Paper No. 1
Filed: July 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,

Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,

Patent Owner.

Case No. IPR2019-01313

U.S. Patent No. 7,496,404

Petition for *Inter Partes Review of*
U.S. Patent No. 7,496,404

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Other Authorities

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 7,496,404 to Meadows et al.
1001	U.S. Patent No. 7,496,404 to Meadows et al.
1002	Prosecution History of U.S. Patent No. 7,496,404
1003	Declaration of Ben Pless
1004	U.S. Patent No. 5,501,703 (“Holsheimer”)
1005	U.S. Patent No. 5,411,537 (“Munshi”)
1006	U.S. Patent No. 4,197,850 (“Schulman”)
1007	U.S. Patent No. 5,702,431 (“Wang”)
1008	IPR2017-01812, Paper No. 79
1009	U.S. Patent No. 5,330,515 (“Rutecki”)
1010	“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”)
1011	U.S. Patent No. 5,591,217 (“Barreras ’217”)
1012	U.S. Patent No. 4,612,934 (“Borkan”)
1013	U.S. Patent No. 5,606,242 (“Hull”)
1014	U.S. Patent No. 5,563,493 (“Matsuda”)
1015	U.S. Patent No. 5,965,997 (“Alwardi”)
1016	U.S. Patent No. 6,026,328 (“Peckham”)
1017	U.S. Patent No. 5,73,313 (“Barreras ’313”)
1018	U.S. Patent No. 5,948,006 (“Mann ’006”)
1019	U.S. Patent No. 6,609,031 (“Law”)
1020	Feb. 9, 2018 Deposition Transcript of Jonathan C. Werder (Redacted)
1021	Mar. 2, 2018 Deposition Transcript of Carla Mann Woods (Redacted)

1022	Jul. 26, 2018 Deposition Transcript of Adam Lipson
1023	May 25, 2018 Deposition Transcript of Paul Meadows
1024	May 30, 2018 Deposition Transcript of David Peterson (Redacted)
1025	May 23, 2018 Deposition Transcript of Joey Chen
1026	Declaration of Adam Lipson, M.D. (IPR2017-01812) (Redacted)
1027	U.S. Patent No. 6,134,470 (“Hartlaub”)
1028	U.S. Patent No. 3,370,203 (“Kravitz”)
1029	U.S. Patent No. 5,909,103 (“Williams”)
1030	U.S. Patent No. 4,082,097 (“Mann ’097”)
1031	U.S. Patent No. 6,185,452 (“Schulman ’452”)
1032	July 13, 2018 Deposition Transcript of Ronald D. Berger, M.D.
1033	U.S. Patent No. 4,041,955 (“Kelly”)
1034	U.S. Patent No. 5,565,005 (“Erikson”)
1035	U.S. Patent No. 5,789,900 (“Hasegawa”)
1036	U.S. Patent No. 3,409,802 (“Savage”)
1037	U.S. Patent No. 3,389,325 (“Gilbert”)
1038	U.S. Patent No. 5,324,310 (“Greeninger”)

I. INTRODUCTION

Nevro Corp. ("Petitioner") submits this petition for *inter partes* review of claims 1-5, 7, 9 and 11-17 ("Claims") of USP 7,496,404 ("'404 patent" or "'404") (Ex.1001), assigned to Boston Scientific Neuromodulation Corporation ("PO"). The '404 is a continuation of the application for USP 6,895,280 ("'280 patent" or "'280"), certain claims of which the Board found unpatentable in IPR2018-01812. IPR2017-01812, Paper No. 79 ("FWD" or "Ex.1008"). In fact, during the '404's prosecution, the Examiner rejected issued claims 1-5 as obvious variations of certain '280 claims, including claims 22-24 and 27, which the Board has already determined are unpatentable. Ex.1002, 297-98, 321; Ex.1008, 4. To overcome the Examiner's rejection, PO submitted a terminal disclaimer with respect to the '280 and its parent, USP 6,516,227 ("'227 patent" or "'227"). Ex.1002, 356-58.

On February 1, 2019, the Board found claims 8, 18, 22-24 and 27 of the '280 unpatentable. Ex.1008, 4. For many of the same reasons identified in the FWD, the Claims here are likewise unpatentable over the presented prior art—including art not considered by the Examiner. Accordingly, the Board should institute trial and cancel the Claims as obvious under §1031.

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

II. COMPLIANCE WITH IPR REQUIREMENTS

A. Certification of Standing (37 C.F.R. §42.104(a))

Nevro certifies the ’404 is available for IPR and Petitioner is not barred or estopped from requesting IPR of the ’404’s claims. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the ’404. The ’404 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 July 19, 2018, the date Petitioner was first served with a complaint alleging infringement of a ’404 claim. *See* §315(b).

B. Mandatory Notice (37 C.F.R. §42.8)

1. Real Party-in-Interest

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

2. Related Proceedings

According to PAIR, the ’404 patent is currently assigned to Boston Scientific Neuromodulation Corporation.

The ’404 patent is a continuation of the application that became the ’280 patent. The ’280 patent is a continuation of the application that became the ’227 patent.

U.S. Patents 7,769,462 and 7,801,615 claim priority back through the application that became the ’404 patent. While not directly related to the ’404

patent, U.S. Patents 7,177,690, 8,918,174 and 9,907,957 claim priority back to the ’227 patent.

The ’280 patent was the subject of IPR Nos. IPR2017-01812 and IPR2017-01920 in which the Board issued a final written decision finding claims 8, 18, 22-24, and 27 unpatentable. The Board’s Final Written Decision on IPR2017-01812 is currently on appeal to the Federal Circuit. Petitioner has separately filed an IPR petition on U.S. Patent 7,177,690 (IPR2019-01216).

The ’404 patent has been asserted against Petitioner in *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp*., Civil Action No. 16-644-CFC in the District of Delaware.

The ’404 patent is not subject to any proceedings filed in the Patent Office.

3. Counsel and Service Information

Lead Counsel	Backup Counsel
Ching-Lee Fukuda Reg. No. 44,334 SIDLEY AUSTIN LLP 787 Seventh Ave. New York, NY 10019 clfukuda@sidley.com (212) 839-7364	Sharon Lee *Pro Hac Vice* to be Requested SIDLEY AUSTIN LLP 1501 K Street, N.W. Washington, D.C. 20005 sharon.lee@sidley.com (202) 736-8510 Ketan Patel *Pro Hac Vice* to be Requested SIDLEY AUSTIN LLP 787 Seventh Ave. New York, NY 10019 ketan.patel@sidley.com (212) 839-5854 Jon Wright Reg. No. 50,720 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 New York Avenue, N.W. Washington, D.C. 20005 jwright-PTAB@skgf.com (202) 772-8651

Nevro consents to service via electronic mail at clfukuda@sidley.com, sharon.lee@sidley.com, ketan.patel@sidley.com, and jwright-PTAB@skgf.com.

C. Fees

The Director is authorized to charge any fees due during this proceeding to Deposit Account No. 50-1597.

D. Service on Patent Owner

Pursuant to 37 C.F.R. §42.105(a) and the Certificate of Service, the petition and exhibits have been served on the correspondence of record for the '404.

III. IDENTIFICATION OF CHALLENGED CLAIMS

Petitioner challenges claims 1-5, 7, 9 and 11-17 as unpatentable based on the following §103 grounds, none of which is redundant.

Ground 1: Holsheimer, Munshi, Schulman, and Wang render claims 1-5 obvious;

Ground 2: Holsheimer, Munshi, and Schulman render claims 7, 9 and 13-17 obvious;

Ground 3: Holsheimer, Munshi, Schulman, and Rutecki render claims 11-12 obvious.

In support of the proposed grounds of rejection, the declaration of technical expert Ben Pless is attached (Ex.1003). Mr. Pless has over 25 years of experience developing and bringing to market implantable medical devices. Ex.1003¶¶5-10.

IV. OVERVIEW AND BACKGROUND IN THE ART

E. The '404 Patent

The '404, like the '280, describes a rechargeable spinal cord stimulation ("SCS") system but adds battery management/protection circuitry. *See* Ex.1001, claim 7. SCS systems are implantable medical devices used to deliver electrical stimulus to portions of a spinal cord for treating chronic pain and other ailments.

SCS was first performed in 1967, and SCS systems have existed since the 1970s. Ex.1010, 30-31; Ex.1003¶41.

By the late 1990s, SCS systems were widely available. *See* Ex.1010, 31-32. By 1999, SCS was "a well accepted clinical method for reducing pain…." Ex.1001, 1:28-29. There were two types of systems. The first included a fully "implantable pulse generator" (IPG) with an internal power source connected to detachable implanted lead wire electrodes.[2] Ex.1001, 1:25-30; Ex.1011, 1:16-25. The IPG generated electrical pulses to be delivered to electrodes placed along spinal cord. Ex.1001, 1:30-35. The second also delivered stimulation through implanted leads but used radio frequency ("RF") signals between an implanted, passive receiver and an external transmitter placed over the site of the receiver. Ex.1011, 1:49-59; Ex.1003¶42.

Like the '280, the '404 purports to improve SCS systems by combining known features into one system. Ex.1001, 2:31-48. The '404 claimed SCS system "includes a replenishable power source…that may be recharged using transcutaneous power transmissions between antenna coil pairs [as well as an] external charger unit, having

[2] Analogous IPG systems, such as cardiac pacemakers, were similarly structured. *E.g.*, Ex.1005, 1:29-31; Ex.1010, 31 (describing SCS as a "nerve pacemaker").

its own rechargeable battery [which] can be used to charge the IPG replenishable power source." Ex.1001, Abstract; *id*., 2:62-66.

The '404 claims are directed toward this purportedly inventive combination, reciting an SCS system that includes "an [IPG]...a replenishable power source...an external power source" along with well known "power source protection circuitry" that allegedly conserve power resources and ensure safe operation in low voltage environments. Ex.1003¶¶36-38.

F. Prosecution History Overview

The '404 application, filed on December 10, 2004, claims priority to U.S. Application 10/307,098 (issued as the '280) which itself claims priority to U.S. Application 09/626,010 (issued as the '227) filed July 28, 2000. Ex.1001, 1:4-11. These applications all claim priority to a provisional application filed July 27, 1999. *Id*. For this proceeding, Petitioner assumes the '404's priority date is July 27, 1999.

While the '404 claims the "novel" addition of a rechargeable power source to an SCS system, the Examiner found such features in the prior art. Ex.1002, 298-99. For example, in a Non-Final Rejection rejecting pending prosecution claims 1-4 and 8, the Examiner found the prior art "disclose[s] an external power source comprising charge and control unit 20 and a power amplifier comprising power source 62." Ex.1002, 298-99. Further, prior art "[c]oil 19 provides a primary coil and coil 18 provides a secondary coil [and] [d]iodes D1 and D2 provide elements of a rectifier

circuit." *Id*. The Examiner concluded "[i]t is inherent control circuit 25 in addition to other elements of the implanted device comprise an integrated circuit." *Id*.

The Examiner also rejected claims 1-7 (issued claims 1-5) as unpatentable over '280 claims 7, 9, 21-25, 27, 28 and 30 for double patenting. Ex.1002, 297-98 ('280 claims and rejected claims "are not patentably distinct from each other because both sets of claims are directed toward obvious variations of an external power source, primary coil and a rechargeable power source").[3] The Examiner allowed pending prosecution claims 9-20 (issued claims 7-18). The reasons for allowance noted the art did not disclose: (1) "[i]nitiating a power-on-reset if the voltage of a rechargeable power source rises above a reset threshold" and (2) "reinitiating stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation…." Ex.1002, 300.

After twice failing to overcome these rejections (Ex.1002, 305-08, 318-21, 329-32), the applicant (1) submitted a terminal disclaimer, (2) cancelled pending dependent claims 4-5, and (3) amended independent claim 1 to include the limitations of claims 4 and 5. Ex.1002, 353-55. The Examiner allowed these claims noting the amended claims require an SCS system "having an electrode array and a

[3] The FWD found claims 22-24 obvious in light of Holsheimer, Munshi, and Wang, each of which is at issue in this Petition. Ex.1008, 73-97.

power amplifier, and comprising circuit elements to provide an alternating current in a secondary coil to initiate a power-up sequence for a powered-down [IPG] to recharge a replenishable power source in the [IPG] as claimed [which were] not taught nor suggested by the prior art of record." Ex.1002, 375.

