Paper No. 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.
Patent Owner.

IPR No. IPR2017-01920

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

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 6,895,280
1002	U.S. Patent No. 6,895,280 File History
1003	Declaration of Mark W. Kroll, PhD
1004	U.S. Patent No. 5,501,703
1005	U.S. Patent No. 5,411,537
1006	U.S. Patent No. 6,609,031
1007	U.S. Patent No. 5,330,515
1008	U.S. Patent No. 5,733,313
1009	"Computer Assisted and Patient Interactive Programming of Dual Octrode Spinal Cord Stimulation in the Treatment of Chronic Pain" by Kenneth M. Alo et al.
1010	U.S. Patent No. 5,948,007
1011	U.S. Patent No. 5,948,006
1012	U.S. Patent No. 6,185,452
1013	U.S. Patent No. 4,082,097
1014	U.S. Patent No. 3,942,535
1015	"Spinal cord stimulation for chronic, intractable pain: superiority of 'multi-channel' devices," by Richard B. North et al.
1016	U.S. Patent No. 5,121,754
1017	U.S. Patent No. 5,571,148
1018	U.S. Patent No. 5,702,431
1019	U.S. Patent No. 4,856,525

Nevro Corp. ("Petitioner") submits this petition for *inter partes* review ("IPR") of claims 8, 18, 22-24, and 27 (the "Challenged Claims" or "Claims") of U.S. Patent No. 6,895,280 (the "'280 patent" or "'280") (Ex.1001), assigned to Boston Scientific Neuromodulation Corporation ("PO"). As explained below, there is a reasonable likelihood that at least one of the Claims is unpatentable over the presented prior art—including art not previously considered by the Office—and accordingly, the Board should institute trial and cancel the Claims as obvious under §103[1].

I. IDENTIFICATION OF CHALLENGED CLAIMS AND GROUNDS OF UNPATENTABILITY

Petitioner challenges claims 8, 18, 22-24, and 27 of the '280 patent. These claims are unpatentable based on the §103 grounds identified below—none of which is redundant. Each of the grounds presented herein is based on U.S. Patent No. 6,185,452 ("Schulman," Ex.1012) and U.S. Patent No. 5,571,148 ("Loeb," Ex.1017)—neither of which were previously before the Office:

Ground 1: Schulman in view of Loeb renders obvious claims 18 and 27;

Ground 2: Schulman in view of Loeb and U.S. Patent No. 5,330,515 ("Rutecki,"

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

Ex.1007) renders obvious claim 8; and

Ground 3: Schulman in view of Loeb, U.S. Patent No. 5,411,537 ("Munshi," Ex.1005), and U.S. Patent No. 5,702,431 ("Wang," Ex.1018) renders obvious claims 22-24.

On July 21, 2017, Petitioner filed two petitions—IPR2017-01811 and IPR2017-01812—collectively challenging 17 claims of the '280 patent. Notices of filing date accorded to petition were issued in both proceedings earlier this week on August 7, 2017, and PO has not yet filed preliminary responses in either proceeding. Each petition challenges a different set of '280 claims:

- IPR2017-01811: Challenges claims 1, 4, 7-9, 11, 18, 19, and 21 on unpatentability grounds that rely on prior art U.S. Patent No. 5,501,703 ("Holsheimer," Ex.1004) as a primary reference.
- IPR2017-01812: Challenges claims 22-24 and 26-30 on unpatentability grounds that rely on prior art Holsheimer or U.S. Patent No. 5,733,313 ("Barreras '313," Ex.1008) as a primary reference.

Since the filing of those two petitions, PO has narrowed the set of '280 patent claims that it is asserting against Petitioner in parallel district court litigation (*see* §IX.B.2) to claims 8, 18, 22-24, and 27. Thus, this Petition challenges just those six claims on unpatentability grounds based on primary references (*i.e.*, Schulman and Loeb) that are different from those in the previously-filed petitions and that

were not previously considered by the Office.

Petitioner respectfully requests that, if the Board institutes trial in IPR2017-01811, IPR2017-01812, and/or this proceeding, the Board align the due dates for any instituted proceedings.

II. INTRODUCTION AND BACKGROUND IN THE ART

A. The ’280 Patent

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

By the late 1990s, many SCS systems were commercially available. *See* Ex.1009, 31-32. As the ’280 observes, by 1999, SCS was already “a well accepted clinical method for reducing pain in certain populations of patients.” Ex.1001, 1:10-11, 23-24. There were two types of SCS systems. The first included a fully “implantable pulse generator” (IPG) with an internal power source and lead wires

with connected electrodes, all of which would be implanted into a patient.[2] Ex.1001, 1:25-30; Ex.1006, 1:36-39. The IPG was configured to generate electrical pulses that would be delivered to the electrodes placed along the patient's spinal cord. Ex.1001, 1:25-30. A second type of SCS system also delivered electrical stimulation through implanted leads but used radio frequency ("RF") signals between an implanted, passive receiver and an externally worn transmitter placed over the site of the receiver. Ex.1006, 1:55-57; Ex.1003¶23.

Most SCS patients experience pain distributed across the spine, with multiple and variable foci. Ex.1009, 31. By the late 1990s, it was well-known

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[2] Other analogous stimulation systems including IPGs, such as cardiac pacemakers and cochlear implants, were similarly structured. *E.g.*, Ex.1005, 1:29-31 ("The basic pacemaker system consists of an electrode attached to the heart and connected by a flexible lead to a pulse generator."); Ex.1019, 1:14-27 ("Electrical stimulators adapted to stimulate bodily tissue are well known….In [] the cochlear implant…, a pair of electrodes are attached to the bodily tissue to be stimulated. Electrical current is then supplied to this electrode pair to provide a stimulation current between the electrodes which passes through the bodily tissue to be stimulated."). *See also* Ex.1009, 31 (describing SCS as a "nerve pacemaker").

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

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

electrode node" (Ex.1001, 4:29-31). Therefore, unlike prior art SCS systems (characterized by the '280 as "multi-channel"), the '280 patent purports to be a true multi-channel system with the ability to simultaneously provide "unique" stimulation fields on multiple channels:

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

Ex.1001, 3:3-21.

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

B. Overview of the Prosecution History

The application that led to the '280 patent was filed on November 27, 2002

and claims priority to U.S. Application 09/626,010 (issued as U.S. Patent 5,416,227), which was filed July 28, 2000 and claims priority to U.S. Provisional Application 60/145,829 filed July 27, 1999. Ex.1001, 1:4-9. For purposes of this proceeding, Petitioner assumes the '280's priority date is July 27, 1999.

While the '280 describes the purported invention as the addition of a rechargeable battery to a multi-channel SCS system, the Examiner found such features in the prior art during the prosecution of the '280. Ex.1002, 280-81. For example, in a Non-Final Rejection rejecting pending prosecution claims on various §§102 and 103 grounds—including based on a combination of Holsheimer and U.S. Patent No. 5,769,877 ("Barreras '877")—the Examiner found Holsheimer "describes an implantable epidural spinal cord stimulator…having applicant's claimed multi-channel pulse generator…whose outputs can be changed independently of one another." *See* Ex.1002, 278-83. The Examiner further found that while it was unclear whether Holsheimer's IPG had a replenishable power source, it would have been obvious in view of Barreras '877, which discloses an implantable medical device with a replenishable power source. Ex.1002, 280-81.

In that Office Action, the Examiner also objected to a number of non-rejected claims for depending from a rejected base claim, but noted those 25 claims would be allowable if rewritten in independent form. Ex.1002, 283. The Examiner also allowed five pending claims. As the reasons for allowance, the

Examiner stated the art did not disclose: (1) "connecting an external trial stimulator (ETS)," (2) "charging a rechargeable battery in the external battery charger using an external power source," or (3) stopping charging of the IPG battery when the charging current or voltage reaches a "prescribed level." Ex.1002, 283-84.

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

C. Known Technologies

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

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

also contain a battery…preferably of the rechargeable type…."); Ex.1012, 1:37-40, 1:66-2:9, 8:64-67; Ex.1008, 4:7-20; Ex.1005, 4:3-10; Ex.1003¶¶25-31.

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

The Examiner also noted additional claimed features in the reasons for allowance. The features relevant to the Challenged Claims here are: (i) connecting an "external trial stimulator" to the SCS system (Ex.1002, 283), and (ii) stopping the charging of the IPG battery when the charging current or voltage reaches a "prescribed level" (Ex.1002, 284). But all of these features were similarly well-known before July 1999, for example:

(i) Rutecki—issued July 1994—teaches use of "***an external stimulus generator***" to conduct stimulation testing before permanent implantation. Ex.1007, 14:3-18; *see also* Ex.1009, 33 (disclosing a "trial stimulator").

(ii) Munshi—issued May 1995—discloses stopping charging of the implanted battery when its voltage "is greater than or equal to V_{max}." Ex.1005, 11:51-60; *see also* Ex.1008, 9:7-16 (disclosing "monitor[ing] the voltage level of the [implanted] power source" and sending a ***"'stop' recharging command"*** when fully charged); Ex.1012, 4:32-34, 6:14-17 (monitoring voltage of battery and terminating charging cycle when devices have been fully charged).

Thus, the Claims are, at most, obvious implementations of an SCS system that recite various well-known features, functioning in predictable combinations, as a person of ordinary skill in the art ("POSA") would have expected at the '280's priority date. Ex.1003¶¶56, 112, 127, 174-75.

III. 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¶¶12-18.

In support of the proposed grounds of rejection, the Declaration of technical

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

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

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

Petitioner expressly reserves the right to argue in litigation different constructions for any term, as appropriate to that proceeding.

1. "multi-channel implantable pulse generator (IPG)" (All Claims, Except Claim 27)

In light of the intrinsic evidence, the term "multi-channel IPG" must be interpreted to be: "an IPG that can simultaneously provide stimulation to two or more channels with different stimulation parameters."[4]

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

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[4] Petitioner has mapped the prior art to this construction. However, the prior art discloses and/or renders obvious the Claims even if "multi-channel IPG" were construed more broadly. Ex.1003¶41. For example, as explained below (§V.B.1.b), Schulman and Loeb teach a multi-channel IPG that can stimulate on multiple channels having different stimulation parameters because each microstimulator is independently programmable with various pulse parameters and multiple microstimulators can be programmed to stimulate at the same time or at different selected times. Thus, Schulman and Loeb teach "multi-channel IPG" even if it were construed more broadly and did not require simultaneous stimulation on multiple channels.

stimulation channel:

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

Ex.1001, 2:18-21; *see also id*., 2:11-15. At the time, such multiplexed single stimulation channel systems were often improperly described as "multi-channel." *See, e.g.*, Ex.1015, 119 ("Although technically single-channel systems gated to multiple contacts, and incapable of simultaneously delivering different signals to separate channels, these devices commonly are described as 'multi-channel.'"); Ex.1003¶¶28-31. Given the ambiguity surrounding the use of the term multi-channel in the field, the patentee clarified how the '280 uses the term by expressly defining the claimed invention and disclaiming multiplexed single-channel stimulation systems:

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

Ex.1001, 3:3-29 (Summary of the Invention). "Where the general summary or description of the invention describes a feature of the invention…and criticizes other products…that lack that same feature, this operates as a clear disavowal of these other products…." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1332-33 (Fed. Cir. 2009); *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1347 (Fed. Cir. 2004); *Eon-Net*, 653 F.3d at 1322; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004); *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

Consistent with these statements, the '280 specification repeatedly and consistently describes the claimed system as capable of simultaneously providing stimulation to two or more channels with different parameters. *See Am. Piledriving Equip. v. Geoquip, Inc.*, 637 F.3d 1324, 1334 (Fed. Cir. 2011) (limiting construction supported where "other statements and illustrations in the patent are consistent with the limiting description."); *Nystrom v. TREX Co, Inc.*, 424 F.3d 1136, 1144-45 (Fed. Cir. 2005). *See, e.g.*, Ex.1001, Abstract (SCS system includes "multiple, independently programmable, stimulation channels…which channels can provide concurrent, but unique stimulation fields"), 10:30-34 (For example, the '280 explains "each channel may be programmed to provide its own specified pattern or sequence of stimulus pulses" and "any of the channels" can be "simultaneous[ly] activat[ed]."), 26:65-67; 10:39-42, 14:21-26, claims 4 & 19.

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

V. THE CHALLENGED CLAIMS ARE OBVIOUS

A. Overview of Primary References

Each of the grounds presented herein is based on Schulman (Ex.1012) and Loeb (Ex.1017)—neither of which was before the Office during prosecution of the '280. Schulman expressly incorporates by reference Loeb's microstimulator system. Ex.1012, 1:15-19 ("Implantable devices for tissue stimulation (i.e., microstimulators) are known in the art. See, e.g., U.S. Pat. Nos….5,571,148, which are ***incorporated herein by reference***."). For purposes of this proceeding and to minimize any disputes between the parties, Petitioner presents Schulman and Loeb as separate references, but reserves the right to contend that they should be treated as a single reference because a skilled artisan would have found that Schulman describes the material to be incorporated from Loeb with sufficient particularity. *Husky Injection Molding Sys. Ltd. v. Athena Automation Ltd.*, 838 F.3d 1236, 1248-49 (Fed. Cir. 2016).

1. Overview of Schulman (Ex.1012)

Schulman was granted from an application that was filed in February 1998 and is prior art under at least §102(e). Ex.1003¶44.

Schulman describes an electrical stimulation system where one or more

microstimulators that contain pulse generators can be implanted into a person to provide nerve or muscle stimulation therapy. Ex.1012, 1:8-14, 2:17-20. Schulman explains that the microstimulators can be used for a "***wide variety of applications to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain***…." Ex.1012, Abstract. Schulman shows that a plurality of microstimulators can be implanted into a person, and that each microstimulator can be separately controlled and configured with various pulse parameters (*e.g.*, amplitude, pulse frequency, pulse width). Ex.1012, 4:40-44, 4:64-5:4, 8:64-67. Each microstimulator "can be actuated (enabled/disabled) or have its characteristics altered via communications with one or more devices external to itself." Ex.1012, 5:5-8.

