current derived from the rechargeable battery in the charger to the primary coil"

Munshi discloses the "external charger 70" includes a an "oscillator circuit 76" that "drives the ***transmitting coil 72*** with an ***alternating current***" through "***power amplifier 78*** which is coupled through a capacitor 80 to the external transmitting coil 72," as shown in Figure 2 below. Ex.1005, 10:38-43.

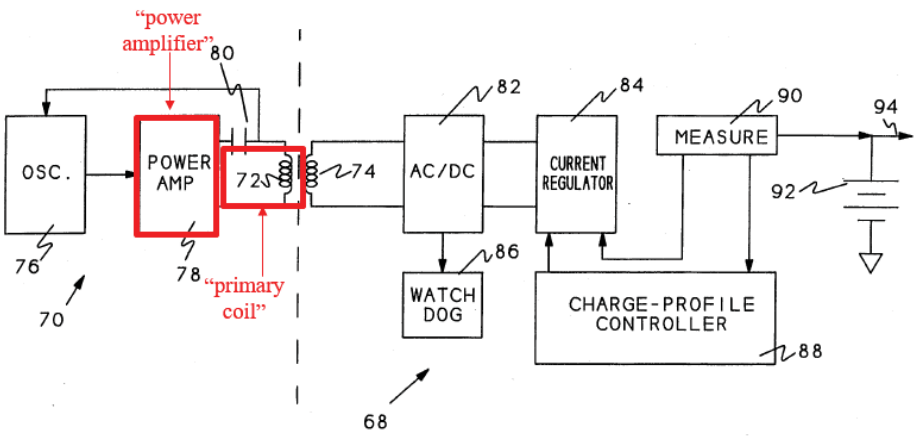


FIG. 2

And, as discussed (§V.E.3.g), Munshi discloses that "[p]ower may be supplied to these circuits from any suitable source, such as…rechargeable external battery pack." Ex.1005, 10:43-47. Therefore, Munshi discloses "a power amplifier" (*e.g.*, power amplifier 78) "for applying alternating current" (*e.g.*, alternating current driven by oscillator circuit 76) "derived from the rechargeable battery in the charger" (*e.g.*, power supplied from the rechargeable battery pack) "to the primary coil" (*e.g.*, driven to the transmitting coil 72). Ex.1003¶¶155-56.

i) [22.h]: "whereby the alternating current in the primary coil is transcutaneously transferred to the secondary implanted coil to the replenishable power source contained in the IPG"

Munshi discloses that "[a]s shown in FIG. 2, the external charger 70 consists of an oscillator circuit 76 that ***drives the transmitting coil 72 with an alternating current***." Ex.1005, 10:38-40. And ***"[e]nergy for recharging the [implanted] battery is coupled through the patient's skin by magnetic induction between an external charging coil 72 and an input coil 74***… disposed just under the skin."

Ex.1005, 10:21-26; *see also id*., 4:3-10 ("[T]he rechargeable (secondary) power source is recharged through the patient's skin by electromagnetic induction from either an A.C. or a D.C. source."), 10:32-37, 10:52-64 ("On the receiving side, the system consists of an AC-to-DC converter 82 for converting the induced AC voltage on the receiving coil 74 to DC…. A rechargeable lithium battery 92 is connected to the above described circuitry."); *see also id.* 12:54-63.

Therefore, Munshi discloses "the alternating current in the primary coil" (*e.g.*, alternating current driven to the transmitting coil) is "transcutaneously transferred" (*e.g.*, through the skin) to the "secondary implanted coiled" (*e.g.*, receiving coil) to the "replenishable power source contained in the IPG" (*e.g.*, rechargeable power source in the implanted system connected to the input or receiving coil). Ex.1003¶157.

j) [22.i]: "alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil as applied by the power amplifier"