G. Known Technologies

By July 1999, both SCS systems and IPGs using replenishable power sources were well-known. Numerous references—in addition to those the Examiner cited—disclose these features. Ex.1005, Abstract ("[A] bioimplantable device…may be operated on a single rechargeable cell…[and] recharged by magnetic induction."); Ex.1011, Abstract ("[T]he capacitive power source is recharged…via an external, RF coupled device…."); Ex.1012, 1:23-26 ("The receiver may be powered internally by…a rechargeable battery pack…."); Ex.1006, 1:66-2:1 ("a charging circuit is provided for recharging the battery").

Even the ancillary features the Examiner found distinguished the '404 claims over the prior art were well-known by July 1999. For example, although the Examiner found the prior art did not disclose "[i]nitiating a power-on-reset if the voltage of a rechargeable power source rises above a reset threshold" (Ex.1002, 375), this technology was commonly known. Ex.1006, 8:2-10 ("[W]hen subsequently the voltage to the memory is increased to a level at least sufficient for the memory's proper operation, preselected parameters are loaded [and] used when

the rest of the HTS circuitry is reconnected to the powering sources...to assure that the circuit produces [safe[stimulating pulses….”); Ex.1013, 10:14-16 (“ASIC 32 is provided with a power-on reset circuit…which generates a reset impulse signal…every time the power supply voltage is applied….”); Ex.1014, 9:35-39 (“When the power source voltage exceeding 4V is supplied…the microprocessor [receives the power on reset signal E1 from the resetting circuit and] executes the initialization....”); Ex.1015, 28:34-40 (describing “conventional circuitry” that “detects that the voltage has fallen below a predetermined voltage level [and then] generates a signal referred to as Power On Reset….”).

Although the Examiner determined the prior art did not disclose “reinitiating stimulation if the [rechargeable power source voltage] rises above the minimum level for stimulation” (Ex.1002, 375), this too was well-known. Ex.1006, Abstract (“[W]hen the voltage level reaches the selected level...the stimulating circuitry [is] reconnected….”); *id*., 3:19-21 (“Once the battery voltage exceeds the desired level, all the rest of the circuits are again reactivated.”); Ex.1011, 8:59-63 (“[A]s soon as voltage regulator 32 develops an output voltage VDD which exceeds low threshold comparator value 42, the [IPG] can immediately begin delivering electric stimulating pulses to the targeted tissue.”); Ex.1016, 19:26-32.

The Examiner allowed claims 1-6 because they recite “an electrode array and a power amplifier, and circuit elements to provide an alternating current in a

secondary coil to initiate a power-up sequence for a powered-down [IPG] to recharge a replenishable power source in the [IPG]" (Ex.1002, 375), but such technology was well-known. Ex.1011, 3:11-17 ("[W]hen voltage Vm is less than a predetermined reference voltage, the implantable stimulator 'goes to sleep,'…The [IPG] is 'woken up' or activated upon receipt of RF coupled commands in a certain sequence."); Ex.1006, 4:17-21 ("HTS 10 is assumed to include an energy-receiving coil…into which energy may be coupled through the skin…from an energy-transmitting coil…which is driven by an external unit…."); Ex.1031, 4:27-35.

Thus, the claims are 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.

H. Person of Ordinary Skill in the Art

The applicable POSA would have had 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.1003¶¶54.

V. CLAIM CONSTRUCTION

Claims "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under §282(b), including construing the claim in accordance with the ordinary and customary meaning of such

claim as understood by [a POSA] and the prosecution history pertaining to the patent." §42.100(b). Claim construction requires consideration of "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citations omitted). Absent any special definitions, claim terms receive their "ordinary and customary meaning" as would be understood by a POSA at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

I. "alignment between the primary and secondary coils" (Claim 1)

In the '280 IPR, PO proposed a narrow construction for this term: "achieving a spatial arrangement of the primary and secondary coils such that charging efficiency is optimized based on measurement of an electrical parameter." Ex.1008, 12. In the FWD, under the broadest reasonable interpretation ("BRI") standard, the Board rejected PO's proposal and construed this term as "achieving a relative position between the primary and secondary coils to permit energy transfer." Ex.1008, 13.

For this Petition, this term need not be construed because, as described below (§VI.A.6.o), the prior art discloses this limitation under either construction.

J. "means for using household AC power to recharge the rechargeable power source in the power source charger" (Claim 3)

Petitioner construes this term as a mean-plus-function term under ¶112(6). The claimed function is "using household AC power to charge up the rechargeable power source in the power source charger" and the corresponding structure includes (1) a charging base station that is either separate from or incorporated in an external charger, (2) an AC power line, and (3) their literal equivalents. *See, e.g.*, Ex.1001, 4:62-65 ("The external portable charger of the IPG system includes: (a) a second rechargeable battery; (b) a recharging base station that recharges the second rechargeable battery from energy obtained from line ac power…."); 40:64-41:4 ("The battery 277 in the charger 208, in the preferred embodiment, comprises a rechargeable battery…When a recharge is needed, energy 293 is coupled to the battery 277 via the charging base station 210 in conventional manner. The charging base station 210, in turn, receives the energy it couples to the battery 277 from an AC power line 211."), Figs. 8, 9A, 9C (elements 210, 211).

K. "external trial stimulator" (Claim 12)

In the '280 IPR, PO proposed the district court's construction: "pulse generator externally-worn by a patient capable of being used outside of the operating room that is used temporarily for evaluation purposes before implantation of the IPG." Ex.1008, 21-22. As explained below (§VI.C.4.a), and as the Board determined

in the FWD (Ex.1008, 22), the prior art teaches this limitation under this construction.

L. "means for non-invasively recharging the replenishable power source through the skin" (Claim 15)

The claimed function is "non-invasively charging the replenishable power source" and the corresponding structure is an external power source (Ex.1001, Fig. 9A, 277), power amplifier (*id*., Fig. 9A, 275), an external coil (*id*., Fig. 9A, 279), an internal coil (*id*., Fig. 9A, 680) and their literal equivalents. *Id*., 41:6-12.

The '404 describes that energy from external battery 277 is transcutaneously transferred to implanted rechargeable power source 180 using a power amplifier 275. Ex.1001, 40:49-41:2. The '404 further discloses that the charging station sends alternating energy to coil 279 (located outside the patient) through the patient's skin such that it is received by another coil 680 and then used to charge the implanted battery 180, as shown in Figure 9A below:

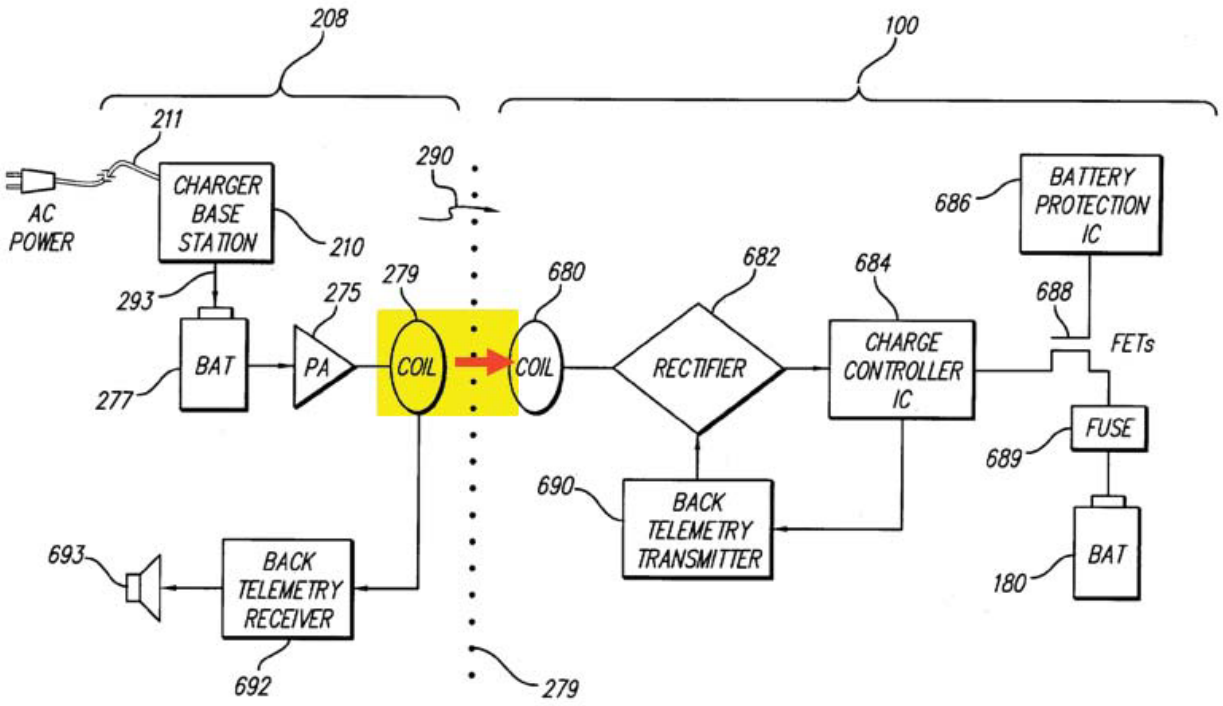


FIG. 9A

Id., 41:6-12.

Accordingly, the components required to recharge the IPG's battery are the external power source 277, power amplifier 275, and coils 279 and 680. Thus, the corresponding structure for a "means for non-invasively recharging the replenishable power source through the skin" is a power source, power amplifier, and two coils placed inside and outside the patient.

VI. THE CHALLENGED CLAIMS ARE UNPATENTABLE

M. Ground 1: Holsheimer, Munshi, Schulman, and Wang Render Claims 1-5 Obvious

1. Holsheimer Overview

Holsheimer issued in 1996 and is §102(b) prior art. Ex.1003¶65. Holsheimer describes an SCS IPG that delivers pulses to a detachable implantable electrode array. Ex.1004, Fig. 1, 3:60-62 ("[IPG] 14 preferably is a [Medtronic] ITREL IIR…with provisions for multiple pulse outputs…."). Holsheimer's system can deliver stimulation pules 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 [SCS] by changing the pulse parameters of at least two separate voltage or current controlled sources." Ex.1004, 1:8-13; *id.*, 1:41-52, 2:24-26. 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.

2. Munshi Overview

Munshi issued in 1995 and is §102(b) prior art. Ex.1003¶¶66-68. Munshi describes techniques for transcutaneously charging a rechargeable power source in a "bioimplantable device" by electromagnetic induction. Ex.1005, 4:3-10. While

Munshi describes its invention primarily in the context of a pacemaker/defibrillator, the invention is applicable to "any other bioimplantable device," including "nerve…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 for transcutaneously receiving electromagnetic energy from another coil in an external charger. Ex.1005, 10:21-26, 10:32-37. The external charger is 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.

3. Schulman Overview

Schulman issued in 1980 and is §102(b) prior art. Ex.1003¶¶69-71. Schulman describes "an implantable human tissue stimulator with a volatile memory." Ex.1006, Abstract. Schulman's invention alleviates pain "by applying stimulating pulses to the nerves proximal to the damaged area." Ex.1006, 1:40-43. Schulman describes circuitry to prevent "the stimulating circuitry from producing pulses as a function of unknown parameters in the memory as a result of inadequate power to the memory from a rechargeable power source…." Ex.1006, Abstract. This protection circuitry "includes voltage sensors, so that when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery and only the memory is powered." *Id*. "If the voltage from the battery first drops, so that insufficient power is supplied to the memory and thereafter

rises...the rest of the circuitry, including the stimulating circuitry, [is] reconnected to the battery" and powered up. *Id*.

4. Wang Overview

Wang issued in 1997 and is §102(b) prior art. Ex.1003¶¶72-77. Wang describes a "transcutaneous energy transmission device…for charging rechargeable batteries in an implanted medical device…." Ex.1007, Abstract. Wang teaches "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." Ex.1007, 5:13-15. Therefore, Wang's system includes "an alignment circuit and indicator…to indicate whether the coils are properly aligned." Ex.1007, 5:15-17; Ex.1003¶¶76.

5. Motivation to Combine

Although Holsheimer does not expressly describe its IPG power source, a POSA would have understood that it—like all implantable, electrically operated devices—needs power to operate, such as from a battery. Ex.1003¶78. A known disadvantage of battery-powered implantable devices, however, was the service life of the device being limited to the battery's life. *Id*.; *see, e.g.*, Ex.1017, 2:20-21 ("[T]he service life of these battery powered [IPGs] is limited to the battery life."); Ex.1018, 1:35-38; Ex.1019, 1:44-46. That is, once the battery was depleted, the device would need to be explanted to replace the battery, causing more patient trauma and higher medical costs. Ex.1003¶78; Ex.1017, 1:23-30, 2:22-27; Ex.1018,

1:38-41; Ex.1019, 1:46-48. As the Board previously recognized, a POSA implementing Holsheimer would have been motivated to address these known concerns. Ex.1008, 75. Ex.1003¶79; MPEP §2143(F).