Schulman acknowledges that microstimulator systems were known in the art and incorporates several such systems, including Loeb's (*see* §V.A.2, below), by reference. Ex.1012, 1:15-19. Schulman explains, however, that because prior art microstimulators were powered by inductively receiving alternating magnetic energy from an externally located power supply, they required the continuous presence of the external power supply, which Schulman describes as a "life style limitation." Ex.1012, 3:40-61, Fig.1; *see also id*., 1:26-34. Thus, Schulman teaches a microstimulator system where each microstimulator is powered by its own ***rechargeable battery*** and, therefore, does not require the continuous use of an

external power source. Ex.1012, 3:62-67, 4:17-21. And the microstimulator's battery can be recharged by "an external charger…[that] periodically generate[s] an AC magnetic field for supplying energy to the [microstimulator's] charging circuit," which then produces a charging current to charge the battery. Ex.1012, 1:66-2:9. *See also* Ex.1003¶¶57-61.

2. Overview of Loeb (Ex.1017)

Loeb issued in November 1996 and is prior art under §102(b). Ex.1003¶45. Like Schulman, Loeb is directed to an implantable electrical stimulation system that uses a plurality of implantable microstimulators where each microstimulator is "individually controllable" and each provides its own stimulation signal. Ex.1017, Abstract, 1:6-13, 4:16-19 ("[E]ach of the microstimulators included within the implanted stimulator of the present invention is totally isolated from and operates independently of the other microstimulators."). Loeb teaches that a plurality of microstimulators can be combined together to form a single multichannel stimulation system, where each of the microstimulators is connected to the same implanted electrode array. Ex.1017, 3:48-54, 7:65-8:1. Figure 2A (below) illustrates an exemplary embodiment of Loeb's disclosed implantable stimulator unit 50 designed for implantation in the cochlea of a human ear. Ex.1017, 7:65-8:6; *see also id*., 8:61-65, 9:4-5.

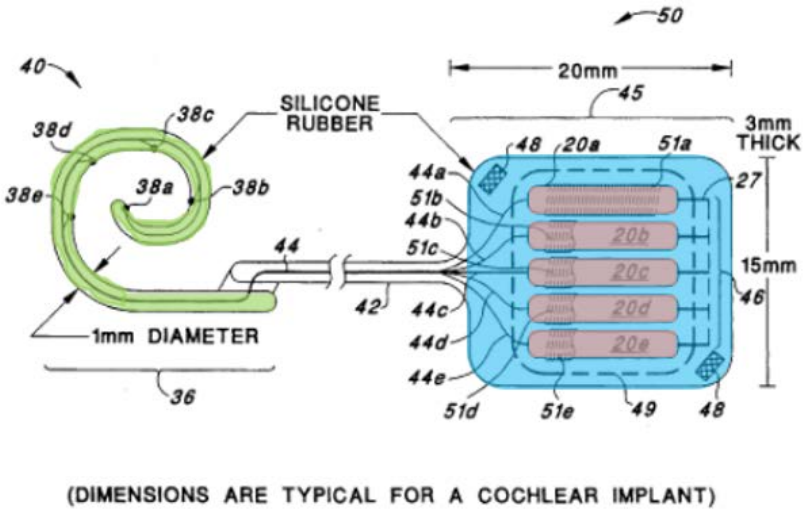

FIG. 2A

Figure 2A shows five microstimulators 20*a*-20*e* (shaded pink) that are "mechanically held together in a stimulator array 45" (shaded blue). Ex.1017, 8:17-20. Electrode array 36 (shaded green) includes a "plurality of stimulating electrode contacts" 38*a*-38*n* that are located "near a distal end 40 of a flexible body 42 that connects the array 36 with the microstimulators 20." Ex.1017, 8:7-12. Each of the electrode contacts 38*a*-38*n* "is in electrical contact with one or more of the electrodes 26 or 27 that protrude out from the ends of each microstimulator 20 through respective conductive wires" 44*a*-44*n*. Ex.1017, 8:12-16.

Figure 4B below shows how stimulator unit 50 works with external processor 60.

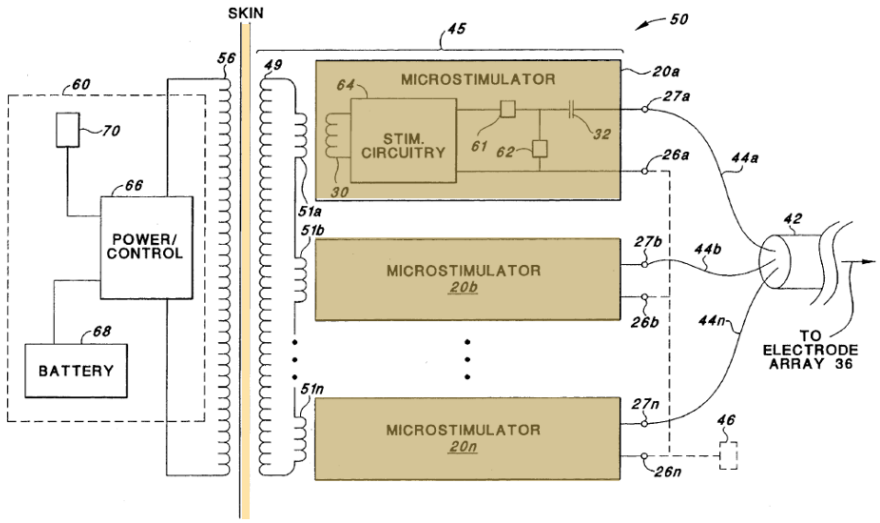

FIG. 4B

As in Figure 2A, the microstimulators 20 are arranged in an array 45 with electrodes 27*a*27*n* connected to electrode array 36 via wire conductors 44*a*-44*n* and electrodes 26*a*-26*n* electrically tied together to form common indifferent electrode 46 or electrically isolated to form a plurality of indifferent electrodes. Ex.1017, 10:44-55. Loeb explains this configuration allows for the creation of a multichannel stimulation system that could be used for many different purposes. Ex.1017, 7:65-8:6.

In Figure 4B, Loeb discloses that the implanted system is controlled by external processor 60—which can be powered by a rechargeable battery 68—that drives external coil 56 with a power signal modulated with a particular microstimulator's address or code to trigger that particular microstimulator to produce a stimulation pulse through its own set of electrodes. Ex.1017, 11:10-13, 11:25-35, 11:40-43; *see also id.*, 7:40-60. The modulated power signal also

specifies the parameters (*e.g.*, amplitude and pulse width) of the stimulation pulse(s) to be generated by the particular microstimulator. Ex.1017, 7:51-60. The implanted stimulator unit 50 captures energy from the external coil 56 through focusing coil 49, which directs that energy to each microstimulator's individual coil 30 via its respective coupling coil 51*a*-51*n*. Ex.1017, 13:4-28. Ex.1003¶¶62-64.

3. Motivation to Combine

Schulman and Loeb both describe electrical stimulation systems that use implantable microstimulators that can be controlled using external devices. A comparison of Loeb's and Schulman's microstimulators (*see* Figures below) shows the two are very similar[5], except that Schulman's microstimulator includes a rechargeable battery so that the user would not be required to always have the external power source in close proximity for the microstimulator to operate. Ex.1003¶65.

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[5] For example, both microstimulators have an IC chip (*e.g.*, Ex,1017, Fig.1 (element 26'); Ex.1012, Fig.5A (element 216)) and electrodes on both sides of the microstimulator (*e.g.*, Ex.1017, Fig.1 (elements 26, 27); Ex.1012, Fig.5A (elements 112a, 112b)). Ex.1003¶65.

Loeb's microstimulator 20 (Ex.1017, Fig.1):

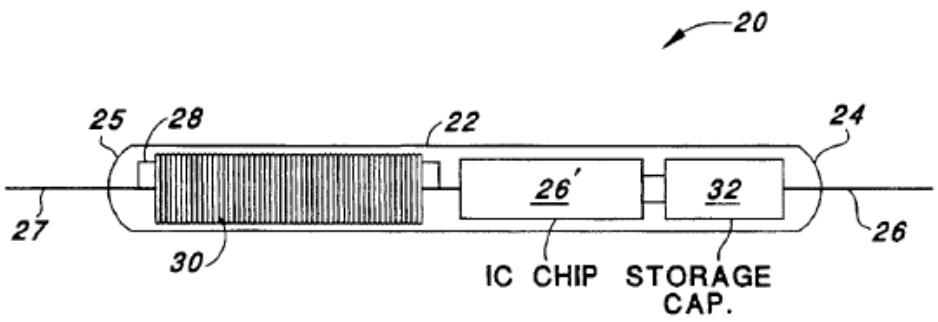


FIG. 1

Schulman's microstimulator 100 (Ex.1012, Fig.5A):

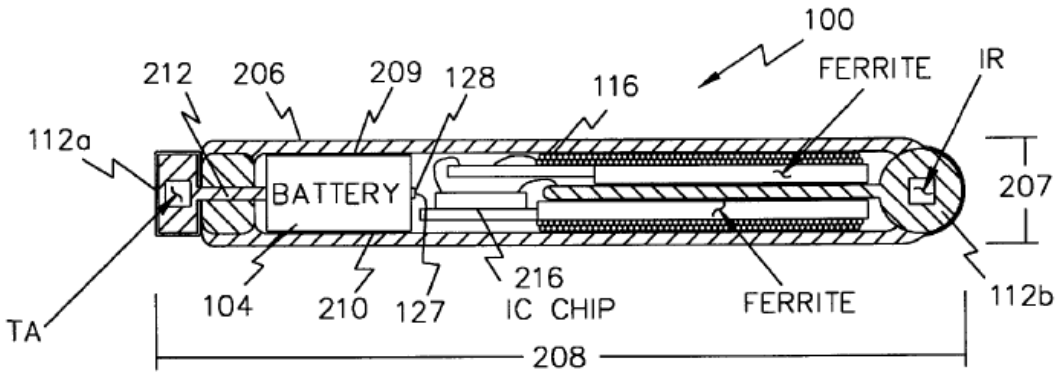


FIG. 5A

Schulman expressly incorporates Loeb by reference, and identifies Loeb as describing an analogous implantable device for tissue stimulation that uses microstimulators. Ex.1012, 1:15-19. A POSA considering Schulman naturally would have considered Loeb, which Schulman expressly incorporates by reference. *Id.*; Ex.1003¶66. A POSA would have looked to Loeb (as well as other cited references) to consider other potential applications and arrangements for Schulman's system. Ex.1003¶66.

Because of the similarities between Schulman's and Loeb's microstimulator systems and because Schulman expressly states that its microstimulators are an improvement to prior art microstimulators like Loeb's (Ex.1012, 1:26-34, 1:55-60), it would have been obvious to arrange a plurality of Schulman's microstimulators into the microstimulator array arrangement taught by Loeb. Ex.1003¶66. Loeb shows this microstimulator array arrangement in, for example, Figures 2A, 2B, 4A, 4B, and 5. A POSA would have been motivated to do so at least because (1) a microstimulator array is less likely to migrate from the implant site than individually implanted microstimulators would, and (2) it would allow the external charger to more efficiently charge the microstimulators' batteries. Ex.1003¶67. First, while the benefit of having multiple, independently programmable and controllable microstimulators would be the same for either configuration, a system using a microstimulator array with an attached electrode array would provide better control in applying stimulation to the targeted area than a system using individually implanted microstimulators that are more susceptible to migrating away from the targeted stimulation area. *Id*. Moreover, a microstimulator array configuration would create better alignment between the coil of the external charger and the coils of the microstimulators and thereby improve the efficiency with which the microstimulators' batteries are charged by the external charger. Ex.1017, 9:28-30 ("Optimum inductive coupling occurs between the internal coils

30 and the external coil when good alignment is achieved."); Ex.1003¶67. As illustrated by Figure 4B of Loeb, arranging microstimulators into a microstimulator array makes it possible to use a "focusing coil," which "improve[s] the coupling efficiency" between the external coil and the microstimulators' coils. Ex.1017, 9:32-45; Ex.1003¶67.

A POSA implementing Schulman's system would have found it obvious to do so using Loeb's multichannel stimulator configuration as it would have been straightforward to use Schulman's improved microstimulators as a substitute for Loeb's microstimulators. Ex.1017, 8:17-20 (in Fig. 2A, "five microstimulators…are mechanically held together in a stimulator array 45"), 9:33-35, 9:47-51, 10:27-30, 10:44-47 ("stimulator 50 includes a plurality of microstimulators 20*a*, 20*b*,…20*n* connected in a microstimulator array 45"); Ex.1003¶68. For example, as illustrated below with respect to Loeb's Figure 5, Loeb's microstimulators 20*a*-20*n* could be swapped out for Schulman's microstimulators 100*a*-100*n* such that Loeb's conductive wires 44 connect to each of Schulman's microstimulator's electrodes 112a and 112b and are in electrical contact with Loeb's electrode contacts 38*a*-38*n* in electrode array 36. Ex.1003¶68.