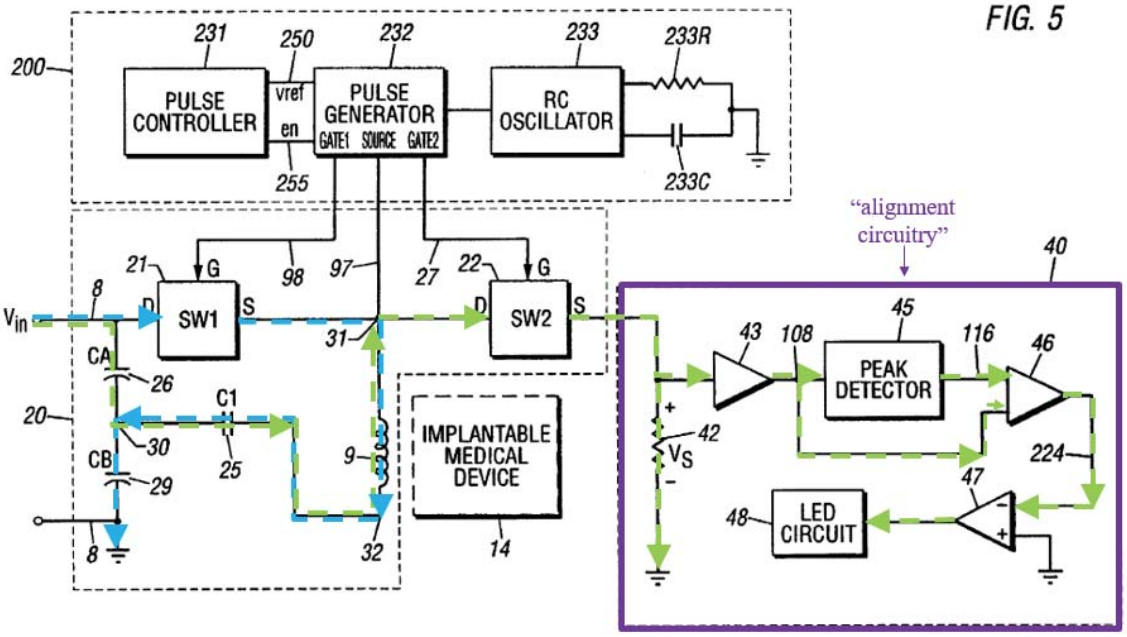
As discussed (*see* §V.E.3.h), Munshi discloses that "ac voltage at the primary coil [is] applied by the power amplifier." And while Munshi discloses that it is desirable to "find the optimum position of maximum energy transfer [between the two coils]…by noting the position at which the coil current is maximized" (Ex.1005, 13:1-5; *see also id*., 12:66-13:1), it does not expressly disclose

"alignment circuity for detecting alignment between the primary and secondary coils" that includes "a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil." However, it would have been obvious to a POSA to include such circuitry in implementing Holsheimer's system in view of Wang. Ex.1003¶¶158-62.

Like Munshi, Wang notes that the "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." Ex.1018, 5:13-15. Accordingly, Wang provides "an ***alignment circuit and indicator****…****to indicate whether the coils are properly aligned***." Ex.1018, 5:15-17; *see also id*. 11:41-46 ("[T]he alignment indicator 40…uses the correlation between the input current and alignment to provide an output signal which indicates when the energy transmission device 50 is sufficiently aligned with the receiving coil 10 of the implanted device 14."), Figs. 1, 5. Therefore, Wang discloses "alignment circuity" (*e.g.*, alignment circuit and indicator) "for detecting alignment between the primary and secondary coils" (*e.g.*, to detect whether the external and implanted coils are properly aligned). Ex.1003¶160.