Munshi addresses this problem, teaching a "rechargeable power source" incorporated into a "bioimplantable battery-powered device" that is recharged through the patient's skin. Ex.1005, 4:3-10; Ex.1003¶79. Accordingly, a POSA would have been motivated to include Munshi's rechargeable power source in Holsheimer's IPG. Ex.1003¶79.

Munshi also suggests the implanted "battery should not be completely discharged," but does not provide details regarding *how* to guard against complete discharge other than signaling the user to recharge. Ex.1005, 9:7-12. Schulman teaches a technique for avoiding complete battery discharge and preserving safe functionality in low-voltage scenarios. Schulman teaches doing so via a rechargeable battery with voltage protection circuitry coupled to a "battery charging circuit…whose function is to recharge the battery when recharging energy is received…." Ex.1006, Abstract, 4:13-17. Accordingly, when the battery may be completely (or nearly completely) discharged, a POSA would have been motivated to combine Munshi's rechargeable battery with Schulman's protection circuitry. Ex.1003¶80.

Munshi acknowledges that, to transmit power from an external device to an IPG, the transmitting and receiving coils need to be in "close proximity." Ex.1005, 12:54-57. Accordingly, a POSA implementing Munshi's system would have looked for advantageous ways of detecting proper alignment between coils. Ex.1003¶81. Wang addresses this problem, teaching "an alignment circuit and indicator…to indicate whether the coils are properly aligned." Ex.1007, 5:15-17; Ex.1003¶81. As the Board previously determined, a POSA would have been motivated to use Wang's alignment circuitry in the Holsheimer/Munshi external charger as Munshi expressly teaches that the external coil can be adjusted to 'find the optimum position of maximum energy transfer." Ex.1008, 92 (citing Ex.1005, 13:1-5). Further, as the Board also previously determined, this combination would have been expected to be successful due to the similarities of the Munshi and Wang systems. Ex.1008, 92; Ex.1003¶82.

Holsheimer (as modified by Munshi), Schulman and Wang describe analogous implantable electrical stimulation systems. Ex.1003¶82. Accordingly, a POSA would have known that features from these references could be combined with a high degree of predictability and that the combination would work as expected. *Id*.

6. Claim 1

a) *[1.preamble]: "A spinal cord stimulation system."*

As the Board previously determined, Holsheimer teaches this limitation. Ex.1008, 74. Holsheimer's Figure 1 depicts a "neurological stimulation system…to stimulate spinal cord 12." *E.g.*, Ex.1004, 3:53-55, Fig. 1, 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, claim 13. To the extent the preamble is limiting, Holsheimer discloses a "spinal cord stimulation system." Ex.1003¶83.

b) *[1.a]: "an [IPG] including at least one integrated circuit (IC) that when powered allows the IPG to generate electrical stimuli, the IPG having a housing"*

Holsheimer discloses an IPG. Ex.1004, Abstract (describing a "pulse generator driving a plurality of electrodes"), 3:56-57 ("The preferred system employs [IPG] 14 to produce a number of independent stimulation pulses.").

Further, Figure 1 shows IPG 14 is a self-contained device with a housing:

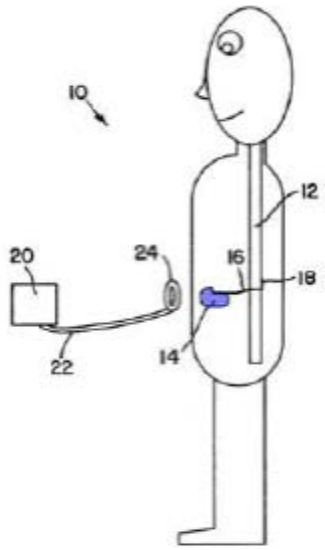


FIG. 1

Although Holsheimer does not expressly disclose an "integrated circuit…that when powered allows the IPG to generate electrical stimuli," such basic circuitry is required for the IPG to operate, and, as the Examiner noted, such "processing circuitry" is necessarily contained in a "housing" to prevent damage to the circuitry. Ex.1002, 298; Ex.1003¶85.

To the extent Holsheimer does not expressly or inherently disclose such circuitry or housing, they are taught by Munshi, which discloses an IPG "hermetically sealed" in a "can" that includes basic circuitry, such as a microprocessor, "bidirectional bus," memory 1(including both ROM and RAM), and timers. Ex.1005, Abstract, 4:27-30, 5:40-45, 49-50, Fig.1. Ex.1003¶¶86-87; Ex.1027, 13:35-40 (recognizing in an SCS system like ITREL that "[a]lthough the present invention is described in conjunction with a microprocessor-based

architecture, it will be understood that it could be implemented in other technology such as a digital logic-based, custom integrated circuit (IC) architecture"). Integrated circuits have long been recognized as "important components in the electronics industry owing to their small size, potentially low cost and ruggedness in comparison with other miniature circuitry." Ex.1028, 1:26-31. Thus, a POSA would have been motivated to incorporate the microprocessor, bus, memory, timers and other components of Munshi into integrated circuits. Munshi's microprocessor is connected to the inputs of two "stimulus pulse generators" by control lines and "transmits pulse parameter data, such as amplitude and width, as well as enable/disable and pulse initiation codes to the generators" on the respective control lines. Ex.1005, 6:9-15.

As explained (§VI.A.5), a POSA would have been motivated to incorporate Munshi's rechargeable battery into Holsheimer's IPG. This rechargeable battery provides charge for each of the recited components in the IC including the stimulator. Ex.1005, 7:4-9; Ex.1003¶80. Accordingly, a POSA would have been motivated to incorporate an IC as taught by Munshi into Holsheimer's IPG. Ex.1003¶¶80-82. 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. *Id.* A POSA could have implemented Munshi's IC in Holsheimer's IPG with a high

degree of predictability. *Id*. Therefore, Holsheimer and Munshi render obvious this limitation.

c) *[1.b]: "a replenishable power source contained within the IPG housing"*

As explained (§VI.A.6.a), Holsheimer discloses a self-contained device with a housing. Ex.1004, Fig. 1. 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. Therefore, Munshi discloses "a replenishable power source" (*e.g.*, the rechargeable battery in the implanted device). Ex.1003¶¶93-94.

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 surgical procedures required. §VI.A.5, Ex.1003¶¶80-82. Because of their similarities (*e.g.*, both are implantable stimulation systems), a POSA would have known the combination would work as expected. *Id*. A POSA could have implemented Munshi's rechargeable battery in Holsheimer's IPG with a high degree of predictability. *Id*. As the Board previously determined, a POSA "would have found it obvious to include in Holsheimer's IPG a replenishable power source that can be charged by induction through the patient's skin, as taught by Munshi."

Ex.1008, 75. Therefore, Holsheimer and Munshi render obvious this limitation. Ex.1003¶¶93-94.

d) *[1.c]: "an implantable electrode array detachably connected to the IPG…having at least two electrodes thereon"*

As the Board previously determined, Holsheimer teaches this limitation Ex.1008, 76-87.

Holsheimer discloses "[a] lead connected to the [IPG] has electrodes at the distal end corresponding to the number of channels...[and] is implanted a few mm apart from the spinal cord…." Ex.1004, 2:25-29, Abstract, 2:54-55, 3:56-59, 6:26-31, 6:66-7:1, 7:22-31, 7:37-62; Figs. 1, 19-20; claim 13. 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 at least two electrodes thereon" (*e.g.*, electrodes on the lead). Ex.1003¶95.

As the Board previously determined, these electrode arrays are detachably connected to Holsheimer's IPG. Ex.1008, 87. IPG 14 in Figure 1 shows a standard connector notch commonly used to depict lead connectors for attaching and detaching leads. Ex.1003¶96.

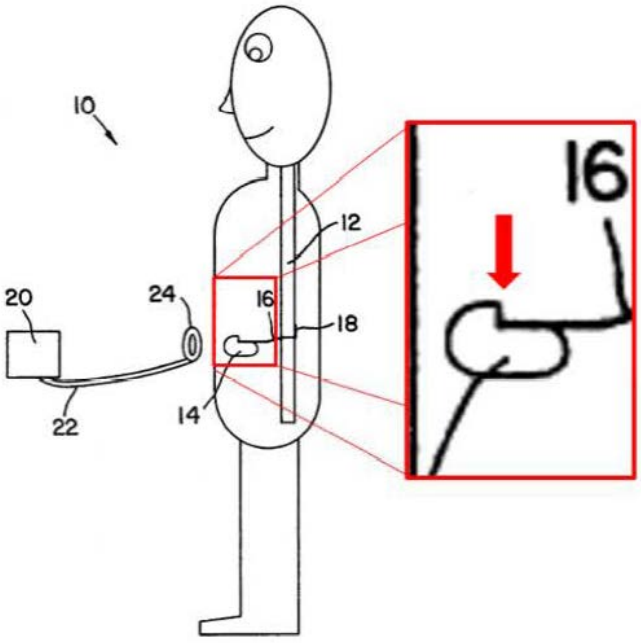


FIG. 1

Holsheimer's IPG "preferably is [a Medtronic] ITREL IIR.…" Ex.1004, 3:60-62. Medtronic's ITREL II® system, like all SCS systems, used detachable leads. Medtronic's corporate representative testified that the ITREL II includes detachable leads. Ex.1020, 9:3-6, 80:14-81:11, 141:19-143:12. One of the '404 inventors also testified that the ITREL system she utilized in 1997 included detachable leads. Ex.1021, 109:4-22. Similarly, Dr. Adam Lipson—PO's expert in the '280 IPR—testified that, beginning in 2001, he implanted ITREL I and II systems, which both utilized detachable leads. Ex.1022, 53:10–55-10.

As confirmed by the testimony of PO's experts and the named '404 inventors, ***all*** SCS systems use detachable leads. During the '280 IPR, Dr. Lipson testified that he has implanted over a thousand SCS systems and ***every SCS system***

he knew of used detachable leads. Ex.1022, 37:18-22; Ex.1026¶¶3-8. Dr. Lipson further testified he had never implanted a lead while it was attached to an IPG and that the leads are detached from the IPG in ***every*** SCS system he has received. Ex.1022, 29:19-30:13, 30:24-31:10, 34:22-35:6. Likewise, according to four named '404 inventors, at the relevant time, ***there were no known SCS systems that did not use detachable leads***. Ex.1021, 279:4-12; Ex.1021, 110:21-111:10; Ex.1024, 295:19-22; Ex.1025, 198:3-22. Accordingly, a POSA would have understood that Holsheimer discloses an SCS system with detachable leads. Ex.1003¶¶97-98; Ex.1008, 80-81.

Further, as the Board previously acknowledged, a POSA would also have understood that the SCS implantation process necessitates detachable leads. Ex.1008, 83-84, 86. During the '280 IPR, Dr. Lipson explained that since the 1990s, SCS systems were implanted in two phases—a trial phase and permanent implantation. Ex.1026¶20. For trial, typically a detached percutaneous lead is implanted in the epidural space using a cannulated needle (tube). Ex.1026¶25; Ex.1022, 27:18-28:22, 29:19-25. The needle is inserted into the patient and the lead is passed through that needle into the epidural space. *Id*. Once the leads are in place, the needle is removed by sliding it out over the lead's non-implanted "free end." Ex.1022, 29:10-14. The "free end" is then attached to an ETS for trial stimulation. Ex.1026¶¶21-22. It is impossible to implant a percutaneous lead with a

stimulator already attached because there has to be a "free end…to be able to remove the delivery needle." Ex.1022, 30:2-23.

For permanent IPGs, the same leads used for the trial may be used. Ex.1022, 37:25-38:24. In those circumstances, the implanted leads are detached from the ETS and attached to the permanent IPG. *Id*. Otherwise, the trial leads are removed and new detached leads are implanted using either the method described above or via a laminectomy for paddle leads. Ex.1026¶24; Ex.1022, 31:11-33:9. The permanent IPG is typically implanted through a second incision. Ex.1022, 32:16-19. Another tube is used to "tunnel" underneath the skin from the lead incision point to the implant site, and the "free end" of the implanted lead is passed through the tube and attached to the IPG. Ex.1022, 33:4-9, 35:7-36:5, 38:25-39:10. SCS systems have been thus implanted since the 1990s. Ex.1022, 41:4-14.

Because all known SCS systems used detachable leads and because the implantation process necessarily requires detachable leads, a POSA would have understood Holsheimer to also disclose the use of detachable leads. Ex.1003¶¶99-101; Ex.1008, 79-84.