Original Loeb, Figure 5:

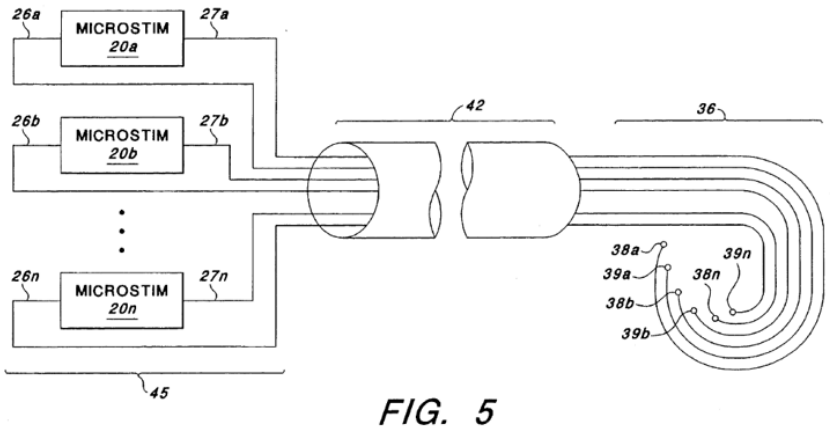


FIG. 5

Schulman and Loeb combination:

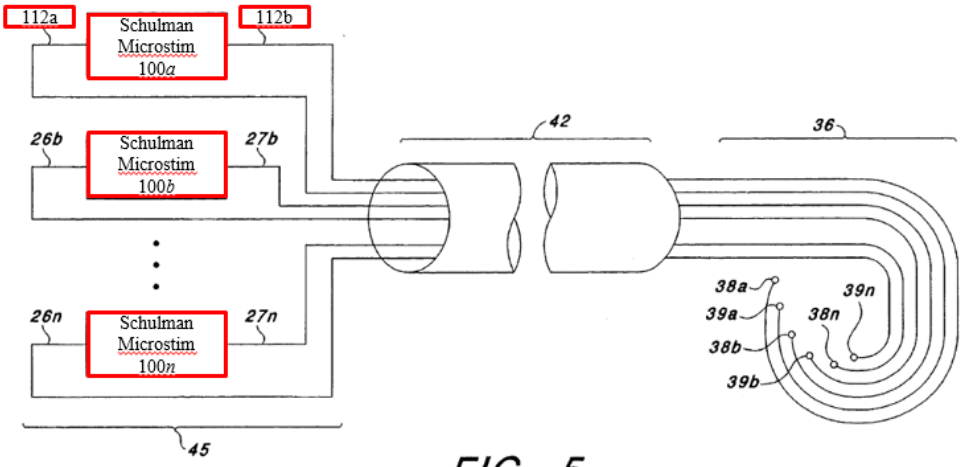


FIG. 5

A POSA would have known that Schulman's improved microstimulators could replace Loeb's microstimulators in the microstimulator array regardless of the size of Schulman's microstimulators. Ex.1003¶¶69-71. For example, because Loeb's main embodiment is for a cochlear implant that requires "a sufficiently small device that can be…implanted under the skin behind the ear," each of Loeb's microstimulators is only 10-15mm in length and the microstimulator array (or main

portion) is "prefer[ably]" 20mm by 15mm by 3mm. Ex.1017, 7:22-24, 8:30-34; *see also id*., 5:35-41, Figs.2A, 2B. Schulman, however, discloses that its system can be used in "a wide variety of applications to stimulate nerves and associated neural pathways." *E.g.*, Ex.1012, Abstract. Loeb likewise indicates that its stimulation device could be used for other applications. Ex.1017, 8:1-6. Thus, although Schulman's microstimulators are typically no larger than 60mm long and 6mm wide (*see, e.g.*, Ex.1012, Abstract), Schulman also expressly discloses that its claimed microstimulator "includes even smaller embodiments, e.g., 15 mm long with an O.D. of 2.2 mm" (Ex.1012, 11:36-41). Moreover, the acceptable size of an implant varies depending on the particular application. Ex.1003¶70. For example, a larger implant can be tolerated for SCS than, *e.g.*, a cochlear implant. *E.g.*, Ex.1001, 2:59-61 (describing SCS implant as "having a rounded case with a 45 mm diameter and 10 mm thickness"); Ex.1017 8:30-34 (describing cochlear implant having dimensions of 20mm by 15mm by 3mm); Ex.1003¶70.

Given the similarities between Schulman's and Loeb's microstimulators and systems, a POSA would have known that features from Schulman and Loeb could be combined with a high degree of predictability and the combination would work as expected. Ex.1003¶71.

B. Ground 1: Schulman and Loeb Render Obvious Claims 18 and 27

1. Claim 18

a) [18.preamble]: "A spinal cord stimulation system" [6]

It was well-known at the time of the '280 that SCS systems comprised implantable medical devices that deliver electrical stimulus to portions of a person's spinal cord or surrounding tissue to stimulate nerves and control chronic pain. *E.g.*, Ex.1006, 1:13-29; Ex.1001, 1:14-17; Ex.1003¶72. Similarly, Schulman discloses a "system for stimulating tissue within a patient's body," including "nerve or muscle[] stimulation…to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain…." Ex.1012, claim 16, Abstract; *see also* claim 1, 1:9-14 ("The present invention relates to devices…for various purposes including tissue, e.g., nerve or muscle, stimulation…."), 1:38-41, 3:21-37

[6] Because the claim body of each claim having the preamble "[a] spinal cord stimulation system" is "structurally complete" and the preamble only "state[s] a purpose or intended use," "[a] spinal cord stimulation system" is not limiting. *See Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951, 956 (Fed. Cir. 2016) (holding preamble term "medical implant" not limiting because it "merely describes a use or purpose" of the claims). In any event, even if it were limiting, the preamble is obvious in view of Schulman, as explained herein.

("***When used as a stimulator, such a device is useful in a wide variety of applications to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain***."); 3:62-67. Although Schulman does not expressly state that its disclosed system is specifically directed to an SCS system, it would have been obvious that Schulman's system could be used for SCS based on Schulman's repeated express teachings that its system has broad application to nerve stimulation for pain relief and because most electrical stimulation systems, regardless of specific medical application, were similarly configured (*see* §II.A). Ex.1003¶73.

Therefore, to the extent the preamble is limiting, Schulman renders obvious a "spinal cord stimulation system." Ex.1003¶¶72-73.

b) [18.a]: "a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry"

As discussed (§IV.1), the proper construction of "multi-channel IPG" in the '280 patent requires the ability to simultaneously deliver stimulation pulses with different stimulation parameters over two or more channels. Unlike systems the '280 criticizes for having "only a single voltage source, and hence only a single stimulation channel" (Ex.1001, 2:11-14, 2:18-21), Schulman's system includes a plurality of microstimulators (and, therefore, a plurality of stimulation channels), each having "stimulation circuitry 110," including a "programmable pulse

generator 178…configured with parameters," to generate its own sequence of desired pulses. Ex.1012, 6:59-7:2, Table I. And each of Schulman's microstimulators can be "separately configured, controlled and/or sensed as part of a system controlling one or more neural pathways within a patient's body." Ex.1012, 8:64-67; *see also id*., 5:5-8. *See also* Ex.1003¶¶74-75.

Schulman also discloses that any number of Schulman's plurality of microstimulators can be programmed to stimulate simultaneously. For example, Schulman discloses that an external device can communicate with the microstimulators, which are preconfigured with an address ID, using "command message[s] 192" having the fields identified in Figure 4 and Table II below. Ex.1012, 8:42-67; *see also id*., 5:5-8. Schulman further shows that such command messages can also be sent by a particular implanted microstimulator. Ex.1012, 5:51-54, 6:44-49, 8:36-41. The "data field portion 200," which is labeled "Microstimulator Data" in Figure 4, "contain[s] command data for the prescribed operation[]." Ex.1012, 8:58-60.

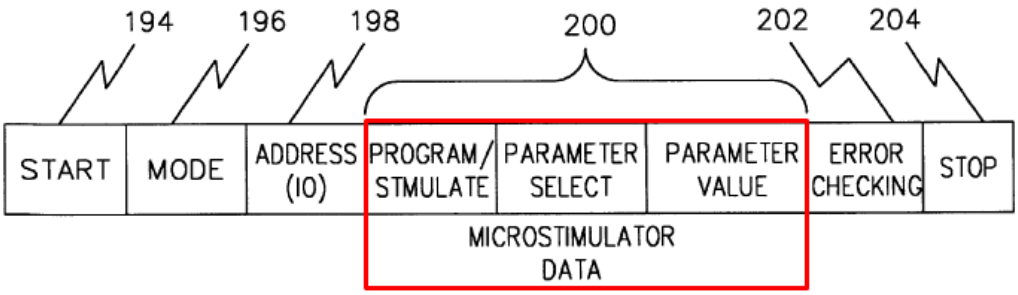


FIG. 4

TABLE II

Message Data Fields		
MODE		ADDRESS (ID)
00 = Stimulator 01 = Sensor 02 = STransponder 03 = SGroup		8 bit identification address 8 bit identification address 4 bit identification address 4 bit group identification address
Data Field Portion		
Program/Stimulate	=	select operating inode
Parameter/ Preconfiguration Select	=	select programmable parameter in program mode or preconfigured stimulation or sensing parameter in other modes
Parameter Value	=	program value

As can be seen from Table II and Figure 4, a command message can be configured to either the "Program" or "Stimulate" operating mode. Ex.1012, Table II, Fig. 4; Ex.1003¶¶76-79. And depending on the mode chosen, the "Parameter/Preconfiguration Select" data field is set to "programmable parameter in program mode" or "preconfigured stimulation in other modes." *Id.*

Schulman explains that it can be beneficial to coordinate the timing of the stimulation provided by multiple microstimulators. Ex.1012, 9:27-29. Schulman shows that one way of providing such timing is to send a coordination message to a specified group of microstimulators instructing each microstimulator to provide stimulation according to its own preconfigured settings. Ex.1012, 9:21-29; Ex.1003¶80. Each microstimulator 100 "can be programmed with a group ID" and when "a microstimulator[] receives a group ID message that matches its stored

group ID, it responds as if the message was directed to its identification address 108. Accordingly, a plurality of microstimulators, e.g., 100*a* and 100*b*, can be commanded with a single message." Ex.1012, 9:21-27. Thus, Schulman's system could send a command to a group of microstimulators with the same group ID and command that group to "Stimulate" according to their "preconfigured stimulation" settings at the same time. Ex.1003¶81. Schulman expressly states that using a group message is "of particular use when precise timing is desired among the stimulation of a group of nerves." Ex.1012, 9:27-29; *see also id*., 5:5-8 ("[E]ach implanted device 100, e.g., microstimulator, can be actuated (enabled/disabled) or have its characteristics altered via communications with one or more devices external to itself."). And, as already discussed, each of Schulman's microstimulators is separately configurable with its own pulse parameters. Ex.1012, 5:5-8, 6:63-7:2, 8:64-67; Ex.1003¶75.

As discussed (§V.A.3), it would have been obvious to arrange a plurality of Schulman's microstimulators to form a multichannel stimulation device that is connected to an electrode array, as suggested by Loeb. Ex.1017, 8:66-9:5; Ex.1003¶82. As Loeb explains, the array of microstimulators is itself enclosed within a "sealed" housing to form a single stimulator unit. Ex.1017, 8:66-9:5 ("As shown in FIG. 2A, the electrode array 36 and the ***microstimulator array 45 are sealed or molded in a body compatible material***….If flexibility is desired, such

material may be, e.g., silicone rubber. If rigidity is desired, such material may be, e.g., epoxy. Regardless of the material used, ***the result is to form an integral implantable multichannel stimulator unit 50***."); *see also id*., 8:17-20 (in Fig. 2A, "five microstimulators…are mechanically held together in a stimulator array 45"), 9:33-35, 9:47-51, 10:27-30, 10:44-47 ("stimulator 50 includes a plurality of microstimulators 20*a*, 20*b*,…20*n* connected in a microstimulator array 45"), Figs.2A, 2B, 4A, 4B, 5; Ex.1003¶83. And, as explained (§V.A.3), because of the similarities between Schulman and Loeb and given Schulman's express incorporation by reference of Loeb, a POSA would have known that features from Schulman and Loeb could be combined with a high degree of predictability and the combination yielding the claimed structure would work as expected. Ex.1003¶71.

Schulman also discloses that each microstimulator (within the microstimulator array, as taught by Loeb) contains its own replenishable power source and processing circuitry:

> The microstimulator 100 of the present invention is comprised of a sealed housing 206…for enclosing ***a power source 102, e.g., a rechargeable battery 104, and power consuming electronic circuitry*** including (1) ***controller circuitry 106*** powered by the power source 102 and having ***address storage circuitry 108*** with an identification address (ID) stored within, (2) ***stimulation circuitry 110*** powered by the power source 102 and operating under control of the controller circuitry 106 for providing drive pulses to one or more electrodes (i.e., transducers)

> 112, and (3) ***receiver means 114*** for providing command and address identification information to the controller circuitry 106.

Ex.1012, 4:4-16; *see also id*. 1:20-22 ("Such known microstimulators are characterized by a sealed housing which contains ***electronic circuitry for producing small electric currents between spaced electrodes***."), 1:41-49, 4:17-18 ("[P]ower source 102 comprises a ***rechargeable battery 104***…."), 4:64-5:1 ("The controller circuitry 106 controls the operation of the stimulation circuitry 110 using a controller 130 (preferably a state machine or microprocessor) according to configuration data within a configuration data storage 132 coupled to controller 130."), 9:32-35 ("The battery 104 conveniently fits within a sealed elongate housing 206 (preferably hermetically sealed) which encases the microstimulator 100."), 11:2-4, Figs.2, 5; Ex.1003¶84.

Therefore, Schulman and Loeb render obvious "a multi-channel implantable pulse generator (IPG)" (*e.g.*, a plurality of Schulman's microstimulators 100 connected in a microstimulator array 45, as taught by Loeb) having "a replenishable power source" (*e.g.*, Schulman's rechargeable battery 104), "a housing" (*e.g.*, sealed housing around the microstimulator array), and "IPG processing circuitry" (*e.g.*, electronic circuitry such as stimulation circuitry, controller circuitry, and storage circuitry). Ex.1003¶¶74-84.

c) [18.b]: "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

Although Schulman does not expressly disclose "an implantable electrode array detachably connected to the IPG" and "having a multiplicity of n electrodes (En) thereon," that feature would have been obvious in view of Loeb's express disclosure of an implantable electrode array having multiple electrodes connected to a microstimulator array. Ex.1003¶85. As discussed (§V.A.3), it would have been obvious to simply substitute in Schulman's rechargeable microstimulators for Loeb's microstimulators such that Schulman's microstimulators are connected in a microstimulator array, as taught by Loeb. *E.g.*, Ex.1017, Figs.2A, 2B, 4A, 4B, 5.

Loeb discloses that each of its microstimulators is connected to an electrode array. Ex.1017, Abstract ("[S]timulation system includes a plurality of implantable microminiature stimulators (microstimulators), ***each being connected to a respective implanted electrode or electrode array***….The electrode or ***electrode array is implanted*** so as to contact nerves and/or tissue that is to be stimulated."). For example, Figure 2A shows "***electrode array 36 includes a plurality of stimulating electrode contacts, 38a, 38b, 38c,…38n***" and that each is located near the "distal end" of a "***flexible body 42 that connects the array 36 with the microstimulators 20***," which are "mechanically" connected in a stimulator array 45. Ex.1017, 8:7-12, 8:17-25; *see also id.*, 7:65-8:15, 8:45-57, 9:6-20, 10:3-20,

Figs. 2B, 4A, 4B, 5 (showing stimulator array 45 connected to electrode array 36).