Wang further discloses "a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil." As described in further detail below, Wang's "alignment circuit and indicator" operates by monitoring the

magnitude of the current through the primary coil and comparing voltage derived from that current to a stored "peak positive voltage," where the peak voltage represents the voltage when the coils are properly aligned. *See* Ex.1018, 12:1-29, Fig. 5; *see also id*., 11:56-63. And the alignment indicator turns on an LED light when the magnitude of the voltage derived from the current through the primary coil is greater than the peak voltage. Ex.1018, 12:21-24. Figure 5 (below) illustrates in blue the current path when switch 21 (SW1) is "on" and switch 22 (SW2) is "off" and in green the current path when switch 21 (SW1) is "off" and switch 22 (SW2) is "on." Ex.1018, 8:64-69, 11:9-14.



As shown in Figure 5, the current on the primary coil 9 is alternating. Ex.1018, 11:20-24. When switch 22 is "on" the current "flows from primary coil 9 through switch 22 and to resistor 42 in alignment indicator 40." Ex.1018, 11:18-

20, Fig. 5. Current flow through resistor 42 generates a voltage,[10] which is amplified by low-pass amplifier 43, and sent to both peak detector 45 and to differential amplifier 46. Ex.1018, 11:20-23, 12:1-8, 12:16-18. The peak detector 45 stores the highest sensed "peak positive voltage" that passes through it and outputs a signal that "corresponds to the peak positive voltage sensed by the peak detector 45." Ex.1018, 12:5-14. That "peak positive voltage" is also provided to the differential amplifier 46, which amplifies the difference between the peak voltage value and the voltage generated across resistor 42. Ex.1018, 12:14-16. The difference is then sent to comparator 47 to compare the difference with ground voltage, and turns on the LED circuit to indicate proper alignment only when the voltage generated at the resistor 42 is evaluated to be greater than the "peak value." Ex.1018, 12:21-26.

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[10] Wang states that the "[d]ue to the symmetric AC current on the primary coil 9" the resistor 42 receives half of the current through the primary coil. Ex.1018, 11:20-24. The resistor 42 and other components in Wang's alignment indicator are nevertheless monitoring AC voltage. Ex.1003¶160. As Wang discloses, the AC current on the primary coil 9 is "symmetric," so one-half of the primary coil's AC current (or DC current) is nevertheless reflective of the AC voltage applied to the primary coil. *Id*.

Therefore, Wang discloses "a back telemetry receiver" (*e.g.*, resistor 42, low-pass amplifier 43, peak detector 45, differential amplifier 46 and/or comparator 47 in alignment indicator 40) "for monitoring the magnitude of the ac voltage at the primary coil" (*e.g.*, monitoring voltage generated at resistor 42 by AC current that flows through primary coil 9). Ex.1003¶¶159-61.

As explained (§V.E.2), a POSA would have found it obvious to use Wang's alignment circuitry to determine whether the coils of the external charger and the implanted device are properly aligned in implementing Holsheimer's system as modified by Munshi. Ex.1003¶162. Holsheimer, Munshi, and Wang are all analogous systems that concern implantable electrical stimulation systems, and Munshi and Wang are directed to solving the same exact problem in that both concern advantageous ways of noninvasively recharging an implanted battery. *Id*. Munshi notes that it is beneficial for the external and implanted coils to be properly aligned to "maximize[]" charging current (Ex.1005, 12:67-13:1) and Wang provides the alignment circuitry that can detect when the coils are properly aligned (*see, e.g.*, Ex.1018, 11:13-17). Accordingly, a POSA would have been motivated to incorporate Wang's beneficial alignment detection circuitry in Munshi's external charger in implementing Holsheimer's system to provide a mechanism that indicates to the patient or user when the coils are properly aligned and charging efficiency is maximized. Ex.1003¶162.

k) [22.j]: "wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored"

Wang teaches that its system "can be tuned so that the amplitude of the AC current through the primary coil 9 decreases when the primary coil 9 is not properly aligned with secondary coil 10." Ex.1018, 11:30-34. As Wang explains, the magnitude of the current through the primary coil "***depends on the power draw of the load on the secondary coil*** and the proximity and orientation of the primary coil 9 to the secondary or receiving coil 10" Ex.1018, 11:24-27, 11:34-37, Fig. 5. Thus, if the primary and secondary coils are misaligned, the amplitude of the current on the primary coil decreases due in part to the reflected impedance from the secondary coil. Ex.1003¶163. And, as discussed (*see* §V.E.3.j), the alignment indicator 40 uses the current flow through primary coil 9 to generate a voltage at resistor 42 and compare it with a "peak voltage." Accordingly, by monitoring the current through the primary coil, the alignment indicator is effectively monitoring the reflected impedance from the secondary coil. Ex.1003¶¶64, 163.