Accordingly, a POSA would have understood that Holsheimer discloses "an implantable electrode array detachably connected to the IPG, the electrode array having at least two electrodes thereon." Ex.1003¶101.

e) *[1.d]: "wherein the electrical stimuli generated by the IPG are selectively delivered to at least one of the electrodes on the electrode array as controlled, at least in part, by electrical circuitry contained within the IC"*

As discussed (§VI.A.6.d), Holsheimer discloses an IPG wherein the electrical stimuli generated by the IPG are selectively delivered to at least one of the electrodes on the electrode array. *See* Ex.1004, Abstract. Holsheimer describes selectively delivering independently controlled pulses to the electrodes. Ex.1004, 1:45-48 ("[P]ost-operative changes in stimulation fields can be obtained by ***selective parametric changes in the pulse generator outputs***."), 2:24-26 (IPG "provides ***independently controlled voltage or current pulses***."), 3:56-59, 3:60-65, claim 15; Ex.1003¶102. A POSA would have understood that such stimulation is controlled by electrical circuitry within the IPG. Ex.1003¶¶103-04.

Further, as discussed (§VI.A.6.b), even if Holsheimer does not expressly or inherently disclose an IC that selectively delivers electrical stimuli, it would have been obvious in view of Munshi, which discloses an implanted stimulator with basic circuitry such as "microprocessor 12" connected to the inputs of two "stimulus pulse generators" by control lines to control stimulation, and that these components were commonly combined into ICs. Ex.1005, 6:9-15; Ex.1027, 13:35-40 (recognizing microprocessor-based architecture could routinely be implemented in IC architecture); Ex.1028, 1:26-31. Accordingly, a POSA would have

understood that the Holsheimer/Munshi combination renders this limitation obvious. Ex.1003¶103-04.

f) *[1.e]: "an implantable secondary coil coupled electrically to the replenishable power source"*

As the Board previously determined, Munshi teaches this limitation. Ex.1008, 87. Although Holsheimer does not expressly disclose "an implantable secondary coil coupled electrically to the replenishable power source," it would have been obvious to include one in Holsheimer's IPG in view of Munshi. *See* §VI.A.5. 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.

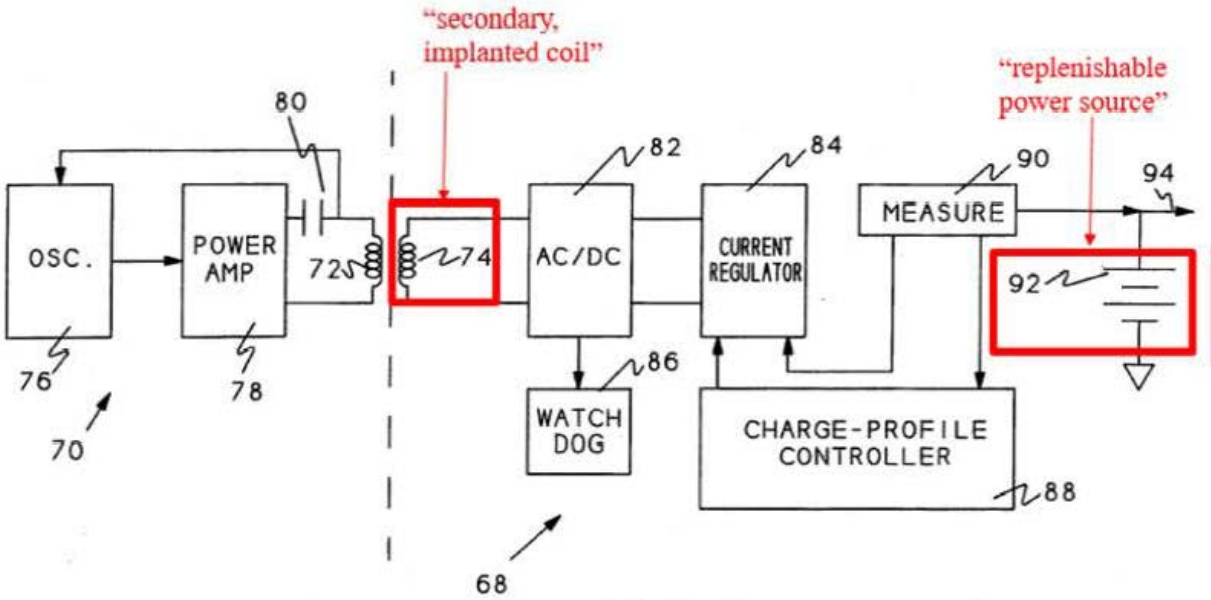


FIG. 2

Therefore, Munshi discloses "an implantable secondary coil" (*e.g.*, receiving coil 74) "coupled electrically" (*e.g.*, connected) to the "replenishable power source" (*e.g.*, rechargeable battery 92). Ex.1003¶¶105-06.

g) *[1.f]: "an external power source charger"*

As the Board previously determined, Munshi teaches this limitation. Ex.1008, 88. Munshi discloses an "external charger 70." Ex.1005, Fig. 2, 10:38-43. Munshi teaches that 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, Fig. 2, 10:20-40, 10:45-47, 10:52-61.

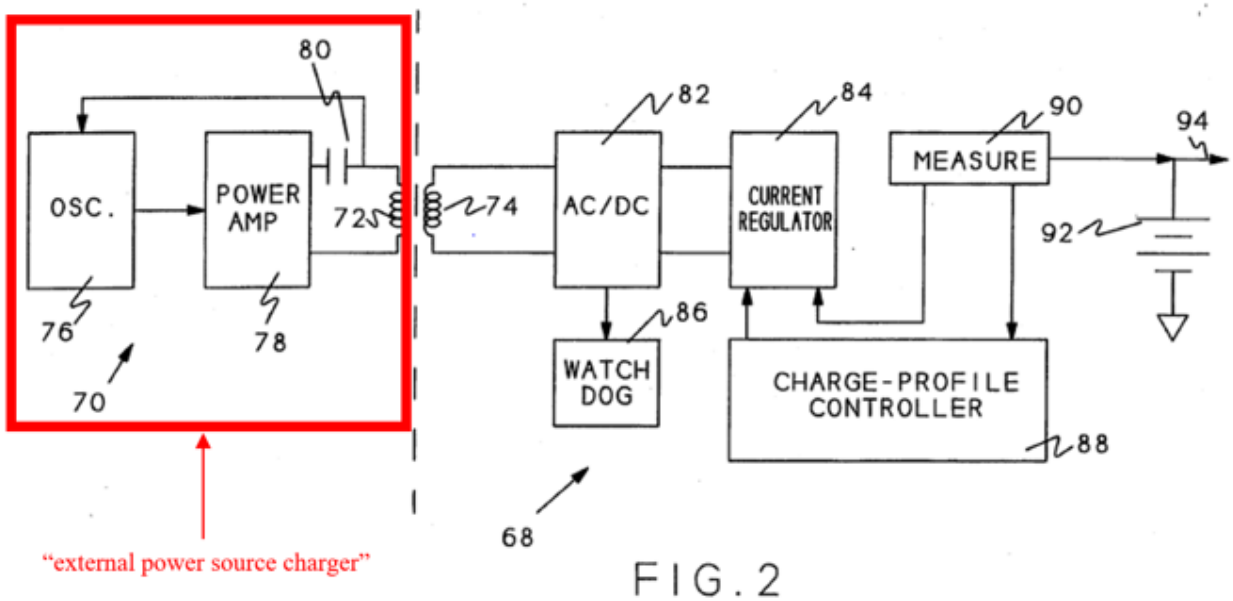


FIG. 2

Therefore, Munshi discloses "an external power source charger" (*e.g.*, external charger 70). Ex.1003¶107.

h) *[1.g]: "a primary coil"*

As the Board previously determined, Munshi teaches this limitation. Ex.1008, 88. Munshi teaches the "external charger 70" includes "an external charging coil 72," as shown in Figure 2. 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"), 10:32-37, 10:38-40, 12:54-57.

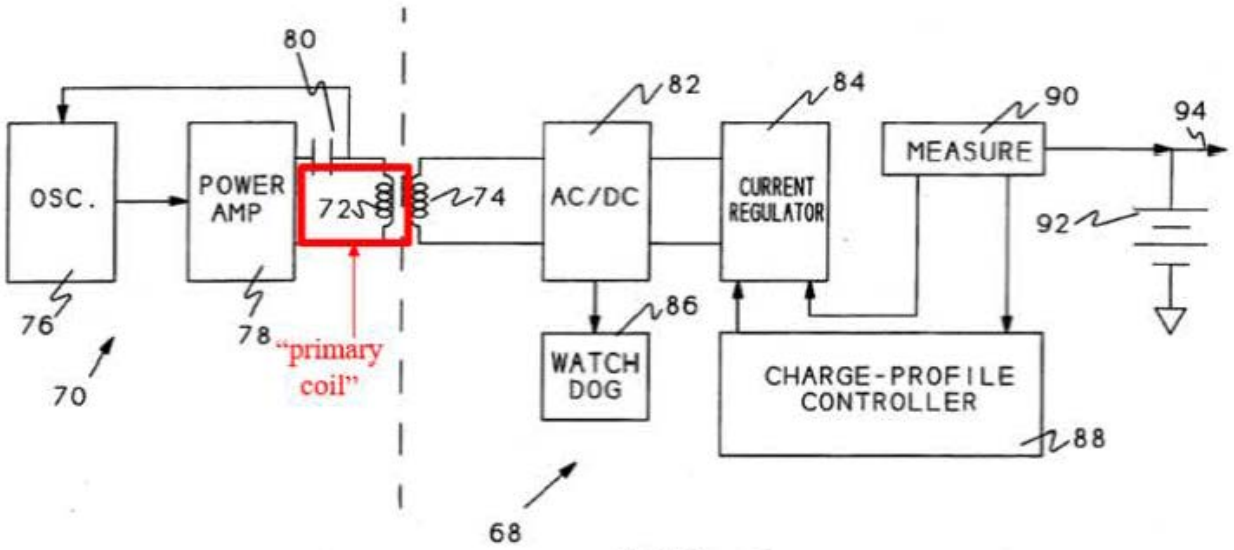


FIG. 2

Therefore, Munshi discloses "an external power source charger" (*e.g.*, external charger 70) "including: a primary coil" (*e.g.*, transmitting coil 72). Ex.1003¶108.

i) *[1.h]: "an external power source contained in the charger, electrically coupled to the primary coil"*

As the Board previously determined, Munshi teaches this limitation. Ex.1008, 88. Munshi discloses various circuitry in "external charger 70," including

"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…." Ex.1005, 10:45-47.

Therefore, Munshi discloses "an external power source" (*e.g.*, external charger 70) "including...an external power source 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¶110.

j) *[1.i]: "a power amplifier that applies alternating current derived from the external power source to the primary coil"*

As the Board previously determined, Munshi teaches this limitation. Ex.1008, 88. Munshi discloses that "external charger 70" includes an "oscillator circuit 76" that "drives the transmitting coil 72 with an alternating current" through "'power amplifier 78 which is coupled…to the external transmitting coil 72," as shown in Figure 2 below. Ex.1005, 10:38-43.