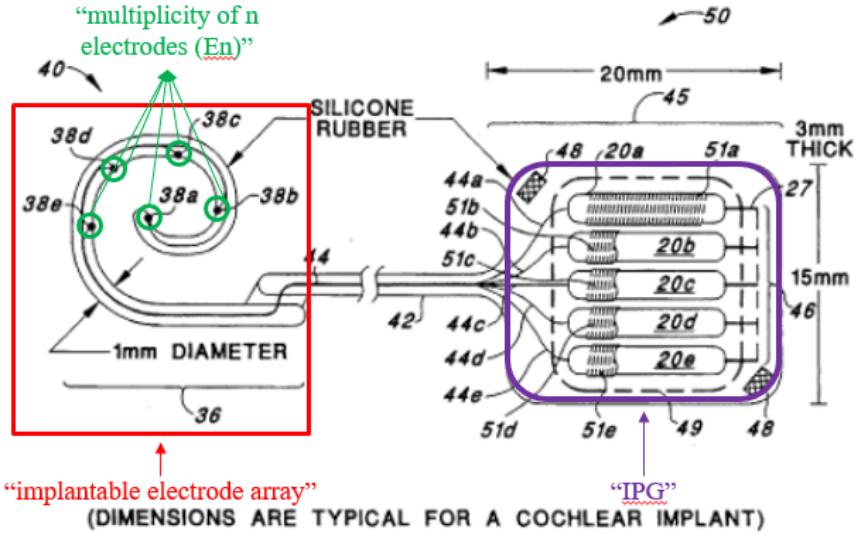


FIG. 2A

Although in Loeb's preferred embodiment the electrode array 36 and microstimulator array 45 are sealed together, it would have been a matter of mere design choice to instead use a detachable version of flexible body 42, which connects the electrode array 36 to the microstimulator array 45 and functions as a lead. Ex.1003¶86. As the '280 admits, many different types of leads were known in the art and could be used with the same IPG. Ex.1001, 9:8-11, 10:19-24. It was well-known at the time that leads can be attached and detached to IPGs, so medical professionals and patients could have the flexibility to select the type of lead that best suits the patient's particular stimulation needs and so malfunctioning leads could be replaced without having to replace the entire IPG. *See, e.g.*, Ex.1016, Abstract, 2:66-3:2 (describing a lead with a "connector" to the IPG); Ex.1003¶87.

d) [18.c]: "a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is independently programmable with different stimulation parameters"

As discussed (§V.B.1.b), Schulman's system includes a "plurality" of microstimulators (or stimulation channels) that can be "***separately configured [and] controlled***" with "***configuration data [that] specifies various programmable parameters***…that effect the characteristics of the drive pulses generated by stimulation circuitry 110 as controlled by the controller 130." Ex.1012, 4:40-42, 4:64-5:4, 8:64-67; *see also id*., 6:59-7:2. For example, Figure 3A shows two implanted microstimulators—100*a* and 100*b*. Ex.1012, Fig.3. Table I (below) identifies the parameters that can be programmed on each microstimulator by sending a command message 192 addressed to a particular microstimulator:

TABLE I

Stimulation Parameters	
Current:	Continuous current charging of storage capacitor
Charging currents:	1, 3, 10, 30, 100, 250, 500 μa
Current Range:	0.8 to 40 ma in nominally 3.2% steps
Compliance Voltage:	selectable, 3–24 volts in 3 volt steps
Pulse Frequency (PPS):	1 to 5000 PPS in nominally 30% steps
Pulse Width:	5 to 2000 μs in nominally 10% steps
Burst On Time (BON):	1 ms to 24 hours in nominally 20% steps
Burst Off Time (BOF):	1 ms to 24 hours in nominally 20% steps
Triggered Delay to BON:	either selected BOF or pulse width
Burst Repeat Interval:	1 ms to 24 hours in nominally 20% steps
Ramp On Time:	0.1 to 100 seconds (1, 2, 5, 10 steps)
Ramp Off Time:	0.1 to 100 seconds (1, 2, 5, 10 steps)

Ex.1012, 6:63-7:2, Tables I-II, 8:42-67, Fig.4. Each microstimulator "can be actuated (enabled/disabled) or have its characteristics altered via communications

with one or more devices external to itself." Ex.1012, 5:5-28 (communications to a microstimulator are sent via command signals addressed to that microstimulator). Ex.1003¶¶88-89.

As discussed (§V.A.3), it would have been obvious to simply substitute in Schulman's rechargeable microstimulators for Loeb's microstimulators such that Schulman's microstimulators are connected in a microstimulator array, as taught by Loeb. *E.g.*, Ex.1017, Figs.2A, 4A, 4B; Ex.1003¶90. And Loeb discloses that its microstimulator arrays can comprise a multiplicity of microstimulators. *E.g.*, Ex.1017, 4:66-5:2 ("four to sixteen channels will usually be sufficient").

For example, Figure 2A illustrates a microstimulator array embodiment with five microstimulators 20*a*-20*e*, which correspond to five stimulation channels. Ex.1017, Fig.2A, 8:17-20; Ex.1003¶90.

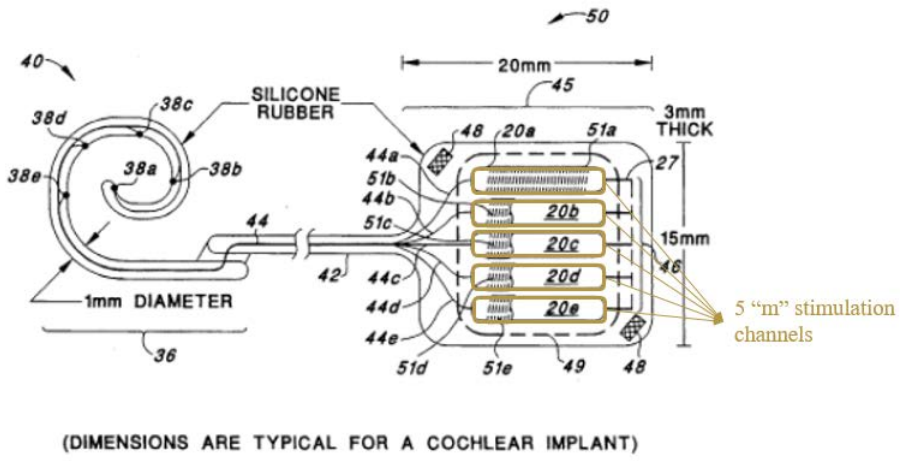


FIG. 2A

As another example, Figure 5 illustrates an embodiment with *n*—but no less

than three—microstimulators, which correspond to *n*—but not less than three—stimulation channels. Ex.1017, Fig.5, 8:45-48; Ex.1003¶91.

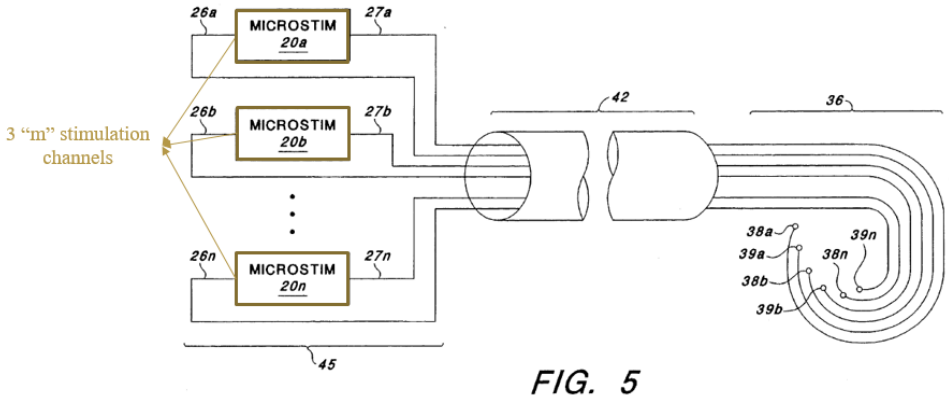


FIG. 5

e) [18.d]: "wherein m is equal to or less than n, and m is 2 or greater"

As explained (§V.A.3), it would have been obvious to arrange a plurality of Schulman's microstimulators into a microstimulator array arrangement, as taught by Loeb. Looking again at Figure 2A, Loeb discloses an embodiment with five ("m") stimulation channels corresponding to the five microstimulators 20*a*-20*e* in the microstimulator array, and five ("n") electrodes 38*a*-38*e* on electrode array 36. Ex.1017, Fig.2A, 8:7-9, 8:17-20; Ex.1003¶92. Therefore, Figure 2A discloses "m is equal to or less than n" (*e.g.*, 5 = 5) and "m is 2 or greater" (*e.g.*, 5 > 2). Ex.1003¶92.

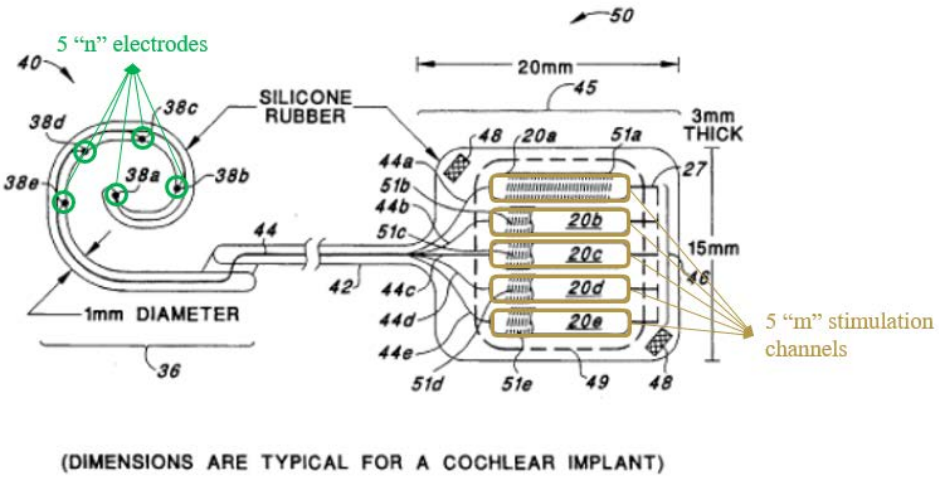


FIG. 2A

Figure 5 of Loeb also discloses this limitation. For example, assuming that 20*n* in Figure 5 below is 20*c*, Figure 5 has three ("m") stimulation channels corresponding to three microstimulators 20*a*-20*c* in the microstimulator array, and six ("n") electrodes (38*a*, 39*a*, 38*b*, 39*b*, 38*c*, 39*c*) on electrode array 36. Ex.1017, Fig.5, 8:45-57; *see also id*., Figs.4A, 4B. Therefore, Figure 5 also discloses "m is equal to or less than n" (*e.g.*, 3 < 6) and "m is 2 or greater" (*e.g.*, 3 > 2). Ex.1003¶93.

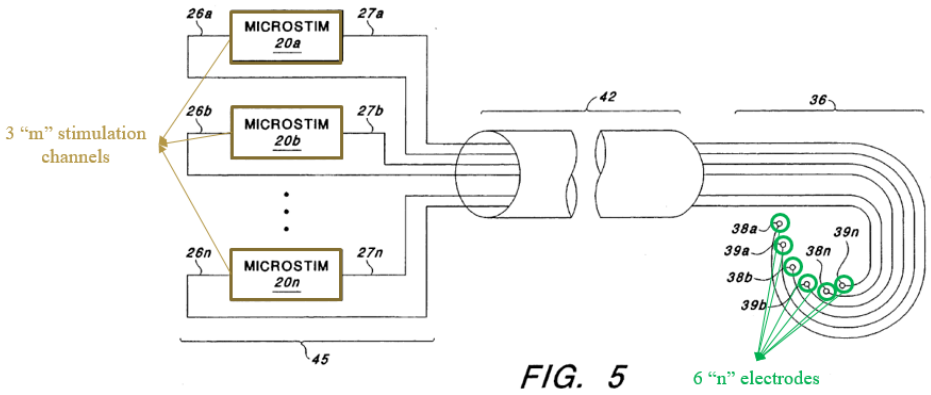


FIG. 5

f) [18.e]: "wherein the IPG contains a soft ramping circuit that ramps up the stimulation pulse magnitude at the beginning of a burst of stimulation pulses in at least one channel"

As discussed (§V.B.1.d), Schulman discloses that each of its microstimulators 100 is configured with various pulse parameters "corresponding to a desired pulse sequence." Ex.1012, 6:63-66. Schulman's Table I identifying the programmable "Stimulation Parameters" includes a "Ramp On Time" parameter:

TABLE I

Stimulation Parameters	
Current:	Continuous current charging of storage capacitor
Charging currents:	1, 3, 10, 30, 100, 250, 500 μa
Current Range:	0.8 to 40 ma in nominally 3.2% steps
Compliance Voltage:	selectable, 3–24 volts in 3 volt steps
Pulse Frequency (PPS):	1 to 5000 PPS in nominally 30% steps
Pulse Width:	5 to 2000 μs in nominally 10% steps
Burst On Time (BON):	1 ms to 24 hours in nominally 20% steps
Burst Off Time (BOF):	1 ms to 24 hours in nominally 20% steps
Triggered Delay to BON:	either selected BOF or pulse width
Burst Repeat Interval:	1 ms to 24 hours in nominally 20% steps
Ramp On Time:	0.1 to 100 seconds (1, 2, 5, 10 steps)
Ramp Off Time:	0.1 to 100 seconds (1, 2, 5, 10 steps)

The "Ramp On Time" parameter controls the duration of time during which electrical stimulus is ramped up before applying electrical stimulus at full operating amplitude. Ex.1003¶¶94-95. At the time the '280 was filed, electrical stimulation systems, including SCS systems, predominantly generated stimulation fields that produced paresthesia to mask pain. Ex.1003¶94; Ex.1006, 1:23-28. In

such systems, abrupt delivery of stimulation pulses can feel like a jolt and cause discomfort to the patient. Ex.1003¶94. Therefore, systems like Schulman's used a ramp up period before applying an electrical stimulus at full operating amplitude. *Id*.