Therefore, Wang discloses "reflected impedance" (*e.g.*, current through primary coil that depends on the" power draw on the secondary coil") "associated with energy magnetically coupled through the primary coil" (*e.g.*, AC current through primary coil 9) "is monitored" (*e.g.*, monitoring current through primary coil in the alignment indicator 40). Ex.1003¶¶64, 163.

4. Claim 23

Claim 23 depends on claim 22 and further recites "an alarm generator that generates an audible alarm signal in response to changes sensed in the reflected impedance monitored by the back telemetry receiver."

As discussed (§V.E.3.j), Wang discloses "a back telemetry receiver" (*e.g.*, resistor 42, low-pass amplifier 43, peak detector 45, differential amplifier 46 and/or comparator 47 in alignment indictor 40) to compare the voltage derived from the current through the primary coil 9 and the "peak voltage" to determine whether the coils are properly aligned. If the voltage derived from the AC current through the primary coil 9 is greater than the "peak voltage" value, then an LED circuit (or audible signal) is turned on. Ex.1018, 12:21-24. Wang teaches that an "output device" other than an LED circuit, such as one that produces an "audible signal," can instead be used to indicate alignment. Ex.1018, 5:20-23 ("visual and/or ***audible signal***…indicat[es] proper alignment"), 11:28-31 ("…LED circuit 48 or ***other output device***...indicate[s] proper positioning"), 11:56-63, 11:63-67, 12:21-24, 14:20-24.

As discussed (§V.E.3.k), by monitoring the current through the primary coil—which changes based on the "power draw from the secondary coil"—Wang's "back telemetry receiver" is effectively monitoring the reflected impedance from the secondary coil. Therefore, Wang discloses "an alarm generator that generates

an audible alarm signal" (*e.g.*, an "output device" provides an "audible signal") "in response to changes sensed in the reflected impedance" (*e.g.*, when the voltage derived from the current through the primary coil becomes greater than the peak value) "monitored by the back telemetry receiver" (*e.g.*, monitored by resistor 42, low-pass amplifier 43, peak detector 45, differential amplifier 46 and/or comparator 47 in alignment indictor 40). Ex.1003¶¶164-65.

A POSA would have been motivated to incorporate Wang's teachings of using an audible signal to indicate proper alignment of the coils because it would be beneficial for a patient or other user to know when the coils are properly aligned so that charging efficiency can be maximized. Ex.1003¶166. Because of the similarities between Holsheimer, Munshi, and Wang, a POSA would have known the combination yielding the structure as claimed would have worked as expected. Ex.1003¶70.

5. Claim 24

Claim 24 depends on claim 23 and further recites "wherein the alarm generator broadcasts a first audible tone when the primary coil is misaligned with the secondary coil, and the first audible tone stops the broadcast when the primary coil is properly aligned with the secondary coil."

Wang teaches an LED circuit turns a light on to indicate proper positioning between the primary coil in the external device and the secondary coil in the

implanted device. Ex.1018, 11:28-31 ("Alignment indicator 40 provides a light emitting diode (LED) in LED circuit 48 or other output device to indicate proper positioning of respect to implant with respect to implanted device 14."). Wang also teaches that instead of or in addition to a visual signal, multiple "audible indications" can used to indicate alignment. Ex.1018, 14:21-24. One way of using the plurality of "audible indications" is to sound an "audible signal" when the coils are properly aligned, as disclosed in Wang. Ex.1018, 5:20-23; *see also id*., 11:28-31, 11:63-67, 12:21-24, 14:20-24. Another obvious option would be to use a first audible signal to indicate misalignment of the coils and a second, different audible signal to indicate their alignment. Ex.1003¶168. A third option would be to use an audible signal only to indicate that the coils are misaligned. *Id*. A POSA would have considered any of these options a matter of mere design choice in implementing Wang's alignment indicator. *Id*. A POSA would have been motivated and found it obvious to combine Holsheimer, Munshi, and Wang for the same reasons discussed above (§V.E.4).