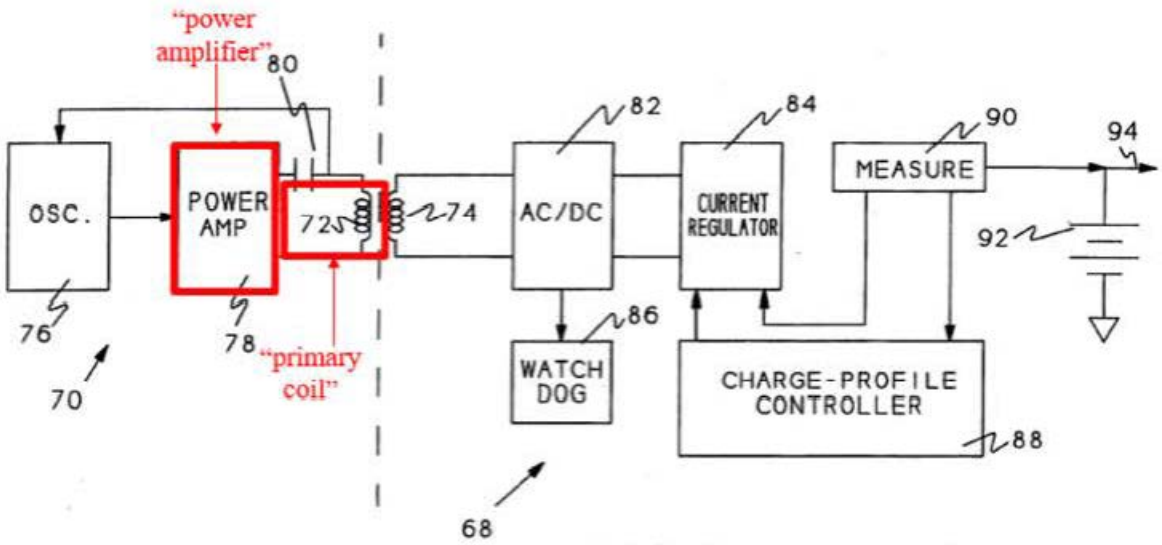


FIG. 2

As discussed (§VI.A.6.b), Munshi discloses that "[p]ower may be supplied to these circuits from…rechargeable external battery pack." Ex.1005, 10:43-47. Therefore, Munshi discloses "a power amplifier" (*e.g.*, power amplifier 78) "that applies alternating current" (*e.g.*, alternating current driven by oscillator circuit 76) "derived from the external power source" (*e.g.*, power supplied from the rechargeable battery pack) "to the primary coil" (*e.g.*, driven to the transmitting coil 72). Ex.1003¶¶111-12.

k) *[1.j]: "whereby the alternating current in the primary coil induces a magnetic field that is transcutaneously coupled to the implantable secondary coil, thereby inducing a corresponding alternating current in the secondary coil, which alternating current in the secondary coil initiates a power-up sequence for a*

powered-down IPG and recharges the replenishable power source contained in the IPG"

Munshi discloses that "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; *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, 12:54-63. Therefore, Munshi discloses "the alternating current in the primary coil" (*e.g.*, alternating current driven to the transmitting coil 72) "induces a magnetic field that is transcutaneously coupled" (*e.g*., coupled through the skin by magnetic induction) to the "implantable secondary coil" (*e.g*., input coil 74), "thereby inducing a corresponding alternating current in the secondary coil" (*e.g.*, "converting the induced AC voltage on the receiving coil 74") and "recharges 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¶113; Ex.1008, 88-89.

Although Munshi expressly discloses "inducing a corresponding alternating current in the secondary coil," it does not expressly disclose that doing so "initiates a power-up sequence for a powered-down IPG." This limitation, however, would

have been obvious to a POSA in view of Schulman. Ex.1003¶114. As discussed (§VI.A.5), Munshi teaches that "the battery should not be completely discharged in a pacemaker type apparatus." Ex.1005, 9:7-9. Due to the potential dangers associated with a completely discharged battery (*e.g.*, corruption of safe operational parameters, damage to the battery and/or damage to the patient), when used in devices where the battery may be completely (or nearly completely) discharged, a POSA would have looked to other references such as Schulman. Ex.1003¶114; Ex.1006, 2:40-44 ("If [stimulation] parameters are to be stored in volatile memory, some means must be provided [in low voltage scenarios] to either protect the memory power supply and/or, if this cannot be done, to reset the memory to prevent dangerous stimulating regimes."); Ex.1029, 1:35-42 ("It is well known that over-discharge of the lithium cell may result in dendritic or metal filaments growing from one side of the cell to the other, or across the intercalating membranes.").

Schulman contains a "volatile memory" that stores safe IPG operational parameters. Ex.1006, 1:64-2:29. Schulman describes protection circuitry that "includes voltage sensors, so that when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery," thus powering down the IPG. Ex.1006, Abstract. Because low voltage scenarios may corrupt the stored operational parameters, Schulman describes that powering down

the IPG allows the memory to continue to draw power and maintain safe function. Ex.1006, 2:30-66.

However, if the voltage "thereafter rises, as a result of recharging [through the current supplied by the secondary coil,] the rest of the circuitry, including the stimulating circuitry, [is] reconnected to the battery" and enabled. Ex.1006, Abstract; *id*., 2:67-3:2 ("If, therefore, the battery is recharged by power from an external source, when the battery level rises to a sufficiently high level, the rest of the circuits are again connected and enabled."). Accordingly, Schulman teaches an "alternating current in the secondary coil" (*e.g.*, "energy-receiving coil 28 into which energy may be coupled through the skin 12 from an energy-transmitting coil 32" (Ex.1006, 4:17-20)) that "initiates a power-up sequence for a powered-down IPG" (*e.g.*, connecting and enabling stimulation circuits if "the battery is recharged by power from an external source [and] the battery level rises to a sufficiently high level"). Ex.1003¶¶115-16.

l) *[1.k]: "a power source replenishing system housed within the IPG"*

As discussed (§VI.A.6.f), Munshi discloses an implantable secondary coil coupled to the rechargeable battery. Further, Munshi teaches that the secondary coil may be used to replenish the battery housed within the IPG. Ex.1005, 10:21-26 ("Energy 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."), 4:3-10, 10:32-37, 10:52-64, 12:54-63.

Accordingly, Munshi discloses a power source replenishing system housed within the IPG (*e.g.*, "input coil 74," "rechargeable lithium battery 92" and all circuitry in between). Ex.1003¶117.

m) *[1.l]: "a rectifier circuit that converts the alternating current induced in the secondary coil to a dc current that is applied to the replenishable power source"*

At the time, it was well known that the purpose of rectifier circuits—as the claim limitation states—is to convert alternating current into direct current. *See* Ex.1030, 4:34-56 ("AC current across winding 18 is rectified to produce a DC voltage"); Ex.1001, 41:12-14 ("Upon receipt of such ac signal…it is rectified by rectifier circuity 682 and converted back to a dc signal"); Ex.1031, 4:27-31 ("[A] coil…supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122."); Ex.1011, 6:55-57 ("The RF coupled power, which is alternating current or AC in nature, is converted by the full bridge rectifier circuit 18 into a high DC voltage."); Ex.1003¶118.

Munshi discloses "[o]n the receiving side, the system consists of an AC-to-DC convertor 82 for converting the induced AC voltage on the receiving coil 74 to DC, an efficient current regulator 84 that regulates the charging current supplied to the implantable rechargeable battery…." Ex.1005, 10:52-56. Because rectifying

circuits were commonly known AC-to-DC converters at the time (*see, e.g.*, Ex.1011, 6:55-57 ("The RF coupled power, which is alternating current or AC in nature, is converted by the full bridge rectifier circuit 18 into a high DC voltage.")), a POSA would have understood that Munshi's AC-to-DC converter was or could have been a rectifier circuit or any other circuit that converts the alternating current induced in the secondary coil to a DC current that is applied to the replenishable power source. Ex.1003¶119 (noting that most, if not all, AC-to-DC converters would have used a rectifier).

n) *[1.m]: "power source protection circuitry for controlling electrical connection and disconnection between the replenishable power source and the at least one IC included within the IPG; whereby the power source protection circuitry allows connection between the replenishable power source and the at least one IC upon transcutaneous transfer of power from the external power source to the replenishable power source"*

Munshi describes a "connection 94...from the rechargeable battery 92 to the other circuits of the implantable device 10." Ex.1005, 10:64-66. Munshi further describes that when the user initiates a transcutaneous charging operation, "[t]he watchdog circuit within the implanted device detects the presence of the activated external charging unit by detecting the induced voltage in the implanted receiver coil, and then activates all implanted circuitry related to battery charging." Ex.1005, 12:58-62.

Though Munshi does not expressly state that connection 94 is used for "controlling electrical connection ***and disconnection***" between the rechargeable battery and the other circuits, a POSA would have found it obvious to use Schulman's protection circuity in combination with Munshi's "connection 94." Ex.1003¶¶120-22. Both references recite connections between the replenishable battery and the IC and both describe storing operational parameters in volatile memory. *See* Ex.1005, 5:49-54; Ex.1006, 1:64-2:46. A POSA would have looked to Schulman because it describes circuitry for protecting data in volatile memory during low voltage conditions. *See* Ex.1006, Title.

Schulman describes protection circuitry that includes voltage sensors, so that "when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery and only the memory is powered." Ex.1006, Abstract. "Only…when the voltage level reaches the selected level, is the rest of the circuitry, including the stimulating circuitry, reconnected to the battery." *Id*. Schulman notes that reconnection occurs while the battery is being charged by the external charger. Ex.1006, 7:14-17.

The Munshi/Schulman combination renders this limitation obvious. Ex.1003¶123.

o) *[1.n]: "alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for*

monitoring the magnitude of an ac voltage at the primary coil as applied by the power amplifier"

In the pending but currently stayed '280 district court litigation with the same term, PO proposed that "alignment circuitry for detecting alignment between the primary and secondary coils" be construed as "circuitry that detects when the primary coil is properly positioned relative to the secondary coil included within the IPG such that reflected impedance is at a minimum." *Boston Scientific Corp. v. Nevro Corp.*, Case 1:16-cv-01163-CFC, D.I. 89, at *8 (D. Del. Oct. 13, 2017). The district court has not yet construed this term.[4] In the '280 FWD, under BRI, the Board did not require "alignment" to be limited to "proper alignment." For the purposes of this Petition, this difference need not be resolved because the prior art teaches this element under either construction.

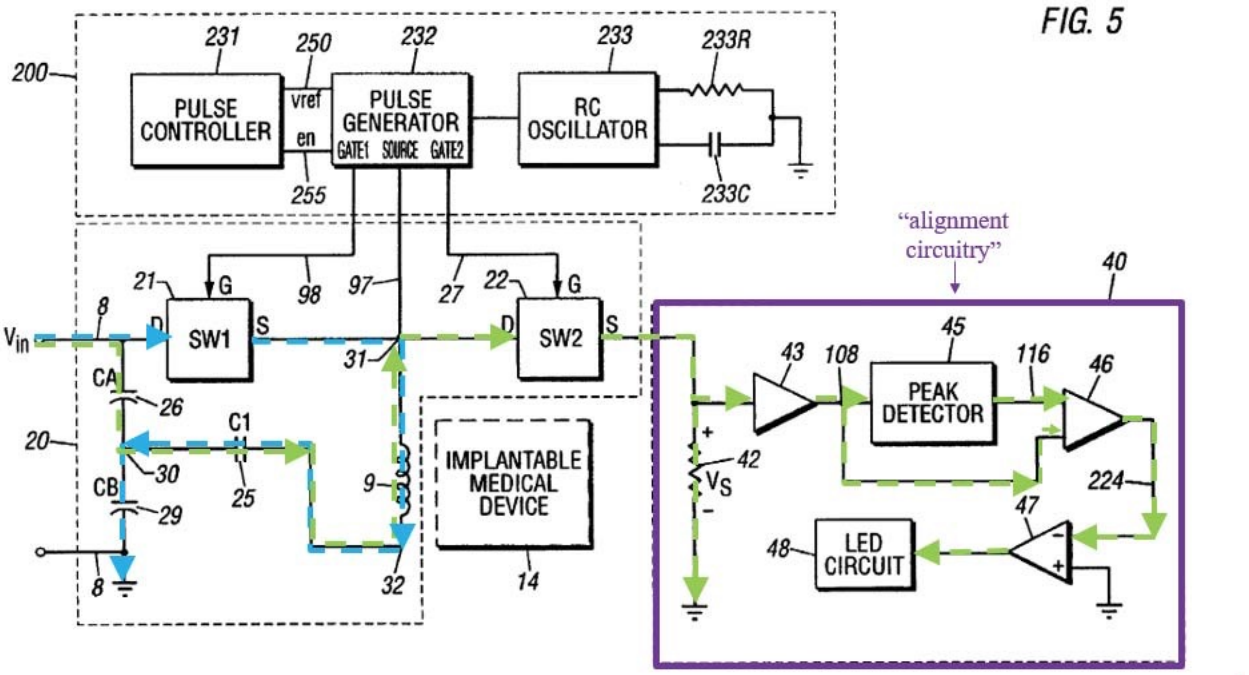
Munshi discloses "a power amplifier that applies alternating current...to the primary coil." §VI.A.6.j. While Munshi discloses that it is desirable to "find the

[4] Subsequent to filing the '280 petitions, Petitioner proposed, in district court, that this term is an indefinite means-plus-function element that lacks for supporting structure. *Id*. In the FWD, the Board did not find that this term was a means-plus-function term. Ex.1008, 12-16. Accordingly, Petitioner shows that the prior art in this Petition render obvious this claim under the Board's prior construction or PO's district court construction.

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), 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 an ac voltage at the primary coil." A POSA would have understood to include such circuitry in implementing Holsheimer's system in view of Wang. Ex.1003¶¶124-28.