Schulman also discloses that the pulses defined by these programmable stimulation parameters, including "Ramp On Time," are "generated by stimulation circuitry 110 as controlled by the controller 130." Ex.1012, 4:64-5:4 ("The controller circuitry 106 controls the operation of the stimulation circuitry 110 using a controller 130…according to configuration data within a configuration data storage 132…. The configuration data specifies various programmable parameters…that effect the characteristics of the drive pulses generated by stimulation circuitry 110 as controlled by the controller 130."). Specifically, programmable pulse generator 178 and voltage multiplier 180—both of which are a part of stimulation circuitry 110—"are configured with parameters (see Table I) corresponding to a desired pulse sequence and specifying how much to multiply the battery voltage…to generate a desired compliance voltage V_c." Ex.1012, 6:59-7:2.

Therefore, Schulman discloses "the IPG" (*e.g.*, plurality of microstimulators 100) "contains a soft ramping circuit" (*e.g.*, controller circuitry 106—including controller 130 and/or configuration data storage 132—and/or stimulation circuitry

110—including pulse generator 178 and/or voltage multiplier 180) "that ramps up the stimulation pulse magnitude at the beginning of a burst of stimulation pulses" (*e.g.*, ramps up stimulation pulse magnitude at the beginning of a burst of stimulation pulses according to "Ramp On Time" parameter) "in at least one channel" (*e.g.*, in at least one microstimulator 100). Ex.1003¶¶96-97.

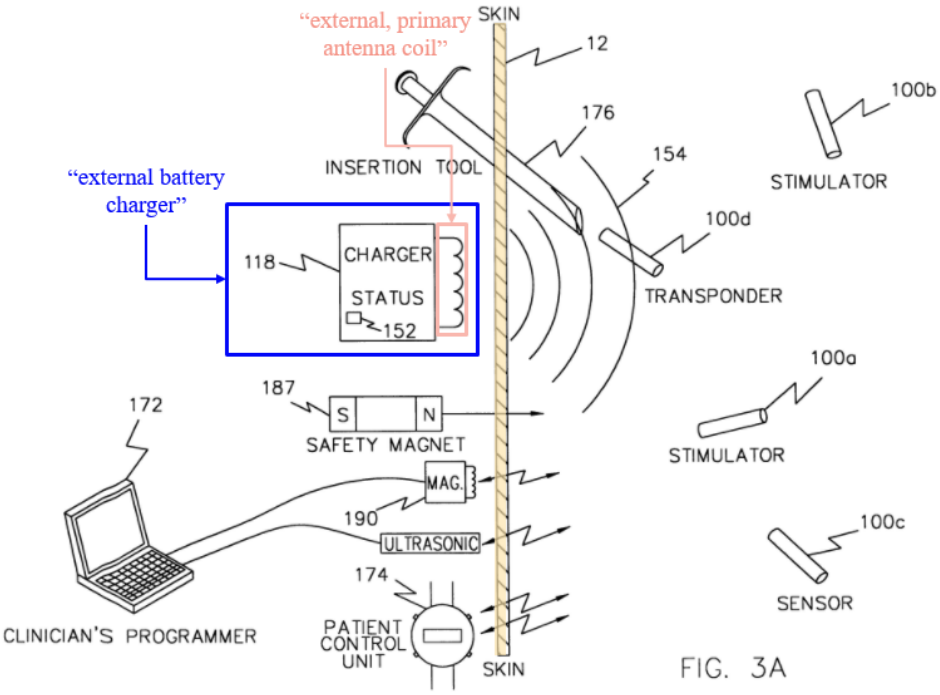
2. Claim 27

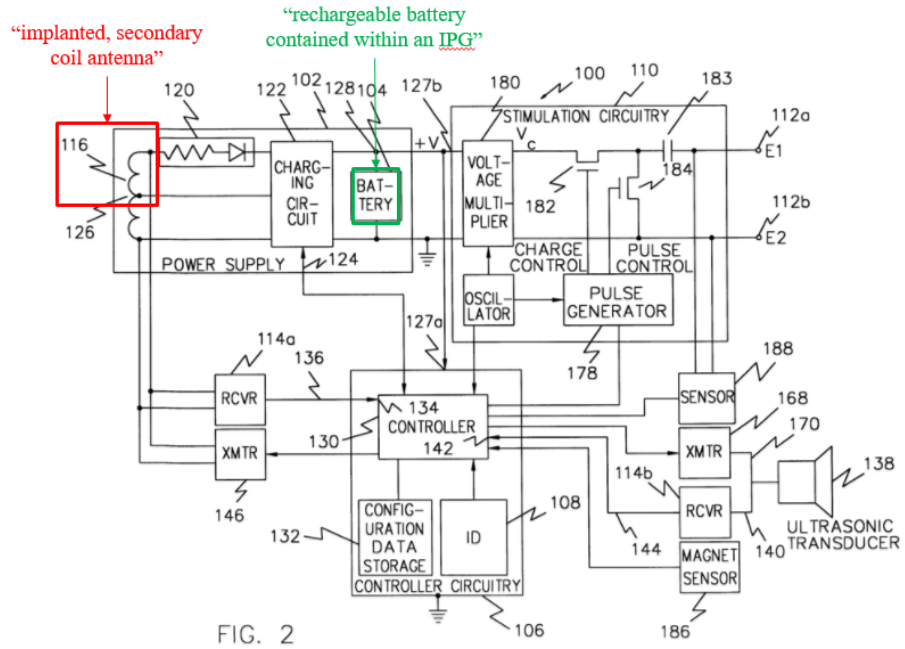
a) [27.preamble]: "A method of charging a rechargeable battery contained within an implantable pulse generator (IPG), which IPG is connected to an implanted, secondary coil antenna, the method employing an external battery charger, which charger contains a rechargeable battery electrically connected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

The preamble of claim 27 specifies several features, all of which are taught by Schulman and Loeb. Schulman alone teaches "[a] method of charging a rechargeable battery contained within an implantable pulse generator (IPG), which IPG is connected to an implanted, secondary coil antenna." Ex.1003¶98. Schulman describes a process for recharging the battery in each implanted microstimulator. Ex.1012, 4:26-56. Schulman discloses that each microstimulator contains a battery and a coil for receiving power from an external charger. It explains that each microstimulator's battery 104 is recharged when its "***coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118***…and responsively supplies…current to a charging

circuit 122…[that] monitors the voltage V on ***battery 104 and charges it*** according to its preferred charging characteristics (current and voltage)." Ex.1012, 4:27-35. Schulman shows the power is transmitted to the microstimulator's coil transcutaneously using an alternating current. Ex.1012, 1:66-2:9 (microstimulator's "charging circuit is capable of producing a charging current in response to an…AC magnetic field" produced by an external charger), 4:40-44 ("In a typical application (see FIG. 3A), a plurality of such devices 100, e.g., microstimulators, are implanted under the skin 12 of a patient's body and simultaneously subjected to an alternating magnetic field 154 from the external power source 118."), 4:52-56, 6:2-4.

The combination of Schulman and Loeb teach that the recharging "method employ[s] an external battery charger, which charger contains a rechargeable battery electrically connected to an external, primary antenna coil." Ex.1003¶¶98-100. Figure 3A (below) shows Schulman's external battery charger (blue) is connected to an external coil (pink). And, as depicted in Figures 2 and 3A below and taught by Schulman, the external charger 118 produces alternating magnetic field 154, which is received by each of the microstimulators 100 through their respective coils 116 to charge their respective rechargeable batteries 104:





Ex.1012, Figs. 2, 3A, 4:27-35.

Although Schulman does not expressly state that its external charger 118 contains its own rechargeable battery, it would have been at least obvious to

include one in light of Loeb's express disclosure of including a rechargeable battery in its external device. Ex.1003¶¶99-100. Loeb's system includes an "external processor 60" that drives "external coil 56" with power and includes a "power source 68, such as a rechargeable battery,…so as to render the processor 60 portable." Ex.1017, 11:9-12, 11:40-43, Fig.4B; *see also id*., Abstract ("Operating power is inductively coupled from the control unit to the microstimulators."), 4:25-31.

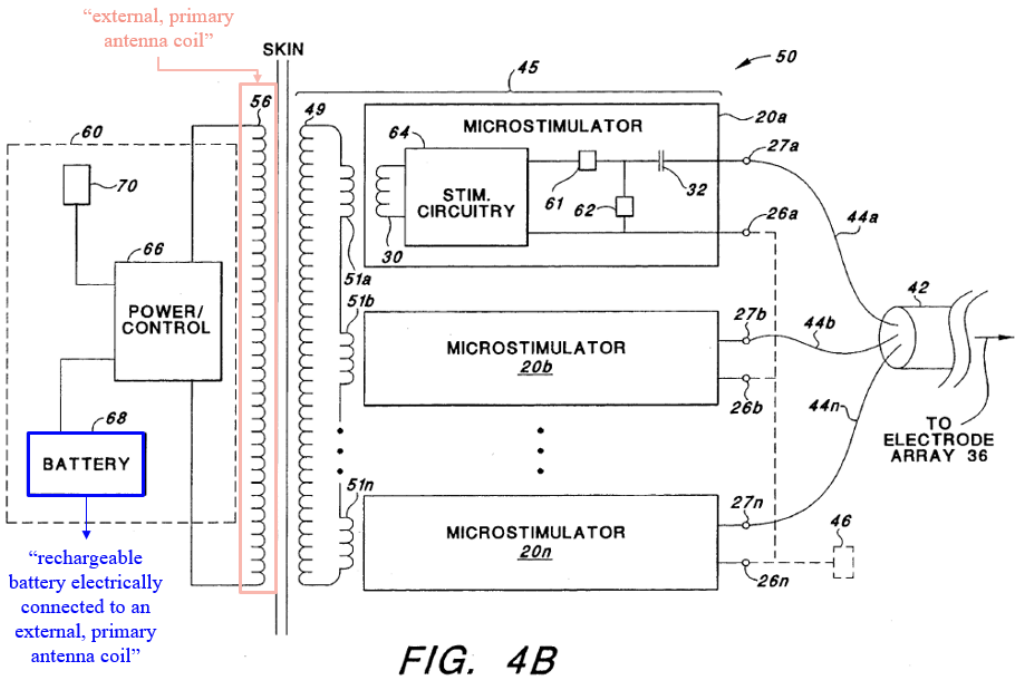


FIG. 4B

Among other things, Loeb's external processor 60 can charge capacitor 32 within each of its microstimulators by transmitting power from external rechargeable battery 68 inductively through its external coil 56. Ex.1017, 10:61-64. Similarly, Schulman's external charger 118 can charge the rechargeable

batteries 104 within each of its microstimulators by transmitting power through its external charger's coil. Thus, it would have been straightforward to use Loeb's external rechargeable battery 68 as the power source in Schulman's external charger 118 and a POSA would have been motivated to do so to improve the portability of Schulman's external charger, as taught by Loeb. Ex.1017, 11:40-43; Ex.1003¶100.

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

As discussed (§V.B.2.a), Loeb discloses that its external power source—which transfers power to the implanted microstimulators—can be powered by a rechargeable battery. *See* Ex.1017, 4:25-31 ("control/power module…contains…a rechargeable or replaceable battery"), 11:9-12 ("external processor 60" drives "external coil 56" with power and includes a "a rechargeable battery,…so as to render the processor 60 portable"), 11:35-43, Fig.4B . Therefore, the external processor 60's rechargeable battery must be charged before the processor 60 can transfer energy to the microstimulator. Ex.1003¶101. And the power to recharge the processor 60's rechargeable battery must come from "an external power source," such as a standard AC power line. *Id*. Therefore, Loeb discloses this limitation.

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

Schulman discloses that power is transmitted to each microstimulator using an inductive link between a coil in the external battery charger and a coil in the microstimulator. Ex.1012, 4:39-44, Fig. 3A(118); Ex.1003¶102. Schulman also explains that prior art microstimulators, such as those taught by Loeb, operate similarly by "deriv[ing] operating power from an internal coil that is inductively coupled to an external AC magnetic field produced, for example, by ***a drive coil mounted proximate to the microstimulator***. An AC voltage induced in the internal coil is rectified and filtered to produce a DC operating voltage which is used to power the electronic circuitry. ***Such an arrangement requires that the user remain in close proximity to the drive coil*** to maintain tissue stimulation." Ex.1012, 1:26-34.

As discussed (§V.A.3), it would have been obvious to arrange a plurality of Schulman's microstimulators to form a multichannel stimulation device that is connected to an electrode array, as taught by Loeb. Ex.1003¶103. Loeb shows an efficient method of powering the multichannel stimulation device, explaining that "[o]ptimum inductive coupling occurs between the internal coils 30 and the external coil when good alignment is achieved. Hence, maintaining proper alignment allows the modulated power signal to be a relatively low power signal." Ex.1017, 9:28-32. And Loeb suggests including an "alignment means…that helps

align the implanted…coils 30…of the implanted microstimulator arrays, with an external coil…." Ex.1017, 9:21-25. Figure 4B shows external coil 56 aligned with implanted focusing coil 49[7]. Ex.1017, Fig.4A, 4B, 9:33-45.