VI. NO SECONDARY CONSIDERATIONS EXIST

As described above, the presented grounds of unpatentability render obvious each of the Claims. No secondary indicia of non-obviousness exist having a nexus to the '280's putative invention contrary to that conclusion. Petitioner reserves its right to respond to any assertion of secondary indicia of non-obviousness advanced

by PO. Ex.1003¶169.

VII. CONCLUSION

Petitioner respectfully submits the evidence presented in this Petition establishes a reasonable likelihood Petitioner will prevail in establishing the Claims are unpatentable, and requests Trial be instituted. Ex.1003¶¶170-71.

VIII. STANDING (§42.104(a))

Petitioner certifies the '280 is available for IPR and Petitioner is not barred or estopped from requesting IPR of the '280 claims. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '280. The '280 has not been the subject of a prior IPR by Petitioner or a privy of Petitioner.

Petitioner certifies this IPR petition is timely filed as it was filed less than one year after December 9, 2016, the date Petitioner was first served with a complaint alleging infringement of a '280 patent claim. *See* §315(b).

The Director is authorized to charge the fee specified by §42.15(a) to Deposit Account No. 50-1597.

IX. PETITIONER'S MANDATORY NOTICES (§42.8(b))

A. Real Party in Interest (§42.8(b)(1))

The real party in interest of this petition is Petitioner Nevro Corp.

B. Other Proceedings (§42.8(b)(2))

1. Patents and Applications

According to PAIR, the '280 patent is currently assigned to Boston Scientific Neuromodulation Corporation.

The '280 patent is a continuation of the application that became U.S. 6,516,227 ("'227 patent"). U.S. Patent Nos. 7,496,404; 7,769,462; and 7,801,615 claim priority back through the application that became the '280 patent.

While not directly related to the '280 patent, U.S. Patent Nos. 7,177,690 and 8,918,174 claim priority back to the '227 patent. U.S. Appl. No. 14/536,672, which is pending, claims priority to the application that became the '227 patent.

2. Related Litigation

The '280 patent has been asserted against Petitioner in *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, Civil Action No. 16-1163-GMS in the District of Delaware.

3. Patent Office Proceedings

The '280 patent is the subject of IPR2017-01811, filed by Petitioner concurrently with this Petition.

C. Lead and Backup Counsel (§42.8(b)(3))

Lead Counsel is Ching-Lee Fukuda (Reg. No. 44,334, clfukuda@sidley.com, 212-839-7364) at the address: Sidley Austin LLP, 787 Seventh Avenue, New York, New York 10019. Backup Counsel are Thomas A.

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D. Service Information (§42.8(b)(4))

Petitioner consents to electronic service by email at: clfukuda@sidley.com, tbroughan@sidley.com, sharon.lee@sidley.com, jwright-PTAB@skgf.com, and blee-PTAB@skgf.com.

Dated: July 21, 2017

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[11] Petitioner will file a motion for Sharon Lee to appear *pro hac vice* according to the Board's orders and rules.

CERTIFICATE OF COMPLIANCE

I hereby certify that this petition complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 13,972 words (as determined by the Microsoft Word word-processing system used to prepare the petition), excluding the parts of the petition exempted by 37 C.F.R. § 42.24.

Dated: July 21, 2017

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of July, 2017, a copy of this Petition, including all attachments, appendices and exhibits, has been served in its entirety by overnight mail on the following counsel of record for patent owner:

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