Like Munshi, Wang notes the "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." Ex.1007, 5:13-15. Wang provides "an ***alignment circuit and indicator… to indicate whether the coils are properly aligned***." Ex.1007, 5:15-17; *id*. 11:41-46, Figs. 1, 5. 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.1007, 12:1-29, 11:56-63, Fig. 5. 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.1007, 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.1007, 8:64-69, 11:9-14.



As shown, the current on the primary coil 9 is alternating. Ex.1007, 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.1007, 11:18-20, Fig. 5. Current flow through resistor 42 generates a voltage, which is amplified by low-pass amplifier 43, and sent to both peak detector 45 and to differential amplifier 46. Ex.1007, 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.1007, 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.1007, 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.1007, 12:21-26.

Accordingly, when the voltage of Wang's current sensing resistor is at its peak (the current through the primary coil is at a peak), the alignment indicator indicates that proper alignment has been achieved. Ex.1007, 12:21-24. The better the alignment between the coils, the more current that is produced from the voltage source. *Id*., 11:24-27, 11:30-37, Fig. 5. Thus, Wang's alignment indicator indicates proper alignment when the voltage across the current sensing resistor is at a peak, and reflected impedance is, therefore, at a minimum. Ex.1003¶126 (explaining Ohm's law (voltage = current * resistance)); Ex.1001, 43:26-28 ("Reflected impedance is at a minimum when proper alignment has been obtained.").

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) and "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 an ac voltage at the primary coil as applied by the power

amplifier" (*e.g.*, monitoring voltage generated at resistor 42 by AC current that flows through primary coil 9). Ex.1003¶¶126-27; Ex.1008, 90-92.

According to the '404, the alignment circuitry's "back telemetry receiver" senses changes in reflected impedance to indicate, *e.g.*, the IPG's battery is fully charged or charger-IPG alignment. Ex.1001, 41:40-51, 43:24-52. Wang's alignment circuitry also monitors reflected impedance to indicate charger-IPG alignment. Wang monitors the magnitude of the current through the primary coil to generate a voltage and compares it with the "peak voltage," which represents the voltage when the coils are properly aligned. The magnitude of the monitored current "depends on the power draw of the load on the secondary coil." *Id*. A POSA would have understood that this change in current is necessarily a function of reflected impedance from the secondary coil. Ex.1003¶¶73, 129. Thus, like the '404's "back telemetry receiver," Wang's alignment circuitry receives information indicating charger-IPG alignment by sensing changes in reflected impedance. Ex.1003¶129.

As explained (§VI.A.5), 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¶128. 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.1007, 11:13-17).

Accordingly, as the Board already found, 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¶128; Ex.1008, 92.

p) *[1.o]: "wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored"*

As the Board previously determined, Wang teaches this limitation. Ex.1008, 92-93. 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.1007, 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.1007, 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¶129. And, as discussed (§VI.A.6.o), 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." By monitoring the current through the primary coil, the alignment indicator is monitoring the reflected impedance from the secondary coil. Ex.1003¶129. Indeed, monitoring reflected impedance to determine alignment was known in the art. Ex.1018, 5:16-25 ("other types of feedback signals could also be used to provide the needed alignment information [including] circuitry [that] may monitor, on a sampled basis, the reflected impedance as seen by the [primary coil]. Such impedance…will reach either a maximum or a minimum when proper alignment is achieved.").

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¶129.

q) *[1.p]: "an alarm generator that generates an audible alarm signal in response to a sensed change in the reflected impedance monitored by the back telemetry receiver."*

As the Board previously determined, Wang teaches this limitation. Ex.1008, 93-94. As discussed (§VI.A.6.o), 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 activated. Ex.1007, 12:21-24. Wang teaches that an "output device" other than an LED—such as one that produces an "audible signal"—can instead be used to indicate alignment. Ex.1007, 5:20-23 ("visual and/or *audible signal*...indicat[es] proper alignment"), 11:28-31, 11:56-63, 11:63-67, 12:21-24, 14:20-24.

As discussed (§VI.A.6.o), 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 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¶¶130-31.

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¶131. 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¶82.

7. Claim 2

Claim 2 depends on claim 1 and adds, "*wherein the external power source charger is portable*." As discussed (§VI.A.6.g), Munshi provides that its external charger "can have an A.C. or a D.C. power source." Ex.1005, 10:20-21. Further, Munshi states that 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. Accordingly, Munshi teaches this limitation.

8. Claim 3

Claim 3 depends on claim 1 and adds, "*wherein the external power source contained in the external power source charger comprises a rechargeable power source, and wherein the spinal cord stimulation system further comprises a means for using household AC power to recharge the rechargeable power source in the power source charger*." As discussed (§VI.A.6.g), Munshi provides that its external

charger "can have an A.C. or a D.C. power source" and that the D.C. power source may be a rechargeable external battery pack (Ex.1005, 10:20-21, 10:45-47):

> [A]n AC-to-DC converter and regulator, together with a local charging controller ***could allow a user to recharge the external battery pack by connecting the system to a standard AC line outlet***.

Ex.1005, 10:38-51. Munshi, therefore, expressly discloses the claimed function of "using household AC power [standard AC power (Ex.1003¶134)] to recharge the rechargeable power source in the power source charger" (*e.g.*, recharge the external battery pack).

As discussed (§V.A), the structure disclosed in the '404 corresponding to the claimed function is a charging base station that is either separate from or incorporated in an external charger, and an AC power line. Munshi expressly discloses this structure through its disclosure of the "rechargeable external battery pack['s]…own charging system," which includes an AC-to-DC convertor, regulator, charging control, and "standard AC line outlet." Ex.1005, 10:47-51. The external battery pack's charging system may be separate from the external charger (as in '404, Fig. 8) or incorporated into the external charger (as in '404, Fig. 9A). Ex.1003¶135-36.

9. Claim 4

Claim 4 depends on claim 1 and adds, "*wherein the alarm generator broadcasts a first audible tone when the primary coil is misaligned with the*

secondary coil, and the generator stops the broadcast of the first audible tone when the primary coil is properly aligned with the secondary coil." As the Board previously determined, this limitation is obvious in view of Wang. Ex.1008, 96-97.

As discussed (§VI.A.6.o), Wang teaches that 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.1007, 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.1007, 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.1007, 5:20-23; *id*., 11:28-31, 11:63-67, 12:21-24, 14:20-24.

An 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¶138. A third option would be to use an audible signal only to indicate that the coils are misaligned. *Id*. As PO's expert admitted in the '280 IPR, when using an audible tone to indicate alignment, these are the only three design options. *See* Ex.1032, 189:4-190:7. When the claimed option is one of only three predictable solutions, that in itself is a reason why a POSA would have made the

specific design choice. *KSR Int'l v. Teleflex*, 550 U.S. 398, 421 (2007) (Where "there are a finite number of identified, predictable solutions, [POSA] has good reason to pursue the known options…."). Accordingly, a POSA would have considered any of these options a matter of mere design choice in implementing Wang's alignment indicator. Ex.1003¶138; Ex.1008, 96-97 (finding that POSA would have found it obvious to modify Wang to audibly indicate misalignment).

10. Claim 5

Claim 5 depends on claim 1 and adds, "*wherein the IPG housing is made from titanium 6-4*." As discussed (§VI.A.6.b), Munshi discloses a "hermetically sealed" "can" implanted stimulator that includes basic circuitry. Ex.1005, Abstract, 4:27-30. Though Munshi does not describe the material of this "can," Wang describes a "housing or 'can' made of titanium or stainless steel." Ex.1007, 6:31-34. The Examiner noted that even where the prior art "fail[s] to disclose the implantable housing made from titanium 6-4...[a POSA] would have found it obvious to make the housing from titanium 6-4 because titanium is known to be biocompatible and well used in implantable devices to seal enclosed electrical components from bodily fluids." Ex.1002, 299. Accordingly, A POSA would have understood that although Munshi does not disclose the specific material of its hermetically sealed can, this disclosure in light of Wang would render the use of titanium 6-4 obvious because IPGs manufactured from titanium 6-4 were well known at the time due to titanium

6-4's desired high electrical resistivity and low magnetic permeability. Ex.1003¶140 (citing Ex.1033, 7:50-8:21).

N. Ground 2: Holsheimer, Munshi, and Schulman Render Claims 7, 9 and 13-17 Obvious

1. Claim 7

a) *[7.preamble]: "A spinal cord stimulation system"*

To the extent the preamable is limiting, Holsheimer discloses it for those reasons discussed for [1.preamble]. *See* §VI.A.6.a; Ex.1003¶141.

b) *[7.a]: "an [IPG]…having a housing"*

Holsheimer discloses this limitation for those reasons discussed for [1.a]. §VI.A.6.b; Ex.1003¶142.

c) *[7.b]: "an implantable electrode array detachably connected to the IPG [and] having at least two electrodes thereon"*

Holsheimer discloses this limitation for those reasons discussed for [1.b]. §VI.A.6.c; Ex.1003¶143.

d) *[7.c]: "a rechargeable power source…"*

The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.a]. §VI.A.6.b; Ex.1003¶144.

e) *[7.d]: "monitoring circuitry…that monitors the voltage of the rechargeable power source and any charging current flowing to the rechargeable power source"*

Munshi discloses that its control circuitry "will allow the patient to know exactly what the state-of-charge is [of the rechargeable power source] simply by

measuring its voltage." Ex.1005, 4:62-66. Further, during charging operations, Munshi monitors the charging current flowing to the rechargeable power source by actively controlling that current. Ex.1005, 4:62-66 ("The control circuitry controls the amplitude of the current [flowing to the rechargeable cell] depending upon its state-of-charge."), 10:52-56. Accordingly, Munshi discloses this limitation. Ex.1003¶145.

f) *[7.e]: "at least one integrated circuit (IC)…electrically couplable to the rechargeable power source [and] providing essential control functions that allow the IPG to operate"*

The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.a]. §VI.A.6.b; Ex.1003¶146.

g) *[7.f]: "a processor electrically coupled to the at least one IC and contained within the IPG housing which issues commands to stop all stimulation if the voltage of the rechargeable power source falls below a minimum level for stimulation"*

Munshi teaches that "the battery should not be completely discharged" but does not provide details regarding how to guard against complete discharge other than to signal the user to recharge the battery. Ex.1005, 9:7-12. Because Munshi "stores various programmable parameters and variables" in volatile memory, a POSA would recognize that additional circuitry is necessary to protect that information in environments where the battery ***is*** completely discharged and would accordingly look to other references to identify methods for conserving power.

Ex.1003¶147. As discussed (§VI.A.5), a POSA would have found it obvious to combine the teachings of Munshi with Schulman on at least this basis. Ex.1006, Title.

Schulman teaches an "arrangement [that] includes voltage sensors, so that when the voltage from the battery drops ***below a selected level***[,] the stimulating circuitry is disconnected from the battery and only the memory is powered." Ex.1006, Abstract; *id*., 2:54-62 ("When the voltage across the battery falls below a preselected level...all of the [stimulator] circuits which draw power…are disconnected from the battery and thereby disabled.").

Although not expressly stated in Schulman, a POSA would have understood that Schulman disconnects stimulation circuity in response to an issued command from a component that monitors the battery level. Accordingly, it would have been obvious to a POSA to modify Munshi in light of Schulman such that Munshi's processor issues commands to stop all stimulation if the voltage of the rechargeable battery falls below a minimum level for stimulation. Munshi notes that its microprocessor 12 "transmits pulse parameter data, such as amplitude and width, as well as ***enable/disable*** and pulse initiation codes to [IPGs] 30, 32." Ex.1005, 6:9-15. Accordingly, a POSA would have recognized that microprocessor 12 is capable of issuing commands to stop (*e.g.*, disable) all stimulation if the voltage of the rechargeable power source falls below a minimum level for stimulation.

Ex.1003¶150. Further, a POSA would have been motivated to do so as this functionality was a well-known technique for conserving energy in implantable devices. Ex.1005, 12:37-41 ("all circuits in the implantable device related to battery charging…are deactivated in order to conserve energy in the implantable battery."); Ex.1034, 20:61-64 ("NEN ANL disables lead status circuit 62 during the positive portion and rest portion of the output signal to conserve power."); Ex.1031, at 7:42-47 ("Additionally, it is desirable that a microstimulator 100 cease operation when its battery voltage reaches a lower limit…as determined by the charging circuitry 122 and communicated to the controller circuitry 106. This ensures reliable operation as well as prolonging the useful life of the rechargeable battery 104.").