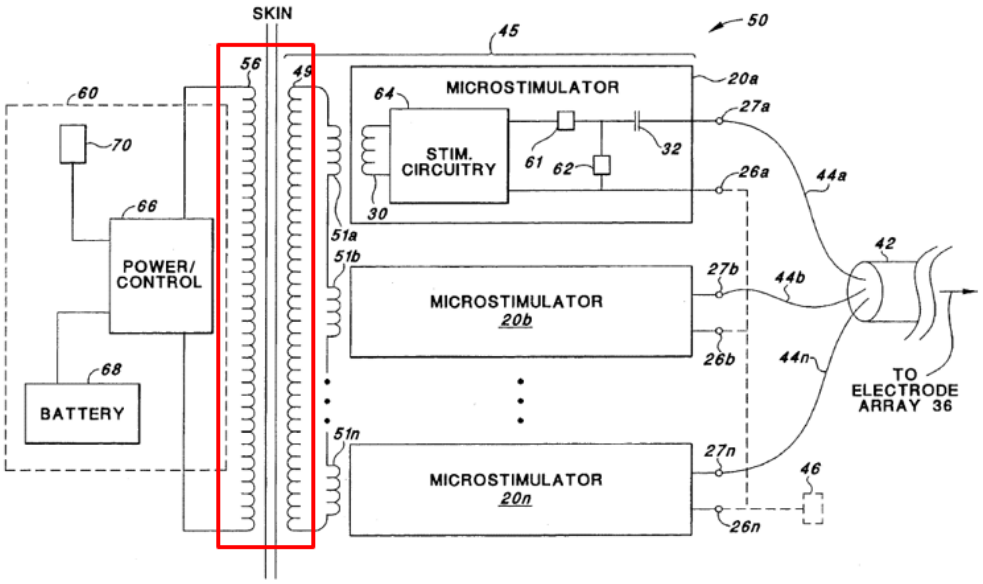


FIG. 4B

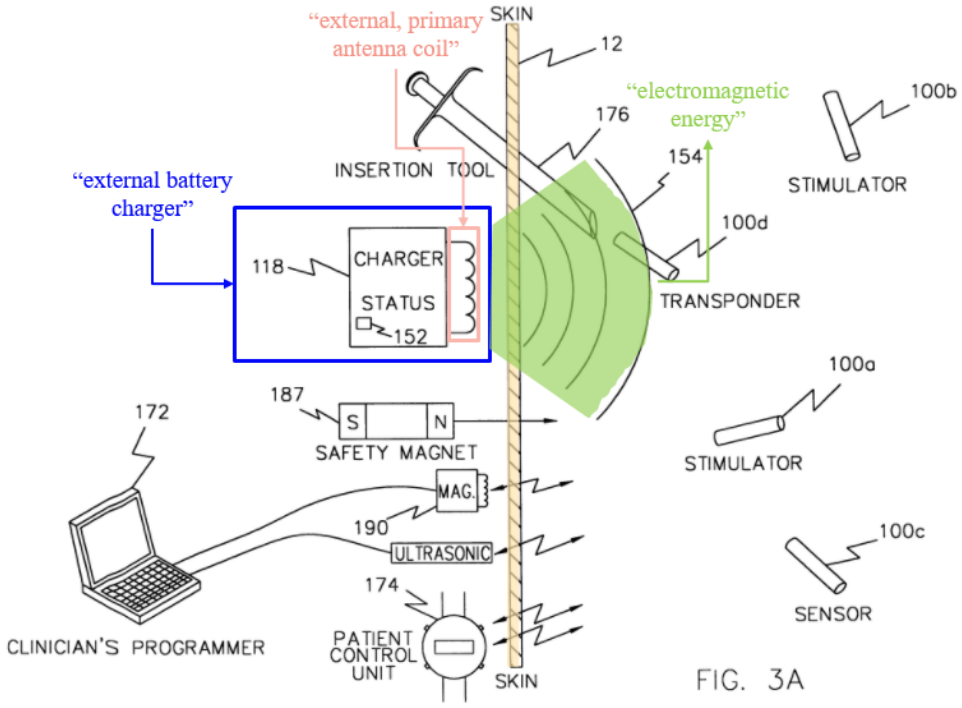
Where a plurality of Schulman's microstimulators are configured into a single stimulation device as suggested by Loeb, a POSA would have found it obvious to charge the batteries in that device using the alignment technique shown in Loeb. Ex.1003¶¶104-05. Therefore, it would have at least been obvious to align Schulman's external charger coil with the coils of the implanted

[7] As explained (§V.A.1), focusing coil 49 directs energy received from external coil 56 to each microstimulator's individual coil 30 via its respective coupling coil 51*a*-51*n*. Ex.1017, 13:4-28.

microstimulator arrays to optimize inductive coupling and preserve the external charger's battery. *Id*.

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

Schulman uses an inductive link between a coil in the external battery charger and a coil in the microstimulator to transmit power. Ex.1012, 4:39-44, Fig. 3A(118). Schulman's external charger 118 generates an "***alternating magnetic field***" that is received by the microstimulators' coil 116. Ex.1012, 4:27-32 ("coil 116 receives ***power in the form of an alternating magnetic field generated from an external power source 118***"), 4:40-44 ("alternating magnetic field 154 from the external power source 118"), 4:49-51 ("[T]he external power source 118 can continue to provide charging power via an alternating magnetic field indefinitely."), 6:2-4; *see also id*., 2:4-6. And Schulman's Figure 3A (below) shows "alternating magnetic field 154" being transmitted out of the coil of external charger 118.



Therefore, Schulman discloses "broadcasting electromagnetic energy" (*e.g.*, generating an alternating magnetic field 154) "through the primary antenna coil" (*e.g.*, external charger 118's coil). Ex.1003¶106.

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

Schulman discloses that each microstimulator's coil receives power from the external charger in the form of alternating current. For example, Schulman explains that each microstimulator's "***coil 116 receives power in the form of an alternating magnetic field*** generated from an external power source 118…***and responsively supplies an AC current*** to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122." Ex.1012, 4:27-31; *see also id.*, 2:1-

3, 4:40-44, 5:29-34.

Therefore, Schulman discloses "receiving the broadcast electromagnetic energy" (*e.g.*, receiving power in the form of an alternating magnetic field) "through the secondary antenna coil" (*e.g.*, through coil 116), "whereby an alternating current is produced in the secondary coil" (*e.g.*, coil 116 supplies AC current). Ex.1003¶107.

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

Schulman expressly discloses that the alternating current received by each microstimulator's coil is rectified. For example, Schulman explains that receiving "coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118…and ***responsively supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122***." Ex.1012, 4:27-31. Schulman further discloses that even in prior art systems "AC voltage induced in the internal coil is rectified and filtered to produce a DC operating voltage which is used to power the electronic circuitry." Ex.1012, 1:29-32; *see also id.*, 3:45-49, Fig. 1. Therefore, Schulman discloses this limitation. Ex.1003¶¶108-09.

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

Schulman discloses that each microstimulator's charging circuit 122, which receives the rectified DC current from the rectifier, both charges the microstimulator's battery and monitors the battery's voltage to prevent overcharging. *E.g.*, Ex.1012, 4:32-35 (charging circuit 122 "***monitors the voltage V on battery 104 and charges it*** according to its preferred charging characteristics (current and voltage)."); Ex.1012, 10:60-64 ("charging circuit 122 is used to ***avoid…overcharge***."); *see also id*., 4:44-49.

Therefore, Schulman discloses "charging the rechargeable battery carried within the IPG" (*e.g.*, charging rechargeable battery 104 in microstimulator 100) "while monitoring the charging current or voltage across the battery as the battery is being charged" (*e.g.*, monitoring voltage on battery 104 during recharging) "to prevent overcharging" (*e.g.*, to avoid overcharge). Ex.1003¶110.

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

Schulman discloses the "charging circuit 122…monitors the voltage V on battery 104" and "once the charging circuit 122 determines that battery 104 has been sufficiently charged" it can detune receiving coil 116 to stop receiving charging power—in which case external power source 118 can provide charging

power indefinitely—and/or "***external power source…continues to provide charging power until it has received status information from each of the implanted devices 100 that its battery 104 is charged***." Ex.1012, 4:32-35, 4:44-56; *see also id*., 5:55-66, 6:14-17.

Therefore, Schulman discloses "stopping the charging at the battery charger" (*e.g.*, terminating external power source 118's charging power) "when the current or voltage at the battery in the IPG reaches a prescribed level" (*e.g.*, battery voltage level in each microstimulator reaches fully charged state and sends its status to the external power source 118). Ex.1003¶111.

C. Ground 2: Schulman, Loeb, and Rutecki Render Obvious Claim 8

1. Overview of Rutecki (Ex.1007)

Rutecki issued in July 1994 and is prior art under §102(b).[8] Ex.1003¶43. Rutecki discloses an implantable "neurostimulator" that includes a "pulse generator" that delivers stimulation therapy to an implanted "nerve electrode array" to "appropriately modulate the electrical activity of the [vagus] nerve." Ex.1007, 6:26-35; *see also id*., 8:42-64. Rutecki's neurostimulator provides "selective electrical stimulation of vagus nerve afferent fiber activity with an

[8] Although Rutecki is cited on the face of the '280 patent, it was never before presented in combination with Schulman and Loeb, as presented here.

implanted neurostimulating device." Ex.1007, 1:7-14. Rutecki teaches that 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 prior to permanent implantation. Ex.1007, 14:3-18. *See also* Ex.1003¶¶113-14.

2. Motivation to Combine

A POSA considering Schulman as modified by Loeb would have looked to related references for additional advantageous features that could be incorporated into Schulman's system. Ex.1003¶115. One such reference is Rutecki, which describes an analogous implantable electrical nerve stimulation system. *Id*. As Rutecki expressly discloses, it was well-known that it is beneficial to conduct tests prior to permanent implantation of an IPG to ensure the patient responds to the stimulation therapy before committing to a fully implanted and permanent system. Ex.1007, 14:3-18; *see also, e.g.*, Ex.1009, 33 (describing SCS system's use of "trial leads" that were externalized and connected to a "trial stimulator"); Ex.1003¶116. If the patient does not respond to the stimulation therapy, the patient can avoid the unnecessary trauma and expense of receiving a fully implanted system. Ex.1007, 14:3-18; Ex.1003¶116. Thus, a POSA would have been motivated to use Rutecki's pre-implantation method of using an external stimulus generator that mimics the operation of Schulman's implantable microstimulator

array so that the efficacy of the therapy can be evaluated prior to permanent implantation. Ex.1003¶116. Because of the similarities between Schulman and Rutecki, a POSA would have known that features from Rutecki could be predictably combined with Schulman. *Id*.

3. Claim 8

a) [8.preamble]: "A spinal cord stimulation system"

To the extent it is limiting, Schulman teaches the preamble for the same reasons as claim [18.preamble]. *See* §V.B.1.a); Ex.1003¶117.

b) [8.a]: "a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry"

Schulman and Loeb teach this limitation for the same reasons as claim [18.a]. *See* §V.B.1.b); Ex.1003¶118.

c) [8.b]: "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

Schulman and Loeb teach this limitation for the same reasons as claim [18.b]. *See* §V.B.1.c); Ex.1003¶119.

d) [8.c]: "a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is independently programmable with different stimulation parameters"

Schulman and Loeb this limitation for the same reasons as claim [18.c]. *See* §V.B.1.d); Ex.1003¶120.

e) [8.d]: "wherein m is equal to or less than n, and m is 2 or greater"

Schulman and Loeb teach this limitation for the same reasons as claim [18.d]. *See* §V.B.1.e); Ex.1003¶121.

f) [8.e]: "an external trial stimulator (ETS)"

Schulman does not expressly disclose "an external trial stimulator," but it would have been obvious to include one in Schulman's system in view of Rutecki. Ex.1003¶¶122-24. As discussed (§V.C.2), in addition to being well-known—as Rutecki expressly discloses—it was an industry standard to conduct tests prior to permanent implantation of an IPG to ensure the patient responds to the stimulation therapy before committing to a fully implanted and permanent system. For such tests, Rutecki discloses using an "external stimulus generator." Ex.1007, 14:8-10. Thus, Rutecki discloses an "external trial stimulator" (*e.g.*, external stimulus generator). Ex.1003¶122-23.

A POSA would have found it obvious to use Rutecki's external stimulus generator in implementing Schulman's system because it is desirable to test the stimulation therapy "to determine whether the pain suffered by the patient under observation is sufficiently relieved to characterize the neurostimulation…as successful treatment" before permanent implantation, as taught by Rutecki. Ex.1007, 14:3-8; Ex.1003¶124. Because of the similarities between Schulman and Rutecki, a POSA would have known the combination yielding the structure as

claimed would have worked as expected. *Id.*

g) [8.f]: "a percutaneous extension which temporarily couples the ETS with the implantable electrode array"

Rutecki discloses that its "external stimulus generator" has "***leads extending percutaneously to the implanted nerve electrode assembly***." Ex.1007, 14:8-10. Rutecki explains that this is a "***temporary arrangement***" to test whether the neurostimulation successfully relieves the patient's pain. Ex.1007, 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¶¶125-26.

D. Ground 3: Schulman, Loeb, Munshi, and Wang Render Obvious Claims 22-24

1. Overview of Wang (Ex.1018)

Wang issued in December 1997 and is prior art under §102(b). Ex.1003¶46. Wang is directed to "[a]n improved transcutaneous energy transmission ["TET"] device…for charging rechargeable batteries in an implanted medical device and to minimize peak temperature rises in the implanted device." Ex.1018, Abstract; *see also id.*, 1:16-22. Wang teaches "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." Ex.1018, 5:13-15. Therefore, Wang's system includes "an alignment circuit and indicator…to indicate whether the coils are properly

aligned." Ex.1018, 5:15-17. *See also* Ex.1003¶¶128-33.

2. Overview of Munshi (Ex.1005)

Munshi issued in May 1995 and is prior art under §102(b). Ex.1003¶42. Munshi similarly describes techniques for transcutaneously (*i.e.*, through the patient's skin) charging a rechargeable power source (*e.g.*, rechargeable battery) in a "bioimplantable device" by electromagnetic induction. Ex.1005, 4:3-10; *see also id*., Abstract, 1:8-17. While Munshi describes its invention primarily in the context of a pacemaker/defibrillator, Munshi teaches that its invention is applicable to "any other bioimplantable device," including "***nerve*** and bone growth ***stimulators***." Ex.1005, Abstract, 1:8-9, 1:20-28, 4:4-5. The implanted device includes a magnetic coil coupled to the power source that can receive electromagnetic energy from another coil in an external charger by way of induction through the patient's skin. Ex.1005, 10:21-26, 10:32-37. The external charger can be powered by an alternating current source and/or a "rechargeable external battery pack with its own charging system…to allow portability of the external unit." Ex.1005, 10:20-21, 10:43-51. *See also* Ex.1003¶¶134-36.

3. Motivation to Combine

A POSA considering Schulman as modified by Loeb would have looked to other related references for additional advantageous features that could be incorporated into Schulman's implanted battery recharging system. Ex.1003¶137.

Such references include Wang and Munshi, both of which describe analogous implantable electrical stimulation systems and, more particularly, analogous systems for recharging an implanted device's battery.

For example, as explained (§V.B.2.c), Schulman acknowledges that to transmit power from an external device to an implanted device the transmitting and receiving coils need to be in "close proximity" to each other. Ex.1012, 1:26-34; 3:55-67. Loeb further teaches that "[o]ptimum inductive coupling occurs between the internal coils 30 and the external coil when good alignment is achieved. Hence, maintaining proper alignment allows the modulated power signal to be a relatively low power signal." Ex.1017, 9:28-32. And Loeb suggests including "some sort of alignment means…that helps align the implanted…coils 30…of the implanted microstimulator arrays, with an external coil," such as including "a magnet or marker 48" in the microstimulator that can be detected by, *e.g.*, a corresponding external magnet. Ex.1017, 9:20-25.

Accordingly, a POSA implementing Schulman's system would have—consistent with Loeb's suggestion—looked for advantageous ways of detecting proper alignment between external and implanted coils. Ex.1003¶¶138-39. Wang addresses this problem and teaches "an alignment circuit and indicator…to indicate whether the coils are properly aligned." Ex.1018, 5:15-17; Ex.1003¶139. A POSA would have been motivated to use Wang's alignment circuitry in Schulman's

system because it would require adding circuitry to only the external charger and "no extra components" in the implanted microstimulator array. Ex.1018, 4:19-26; Ex.1003¶140. Indeed, Wang's alignment circuitry would allow removing Loeb's suggested "magnet or marker 48" from the implanted microstimulators. Ex.1003¶140. Because these systems are implanted into a patient's body, it was well-known and desired at the time to minimize the size, and therefore footprint, of the implanted device within the patient's body. *Id*.

Schulman, Wang, and Munshi describe analogous systems for non-invasively recharging batteries in an implantable medical device. Ex.1003¶¶141-42. For example, all three systems charge the implanted battery transcutaneously by transmitting energy to the implanted device's receiving coil through the coil of an external charger. Accordingly, a POSA would have known that features from Schulman, Wang, and Munshi could be combined with a high degree of predictability and that the combination would work as expected. *Id*.

4. Claim 22

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

To the extent it is limiting, Schulman teaches the preamble for the same reasons as claim [18.preamble]. *See* §V.B.1.a); Ex.1003¶143.

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

Schulman and Loeb teach this limitation for the same reasons as claim

[18.a]. *See* §V.B.1.b); Ex.1003¶144.

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

Schulman and Loeb teach this limitation for the same reasons as claim [18.b]. *See* §V.B.1.c); Ex.1003¶145.

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

Schulman discloses that its implanted microstimulator includes ***coil 116***, which "receives power in the form of an alternating magnetic field…and responsively supplies…current to a charging circuit 122" that charges the rechargeable battery. Ex.1012, 4:27-35; *see also id*. 1:66-2:9, 4:4-7, 4:17-21 ("[P]ower source 102 comprises a rechargeable battery 104 used in conjunction with a charging circuit to provide sufficient power….").

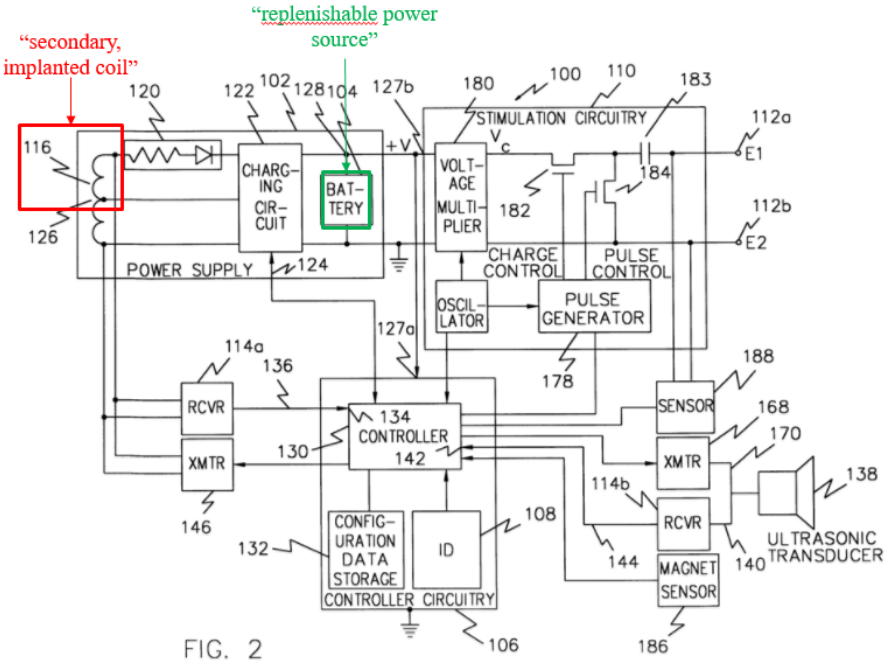


FIG. 2

Therefore, Schulman discloses "a secondary, implanted coil" (*e.g.*, coil 116) "coupled electrically" (*e.g.*, connected) to the "replenishable power source" (*e.g.*, rechargeable battery 104). Ex.1003¶146.

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

Schulman discloses an "external power source 118" that generates an alternating magnetic field that is used for charging battery 104. Ex.1012, 4:27-35; *see also id.*, 2:4-6 ("external charger is used to periodically generate an AC magnetic field for supplying energy to the aforementioned charging circuit"), 4:40-44, 4:49-56 ("external power source 118 can continue to provide charging power via alternating magnetic field indefinitely" or until informed that the battery 104 is charged), 5:55-60 (describing "charger 118"), 6:8-17 (same), Fig.3A.

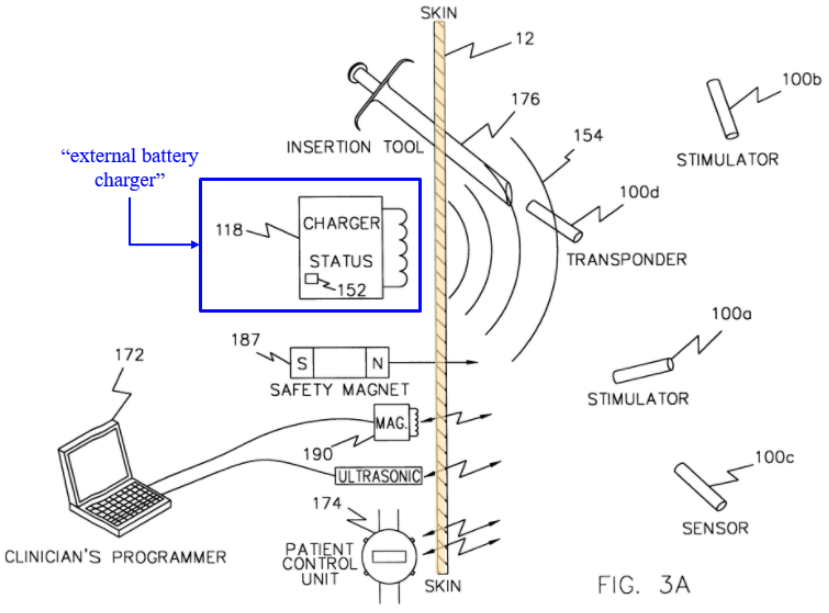
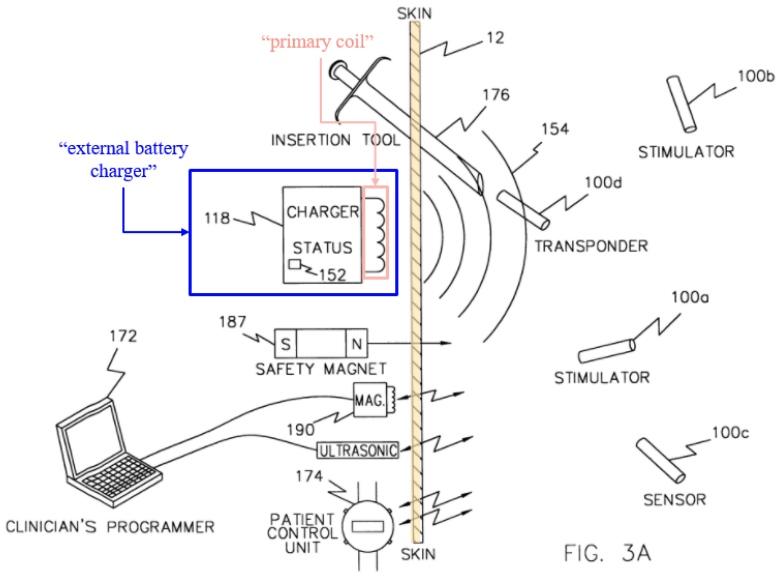


FIG. 3A

Therefore, Schulman discloses "an external battery charger" (*e.g.*, external power source 118). Ex.1003¶147.

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

Figure 3A (below) shows that Schulman's external power source 118 includes a coil. Ex.1003¶¶148-49.



And, in explaining the prior art, Schulman explains that an alternating magnetic field—such as that generated by the external power source 118 (*see*, *e.g.*, Ex.1012, 4:40-44)—is produced by an "externally mounted coil 18 that is energized by a transmitter 20." Ex.1012, 3:40-45, Fig.1.

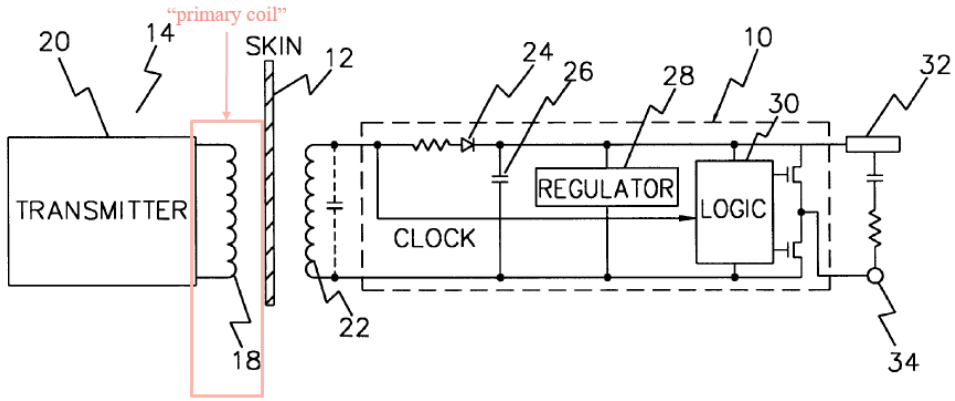


FIG. 1

Therefore, Schulman discloses "an external battery charger" (*e.g.*, external power source 118) "including: a primary coil" (*e.g.*, coil shown in Fig. 3A). Ex.1003¶¶148-49.

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

As discussed (§V.B.2.a), Schulman does not expressly state that its external charger 118 contains its own rechargeable battery, but it would have been at least obvious to include one in light of Loeb's express disclosure of including a rechargeable battery in its external transmitter. Ex.1003¶150. Loeb's system includes an "external processor 60" that drives its "external coil 56" with power and includes a "power source 68, such as a rechargeable battery,…so as to render the processor 60 portable." Ex.1017, 11:9-12, 11:40-43, Fig.4B; *see also id.*, 4:25-31.

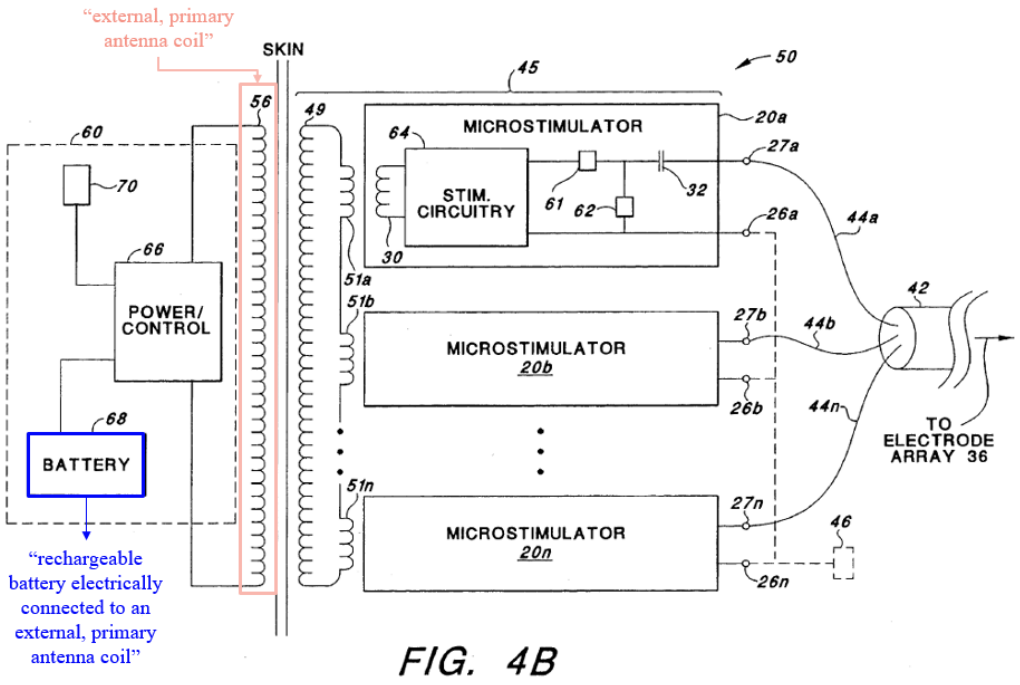


FIG. 4B

Loeb's external processor 60 can charge capacitor 32 within each of its microstimulators by transmitting power from external rechargeable battery 68 inductively through its external coil 56. Ex.1017, 10:61-64. Similarly, Schulman's external charger 118 can charge the rechargeable batteries 104 within each of its microstimulators by transmitting power through its external charger's coil. Thus, it would have been straightforward to use Loeb's external rechargeable battery 68 as the power source in Schulman's external charger 118 and a POSA would have been motivated to do so to improve the portability of Schulman's external charger, as taught by Loeb. Ex.1017, 11:40-43; Ex.1003¶151.