Accordingly, a POSA would have understood that the combination of Holsheimer, Munshi, and Schulman renders this limitation obvious. Ex.1003¶150.

h) *[7.g]: "power source protection circuitry within the IPG housing that controls electrical connection and disconnection between the rechargeable power source and the at least one IC, wherein the power source protection circuitry disconnects the rechargeable power source from the at least one IC if the voltage of the rechargeable power source falls below a power disconnect level, and reconnects the rechargeable power source and the at least one IC if the voltage of the rechargeable power source rises above a power reconnect level"*

As discussed (§VI.B.1.g), Schulman describes a memory protection circuit ("MPC 25") that incorporates a low voltage indicator ("LVI") with one threshold

that monitors the voltage of the battery, and a high voltage indicator ("HVI") with a second threshold that monitors the voltage of the battery. Ex.1006, 4:51-5:2. In order to conserve power and preserve data stored in memory, "when the voltage from the battery drops below a selected level[,] the stimulating circuitry is disconnected from the battery and only the memory is powered." Ex.1006, Abstract; *id*., 2:54-62. The memory, however, remains connected to the battery and "keeps draining the battery power." Ex.1006, 6:54-59. Schulman describes that, at a second threshold level, "since the voltage applied to the memory 20 is less than is necessary for safe operation of the memory, the parameters, which are stored in it, can no longer be relied upon." Ex.1006, 6:41-44.

Although Schulman does not expressly state that, at this stage, the memory (and thus the entire integrated circuit) is disconnected from the battery, a POSA would have understood that the memory should be disconnected at this second threshold level to prevent over-discharge of the battery. As discussed above, it was well known that over-discharge of the battery can damage or diminish the lifespan of a battery. Ex.1029, 1:35-42 ("It is well known that over-discharge of the lithium cell may result in dendritic or metal filaments growing from one side of the cell to the other, or across the intercalating membranes. This electrically conductive crystalline structure can short circuit the cell and permanently destroy the cell's operation."); Ex.1035, 1:24-28 ("[O]verdischarge would decompose substances

sealed in the…battery and would thereby lower the capacity of the battery. If the battery is repeatedly…overdischarged, the decrease in battery capacity is accelerated until the service life of the battery expires."). Although Schulman states that below the second threshold, the parameters stored in the memory "can no longer be relied upon" (Ex.1006, 6:41-44, 7:66-8:2), it does not describe additional circuitry to protect against overdischarge of the battery past the second threshold. Because Munshi discloses a rechargeable lithium cell battery (Ex.1005, 7:10-8:29)—which is the type of battery that runs the risk of overdischarge (Ex.1029, 1:35-42)—a POSA would have understood that the memory (and thus the entire IC) should be disconnected from the battery when its data is no longer reliable in order to prevent the battery from further "draining the battery power" and damaging the Munshi's rechargeable lithium battery. Ex.1003¶¶152-53.

Schulman further discloses that only "when the [battery] voltage level reaches the ***selected level*** [(*e.g.*, "the power reconnect level")], is the rest of the circuitry, including the stimulating circuitry, reconnected to the battery." Ex.1006, Abstract; *id.*, 3:67-4:2 ("If, therefore, the battery is recharged by power from an external source, when the battery level rises to a sufficiently high level, the rest of the circuits are again connected and enabled.").

To the extent PO alleges that power disconnect level and power reconnect occur at the same voltage, Schulman makes clear that the invention is not limited to specific voltage markers for any of the disclosed protection mechanisms:

> It should be clear that the invention is not intended to be limited [to the disclosed embodiment.] The point that should be kept in mind is that in accordance with the present invention, once the voltage to the memory 20 drops below ***a safe level*** for the proper memory operation (e.g., 3.4 v) the parameters stored therein can no longer be relied upon. Thus, when subsequently the voltage top the memory is increased to a level ***at least sufficient for the memory's proper operation***, preselected parameters are loaded into the memory.

Ex.1006, 7:60-8:6. Accordingly, Schulman instructs and a POSA would have understood that Schulman leaves the voltage thresholds for power disconnect and power reconnect to the design choice of the user programming the circuit. Ex.1003¶155.

i) *[7.h]: "wherein the processor initiates a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold"*

Schulman describes a high voltage indicator (HVI), that senses the voltage of the battery via an up converter. Ex.1006, 4:62-64. The function of HVI 40 is to determine whether the up converted battery voltage falls below a reset threshold. Ex.1006, 4:64-68. When the voltage falls below this threshold, it is assumed that any operational parameters stored in volatile memory can no longer be relied upon.

Ex.1006, 3:2-7. "Thereafter, when the battery is recharged, and when the memory is again powered ***by sufficient voltage*** [(*e.g.*, when "the voltage of the rechargeable power source rises above a reset threshold")] the memory is loaded with preselected parameters from a memory reset source in the HTS, e.g., a read only memory (ROM)." Ex.1006, 3:11-15. Only after the memory has been loaded with preselected parameters from the memory reset source (*e.g.*, when "the processor initiates a power-on-reset"), can the stimulation circuits be reconnected to the battery and stimulation resume. Ex.1006, 3:15-21 ("These parameters are chosen so that thereafter when the [IPG] is reactivated the parameters, present in the memory, are of preselected values, which result in the generation of safe stimulating pulses…Once the battery voltage exceeds the desired level, all the rest of the circuits are again reactivated.").

Further, as discussed (§VI.B.1.h), Schulman makes clear that the "reset threshold" is not limited to a specific voltage. *See* Ex.1006, 7:56-8:10; Ex.1006, 3:11-14 ([W]hen the battery is recharged, and when the memory is again powered ***by sufficient voltage***, the memory is loaded with preselected parameters from a memory reset source.").

Accordingly a POSA would have understood that Schulman discloses a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold. Ex.1003¶156-58.

j) *[7.i]: "wherein the processor reinitiates stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation."*

Schulman discloses this limitation for those reasons discussed for [7.g]. §VI.B.1.h; Ex.1003¶¶156-58. Specifically, Schulman describes a memory protection circuit ("MPC 25") that incorporates a low voltage indicator ("LVI") with one threshold that monitors the voltage of a battery, and a high voltage indicator ("HVI") with a second threshold. Ex.1006, 4:51-5:2. In the preferred embodiment, stimulation is disabled when the battery voltage drops below 1.1 v (Ex.1006, 5:20-24) and is enabled when voltage exceeds 1.1 v (Ex.1006, 6:9-17 ("[W]hen the [battery voltage] reaches 1.1 v…all the circuits are again connected in the HTS and are once more powered by the voltage from battery 15…."); Ex.1006, 2:67-3:2 (stating that stimulation circuits are "connected and enabled" if "the battery is recharged by power from an external source[and] the battery level rises to a sufficiently high level….").

2. Claim 9

Claim 9 depends on claim 7 and adds:

a) *[9.a]: "an implantable secondary coil coupled electrically to the rechargeable power source"*

The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.e]. §VI.A.6.f; Ex.1003¶¶105-06.

b) *[9.b]: "an external power source charger"*

The Holsheimer and Munshi combination disclose this limitation for those reasons discussed for [1.e]. §VI.A.6.f; Ex.1003¶¶105-06.

c) *[9.c]: "a primary coil"*

The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.g]. §VI.A.6.h; Ex.1003¶108.

d) *[9.d]: "an external power source contained in the external power source charger, electrically coupled to the primary coil"*

The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.h]. §VI.A.6.i; Ex.1003¶¶109-10.

e) *[9.e]: "a power amplifier for applying alternating current derived from the external power source to the primary coil"*

The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.i]. §VI.A.6.j; Ex.1003¶¶111-12.

f) *[9.f]: "whereby the alternating current in the primary coil induces a magnetic field that is transcutaneously coupled to the implantable secondary coil, thereby inducing a corresponding alternating current in the secondary coil, which alternating current in the secondary coil recharges the rechargeable power source."*

The Holsheimer and Munshi combination disclose this limitation for those reasons discussed for [1.j]. §VI.A.6.k; Ex.1003¶¶113-16.

3. Claim 13

Claim 13 depends on claim 7 and adds, "*wherein the rechargeable power source in the IPG comprises a rechargeable battery*." The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.b]. §VI.A.6.c; Ex.1003¶¶93-94. For example, Munshi is "directed towards a rechargeable battery-powered biomedical device." Ex.1005, 1:8-9 ("[o]ur invention is directed towards a rechargeable battery-powered biomedical device"). Therefore, Munshi discloses a system "wherein the rechargeable power source in the IPG comprises a rechargeable battery." Ex.1003¶168.

4. Claim 14

Claim 14 depends on claim 13 and adds, "*wherein the rechargeable battery is a lithium-ion battery having at least 720 mWhr capacity*." Munshi describes the battery as a "rechargeable lithium battery 92." Ex.1005, 10:62-64, Fig.2. Munshi explains that the rechargeable batteries suitable for use in this invention include a "lithium-ion system" (Ex.1005, 7:49-55). The advantages of using lithium-ion batteries include that the "number of cycles for a conventional lithium battery is only about 200 cycles, whereas that for a lithium ion cell is as high as 1200 cycles." Ex.1005, 7:67-8:4. Therefore, Munshi discloses "the rechargeable battery is a lithium-ion battery." Ex.1003¶170.

Munshi also discloses that the rechargeable lithium-ion battery has "at least 720 mWhr capacity." Ex.1003¶¶171-72. In discussing the "multistep fast charge" functionality, Munshi describes "a rechargeable [cell] of 400 mAh." Ex.1005, 11:8-10. "Multistep fast charge," depicted in Figure 4, starts with "a first charge step of 500 mA current to a preselected voltage level" and "[o]nce this level is reached, the next step could be 250 mA to a preselected level," and so on. Ex.1005, 11:10-15. "The preselected voltage could be close to the [battery's] full charge voltage." Ex.1005, 11:16-17. Figure 4 below shows the preselected voltage close to the full charge voltage for this 400 mAh rechargeable cell is about 4 V.

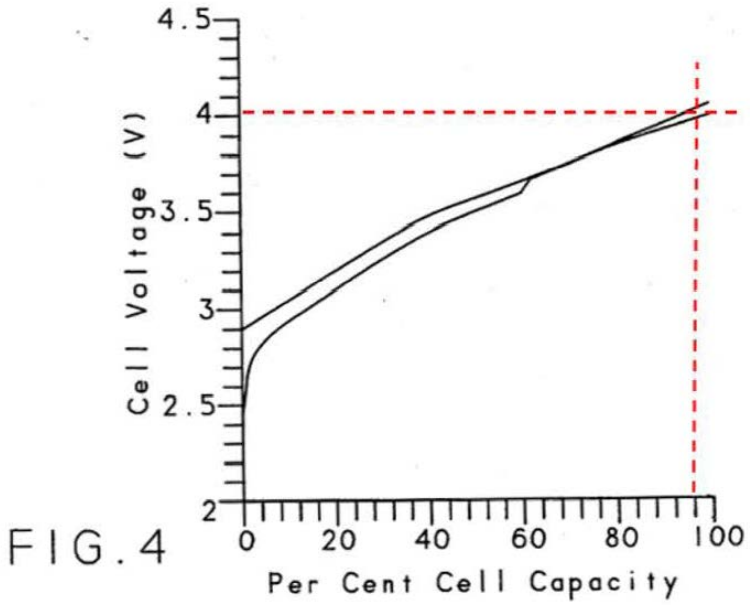


FIG. 4

Energy in mWh (milliwatt-hours) is equal to the electric charge in mAh (milliamp-hours) multiplied by the voltage (V)—*i.e.*, mWh = mAh x V. Ex.1003¶172. Therefore, the energy in mWh of the 400 mAh rechargeable cell capacity is:

400mAh x 4V = l,600mWh. Thus, Munshi discloses the rechargeable lithium-ion battery has "at least 720 mWhr capacity." Ex.1003¶¶171-72.

5. Claim 15

Claim 15 depends on claim 13 and adds, "*means for non-invasively recharging the battery through the skin*." The Holsheimer and Munshi combination discloses this limitation for those reasons discussed for [1.e], [1.f], [1.g] and [1.i]. §VI.A.6.f-j; Ex.1003¶¶173-74.

As described above, Munshi discloses the claimed structure: an external charger (§VI.A.6.g, Ex.1005, 12:54-57, Fig. 2, 10:20-40, 10:45-47, 10:52-61), a power amplifier (§VI.A.6.j, Ex.1005, Fig. 2, 10:38-43) an external coil (§VI.A.6.h, Fig. 2, Ex.1005, 10:20-26, 10:32-37, 10:38-40, 12:54-57) and an internal coil (§VI.A.6.f, Ex.1005, 10:24-26, 10:32-37, 12:54-57). The components allow a "user [to] initate[] 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" (*e.g.*, non-invasively recharging the battery through the skin). Ex.1005, 12:54-57.

6. Claim 16

Claim 16 depends on claim 7 and adds, "*wherein the IPG housing is made from titanium 6-4*." Munshi discloses this limitation for those reasons discussed for claim 5. §VI.A.10; Ex.1003¶140.

7. Claim 17

a) *[17.preamble]: "A method for controlling shutdown and restart of an [IPG] containing a rechargeable power source and at least one integrated circuit (IC) that when powered renders the IPG operable, the method comprising:"*

To the extent the preamble is limiting, the Holsheimer, Munshi and Schulman combination discloses it for those reasons described above. *See* §VI.B.1; Ex.1003¶177. Specifically, Munshi describes an IPG with a microprocessor that "transmits pulse parameter data, such as amplitude and width, as well as enable/disable [(*e.g.*, "[a] method for controlling shutdown and restart of an [IPG]")] and pulse initiation codes…." Ex.1005, 6:9-15. Munshi further contains a rechargeable battery (*e.g.*, "rechargeable power source"). *See* Ex.1005, 10:20-21; Ex.1008, 74-75. Finally, as described above (§VI.B.1.f), a POSA would have understood that the circuitry of Holsheimer and Munshi—which render the IPG operable—could be incorporated into an integrated circuit. *See* Ex.1005, Abstract, 4:27-30, 5:40-45, 49-50, Fig.1.; Ex.1004, Fig. 1; Ex.1027, 13:35-40; Ex.1028, 1:26-31; Ex.1002, 298; Ex.1003¶178.

8. *[17.a]: "monitoring the voltage of the rechargeable power source and any charging current flowing to the rechargeable power source"*

Munshi discloses this limitation for those reasons discussed for [7.d]. §VI.B.1.e; Ex.1003¶145.

9. *[17.b]: "issuing commands to stop all stimulation pulses if the voltage of the rechargeable power source falls below a minimum level for stimulation"*

The Munshi and Schulman combination discloses this limitation for those reasons discussed for [7.f]. §VI.B.1.g; Ex.1003¶¶147-50.

10. *[17.c]: "electrically disconnecting the rechargeable power source from the at least one IC if the voltage of the rechargeable power source falls below a power disconnect level"*

The Munshi and Schulman combination discloses this limitation for those reasons discussed for [7.d]. §VI.B.1.e; Ex.1003¶145.

11. *[17.d]: "electrically reconnecting the rechargeable power source to the at least one IC if the voltage of the rechargeable power source rises above a power reconnect level"*

The Munshi and Schulman combination discloses this limitation for those reasons discussed for [7.g]. §VI.B.1.h; Ex.1003¶¶151-55.

12. *[17.e]: "initiating a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold"*

The Munshi and Schulman combination discloses this limitation for those reasons discussed for [7.h]. §VI.B.1.i; Ex.1003¶¶156-58.

13. *[17.f]: "reinitiating stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation."*

The Munshi and Schulman combination discloses this limitation for those reasons discussed for [7.i]. §VI.B.1.j; Ex.1003¶159.

O. Ground 3: Holsheimer, Munshi, Schulman, and Rutecki Render Claims 11-12 Obvious

1. Rutecki Overview

Rutecki issued in 1994 and is §102(b) prior art. Rutecki discloses an implantable "neurostimulator" that includes a "pulse generator" that delivers therapy to an implanted "nerve electrode array" to "appropriately modulate the electrical activity of the [vagus] nerve." Ex.1009, 6:26-35; *id*., 8:42-64. Rutecki provides "selective electrical stimulation of vagus nerve afferent fiber activity with an implanted neurostimulating device." Ex.1009, 1:7-14.

Rutecki's system includes external components, such as "a programming wand for telemetry of parameter changes to the stimulus generator and monitoring signals from the generator, and a computer and associated software for adjustment of parameters and control of communication between the generator, the programming wand and the computer." Ex.1009, 10: 11-18. Additionally, Rutecki teaches that, prior to permanent implantation, tests should be conducted with an "external stimulus generator" with "leads extending percutaneously to the implanted nerve electrode assembly" to ensure the efficacy of the stimulation therapy. Ex.1009, 14:3-18.

2. Motivation to Combine

A POSA considering Holsheimer would have looked to related references, including Rutecki, for additional advantageous features that could be incorporated.

Ex.1003¶188. Rutecki describes an analogous implantable nerve stimulation system. For example, Holsheimer discloses a programmer that can be used to select various pulse output options post-implantation, but does not provide any detail on how those options can be changed. Ex.1004, 3:65-4: 2. Rutecki provides these details and describes how to change pulse output options in the IPG. Ex.1003¶188. Because of their similarities, a POSA would have known that features from Rutecki could be predictably combined with Holsheimer. Ex.1003¶189.

3. Claim 11

Claim 11 depends on claim 7 and adds:

a) *[11.a]: "external components including a handheld programmer that may be selectively placed in telecommunicative contact with the IPG"*

Holsheimer employs a "programmer 20 which is coupled via conductor 22 to radio frequency antenna 24" to "permit[] attending medical personnel to select the various pulse output options after implant using radio frequency communications." Ex.1004, 3:65-4:2. Figure 1 shows programmer 20 is external. Ex.1004, Fig.1.

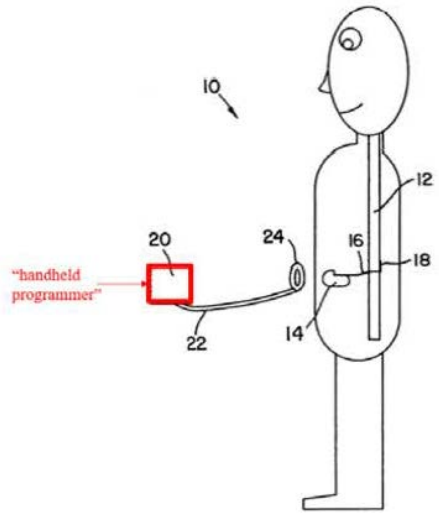


FIG. 1

Accordingly, Holsheimer discloses this limitation. Ex.1003¶¶191-92.

b) *[11.b]: "a clinician programmer that is selectively coupled with the handheld programmer (HHP)"*

While Holsheimer discloses its external programmer "permits attending medical personnel to select the various pulse output options after implant using radio frequency communications" (Ex.1004, 3:67-4:2, Fig. 1), it does not expressly disclose how to program the programmer with selected parameters to change pulse output options. A POSA would have found it obvious to look to other references such as Rutecki for this information, which explicitly teaches using an external computer in combination with external programming wand to program (and reprogram) pulse parameter settings in the IPG. Ex.1009, 10:11-17 ("Components external to the patient's body include a programming wand…and a computer and associated software…."). Rutecki includes an external "programming wand for

telemetry or parameter changes to the stimulus generator and monitoring signals from the generator, and a computer and associated software for adjustment of parameters and control of communication between the generator, the programming wand and the computer." Ex.1009, 10:11-17; *id*., 9:59-65, 10:62-67, 12:2-12. "Once the system is programmed, it operates continuously at the programmed settings until they are reprogrammed…by means of the external computer and the programming wand." Ex.1009, 10:67-11:4.

Therefore, Rutecki discloses "a clinician programmer" (*e.g.*, computer with associated software) "that is selectively coupled with the handheld programmer" (*e.g.*, that communicates adjusted parameters to the implanted stimulator via the programming wand). Ex.1003¶193.

A POSA would have found it obvious to incorporate Rutecki's computer for interacting with Holsheimer's external programmer, to program Holsheimer's IPG because, as Rutecki teaches, it "permit[s] noninvasive communication with the generator after the latter is implanted" and allows the pulse parameters to be calibrated "according to the needs of the particular patient." Ex.1009, 11:12-17, 12:10-12; Ex.1003¶194. Because of the similarities between Holsheimer and Rutecki (*e.g.*, implantable electrical stimulation systems), a POSA would have known the combination yielding the structure as claimed would have worked as expected. *Id*.

c) *[11.c]: "a portable charger that may be inductively coupled with the IPG in order to recharge the IPG rechargeable power source."*

As discussed (§VI.A.2), Munshi describes a "bioimplantable device" with a rechargeable power source that can be inductively recharged through the patient's skin. Ex.1005, 4:3-10, Abstract, 1:8-17. Munshi's external charger can be powered by a "rechargeable external battery pack with its own charging system...to allow portability of the external unit." Ex.1005, 10:43-47.

Munshi further teaches the recharging occurs via inductive coupling between an external charging coil and an implanted coil in the implanted device. 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. .. disposed just under the skin."); *id*., 10:27-37, Fig.2.

Therefore, Munshi discloses "a portable charger" (*e.g.*, portable external charger) "that may be inductively coupled with the IPG" (*e.g.*, induction between external charging coil and implanted coil) "in order to recharge the IPG power source" (*e.g.*, to recharge the bioimplantable device's power source). Ex.1003¶195-98.

4. Claim 12

Claim 12 depends on claim 7 and adds:

a) *[12.a]: "an external trial stimulator (ETS)"*

Holsheimer does not expressly disclose "an external trial stimulator," but it would have been obvious to include one in Holsheimer's system in view of Rutecki. In addition to being well known—as Rutecki expressly discloses—it was industry standard to conduct tests prior to permanent implantation to ensure the patient responds to therapy before committing to a permanent system. Ex.1009, 14:3-7, 14:10-18; Ex.1010, 33; Ex.1003¶¶200-01. For such tests, Rutecki discloses using an "external stimulus generator" that is worn for "short term tests…to determine whether" the patient responds to therapy (*e.g.*, pulse generator externally-worn by a patient that is used temporarily for evaluation purposes before implantation of the IPG). Ex.1009, 14:8-18; Ex.1003¶201. PO's expert previously testified that external trial stimulators are designed for use both inside and outside of the operating room. Ex.1022, 58:16-25, 59:2-7.

A POSA would have found it obvious to use Rutecki's external stimulus generator in implementing Holsheimer because it is desirable to test the therapy "to determine whether [pain] is sufficiently relieved to characterize the neurostimulation…as successful treatment" before permanent implantation, as taught by Rutecki. Ex.1009, 14:10-18; Ex.1003¶202; Ex.1008, 137-39 (finding a

POSA would have found it obvious to employ Rutecki's external trial stimulator in a stimulation system because "it was well known to be advantageous to test the efficacy of stimulation therapy before permanent implantation"). Because of the similarities between Holsheimer and Rutecki, a POSA would have known the combination would have worked as expected. *Id*.

b) *[12.b]: "a percutaneous extension which temporarily couples the ETS with the implantable electrode array."*

Rutecki's "external stimulus generator" has "leads extending percutaneously to the implanted nerve electrode assembly." Ex.1009, 14: 8-10. This is a "temporary arrangement" to test whether the neurostimulation successfully relieves pain. Ex.1009, 14:10-17. Therefore, Rutecki discloses "a percutaneous extension" (*e.g*., leads extending percutaneously) "which temporarily" (*e.g.*, temporary arrangement) "couples the ETS with the implantable electrode array" (*e.g*., external stimulus generator has leads to the implanted nerve electrode assembly). Ex.1003¶203-04; Ex.1008, 139 ("Rutecki discloses that leads extend percutaneously to couple the external stimulus generator to the implanted electrodes").

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.

Dated: July 15, 2019

Respectfully Submitted,

/Ching-Lee Fukud/a
Ching-Lee Fukuda
Reg. No. 44,334
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
clfukuda@sidley.com
(212) 839-7364
Lead Counsel for Petitioner Nevro

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 13,939 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 15, 2019

Respectfully Submitted,

/Ching-Lee Fukuda/
Ching-Lee Fukuda
Reg. No. 44,334
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
clfukuda@sidley.com
(212) 839-7364
Lead Counsel for Petitioner Nevro

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 15th day of July, 2019, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by Federal Express on the following counsel:

PAIR Correspondence Address for US Patent No. 7,496,404:

Boston Scientific Neuromodulation Corp.
c/o Lowe Graham Jones
701 Fifth Avenue
Suite 4800
Seattle, WA 98104

Litigation Counsel:

Karen L. Pascale
Young Conaway Stargatt & Taylor LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801

Matthew M. Wolf
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Avenue, N.W.
Washington, DC 20001

Dated: July 15, 2019

Respectfully Submitted,

/Ching-Lee Fukuda/
Ching-Lee Fukuda
Reg. No. 44,334
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
clfukuda@sidley.com
(212) 839-7364
Lead Counsel for Petitioner Nevro