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

Although Schulman does not expressly disclose "a power amplifier," it

would have been at least obvious to include one in Schulman's external charger. Schulman discloses that its external power source 118 generates an "***AC*** [or alternating current] magnetic field." Ex.1012, 2:1-6, 4:27-32 ("***alternating*** magnetic field generated from an external power source 118"), 4:49-51, 6:2-4. And, as discussed (§V.D.4.g), it would have been obvious to use Loeb's external device 60's rechargeable battery 68 as the power source for Schulman's external power source 118. Ex.1003¶¶152-53. Because batteries are direct current ("DC") sources, the DC power from the external charger's battery must be converted to AC for Schulman's external power source to transmit an "alternating magnetic field" through its transmitting coil. Ex.1003¶¶153-54. Loeb describes circuitry that performs this conversion so that the DC—from the external device's battery—is converted to AC and applied to the external device's coil. Ex.1017, 12:11-13, 12:16-25, Fig.6; Ex.1003¶¶154-55. As the '280 acknowledges, it was well-known in the art that power amplifiers were used to convert DC power to an AC signal:

> A power amplifier 275, included within the portable charger 208, ***enables the transfer of energy from the battery 277 to the implant power source 180***. ***Such circuitry 275 essentially comprises DC-to-AC conversion circuitry that converts dc power from the battery 277 to an ac signal that may be inductively coupled*** through a coil 279 located in the external charging head 272…with another coil 680 included within the IPG 100, ***as is known in the art***.

Ex.1001, 41:62-42:3. Therefore, a POSA would have found it obvious to include a

known "power amplifier" in Schulman's external power source 118 to perform the DC to AC conversion. Ex.1003¶156.

To the extent it is argued further disclosure is required, Munshi expressly discloses that its analogous "external charger 70," which can also be powered by a "rechargeable external battery pack," includes a "power amplifier 78" that "drives the ***transmitting coil 72*** with an ***alternating current***," as shown in Figure 2 below. Ex.1005, 10:38-47.

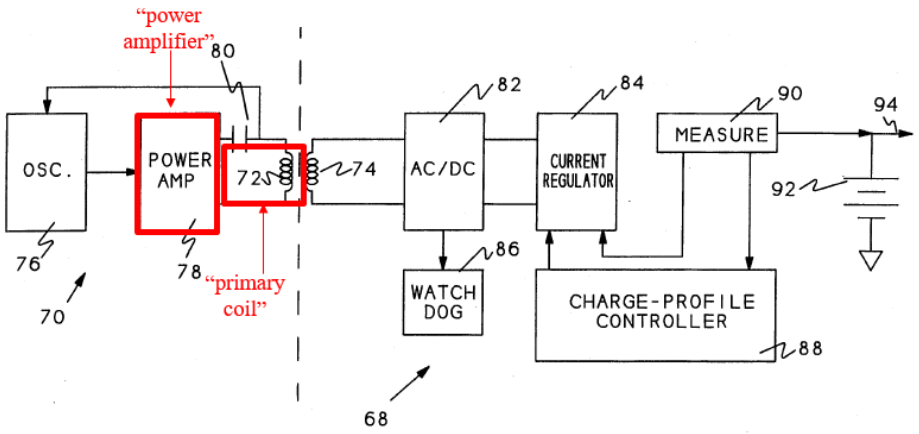


FIG. 2

As discussed (§V.D.3), because of the similarities between Schulman's and Munshi's battery recharging systems for implanted devices, a POSA would have found it obvious and routine to use Munshi's power amplifier in Schulman's external charger and would have known that the combination yielding the claimed structure would work as expected. Ex.1003¶¶157-58.

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

Schulman discloses that the microstimulator's "***coil 116 receives power in the form of an alternating magnetic field generated from external power source 118***…and responsively supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122. The charging circuit 122 then monitors the voltage V on ***battery 104 and charges it*** according to its preferred charging characteristics (current and voltage)." Ex.1012, 4:27-35; *see also id*., 1:66-2:9, 4:40-44 ("a plurality of such devices 100, e.g., microstimulators, are implanted under the skin 12 of a patient's body and simultaneously subjected to an alternating magnetic field 154 from the external power source 118"). And, as depicted in Figure 3A (below), the alternating magnetic field 154 from external power source 118 is being transferred transcutaneously through skin 12 in contrast to "hypodermic needle type insertion tool 176," which penetrates the skin. Ex.1012, 6:55-57.

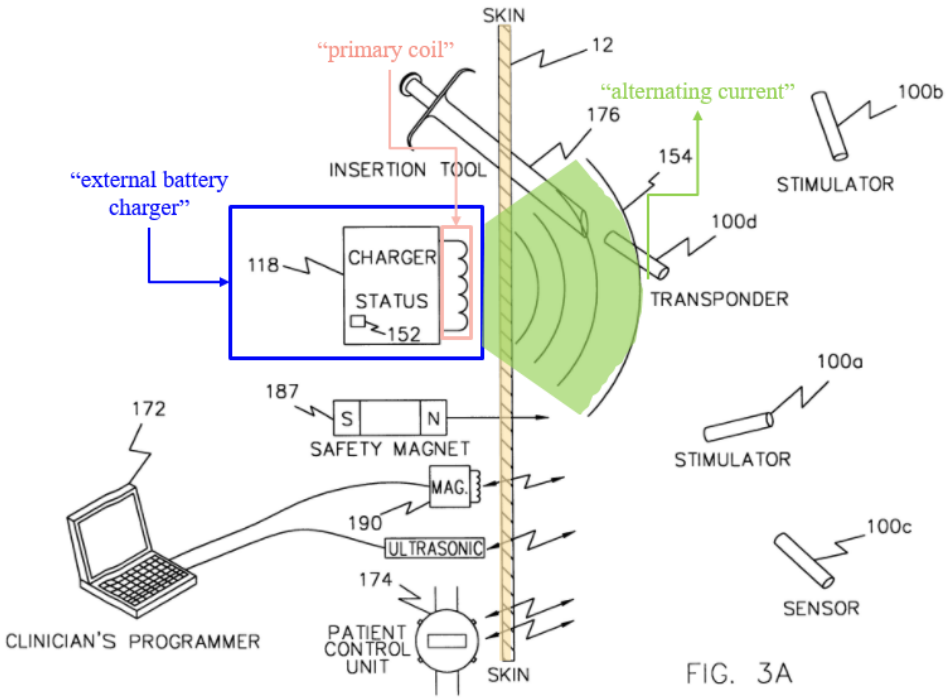


FIG. 3A

Therefore, Schulman discloses "the alternating current in the primary coil" (*e.g.*, AC magnetic field 154 through external power source 118's coil) is "transcutaneously transferred" (*e.g.*, transmitted through the skin) to the "secondary implanted coiled" (*e.g.*, coil 116) to the "replenishable power source contained in the IPG" (*e.g.*, rechargeable battery 104 in microstimulator 100). Ex.1003¶159.

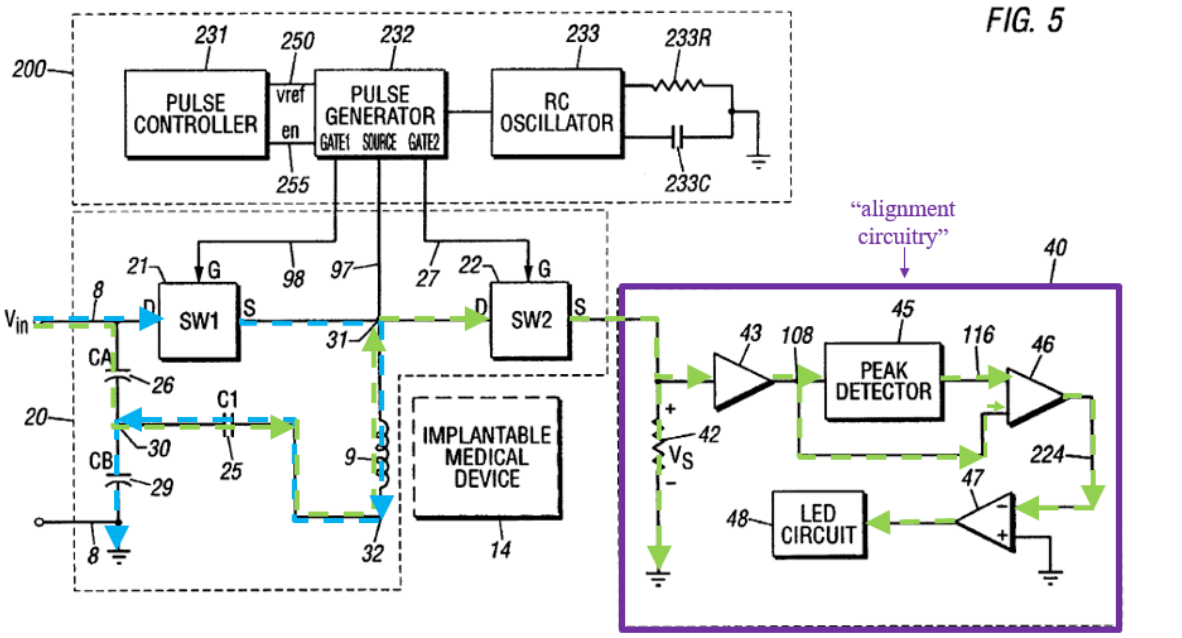
j) [22.i]: "alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil as applied by the power amplifier"

Neither Schulman nor Loeb expressly disclose this limitation, but it would have been obvious in view of Wang's express teachings of its alignment circuitry.

Loeb acknowledges that "[o]ptimum inductive coupling occurs between the internal coils…and the external coil when good alignment is achieved" and that proper alignment saves energy because it "allows the modulated power signal [from the external device] to be a relatively low power signal." Ex.1017, 9:28-32. Like Loeb, Wang notes that the "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." Ex.1018, 5:13-15. Accordingly, Wang provides "an ***alignment circuit and indicator***…***to indicate whether the coils are properly aligned***." Ex.1018, 5:15-17; *see also id*. 11:41-46 ("[T]he alignment indicator 40…uses the correlation between the input current and alignment to provide an output signal which indicates when the energy transmission device 50 is sufficiently aligned with the receiving coil 10 of the implanted device 14."), Figs. 1, 5. Therefore, Wang discloses "alignment circuity" (*e.g.*, alignment circuit and indicator) "for detecting alignment between the primary and secondary coils" (*e.g.*, to detect whether the external and implanted coils are properly aligned). Ex.1003¶¶160-63.

Wang further discloses "a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil." As described in further detail below, Wang's "alignment circuit and indicator" operates by monitoring the magnitude of the current through the primary coil and comparing voltage derived from that current to a stored "peak positive voltage," where the peak voltage

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



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

20, Fig. 5. Current flow through resistor 42 generates a voltage,[9] which is amplified by low-pass amplifier 43, and sent to both peak detector 45 and to differential amplifier 46. Ex.1018, 11:20-23, 12:1-8, 12:16-18. The peak detector 45 stores the highest sensed "peak positive voltage" that passes through it and outputs a signal that "corresponds to the peak positive voltage sensed by the peak detector 45." Ex.1018, 12:5-14. That "peak positive voltage" is also provided to the differential amplifier 46, which amplifies the difference between the peak voltage value and the voltage generated across resistor 42. Ex.1018, 12:14-16. The difference is then sent to comparator 47 to compare the difference with ground voltage, and turns on the LED circuit to indicate proper alignment only when the voltage generated at the resistor 42 is evaluated to be greater than the "peak value." Ex.1018, 12:21-26.

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[9] Wang states that the "[d]ue to the symmetric AC current on the primary coil 9" the resistor 42 receives half of the current through the primary coil. Ex.1018, 11:20-24. The resistor 42 and other components in Wang's alignment indicator are nevertheless monitoring AC voltage. Ex.1003¶162. As Wang discloses, the AC current on the primary coil 9 is "symmetric," so one-half of the primary coil's AC current (or DC current) is nevertheless reflective of the AC voltage applied to the primary coil. *Id*.

Therefore, Wang discloses "a back telemetry receiver" (*e.g.*, resistor 42, low-pass amplifier 43, peak detector 45, differential amplifier 46 and/or comparator 47 in alignment indicator 40) "for monitoring the magnitude of the ac voltage at the primary coil" (*e.g.*, monitoring voltage generated at resistor 42 by AC current that flows through primary coil 9). Ex.1003¶¶160-63.

As explained (§V.D.3), a POSA would have been motivated and 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 Schulman's system as modified by Loeb. Ex.1003¶¶164-66. For example, as discussed, it would have been obvious to arrange Schulman's microstimulators in a microstimulator array, as taught by Loeb, by substituting in Schulman's microstimulators for Loeb's microstimulators. For example, as with Loeb's Figure 5(*see* §V.A.3), Loeb's microstimulators 20*a*-20*n* could be replaced with Schulman's rechargeable microstimulators 100*a*-100*n* in Loeb's Figure 4B embodiment, as illustrated below. Ex.1003¶164.

Original Loeb, Figure 4B:

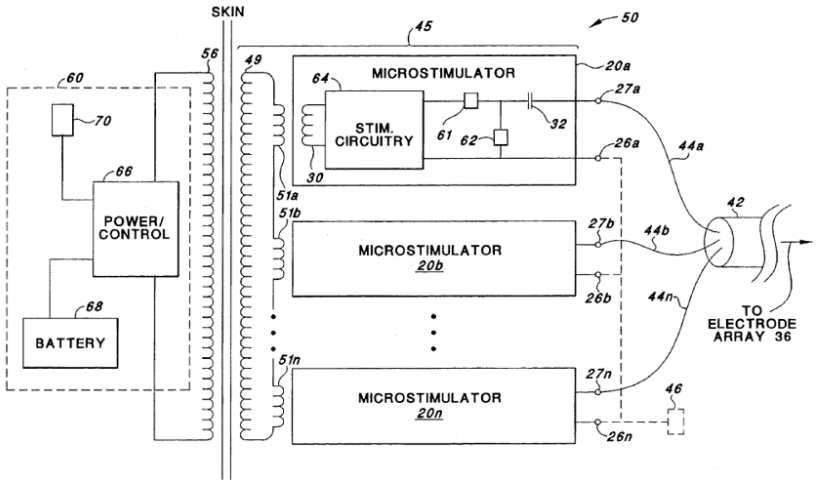

FIG. 4B

Schulman and Loeb combination:

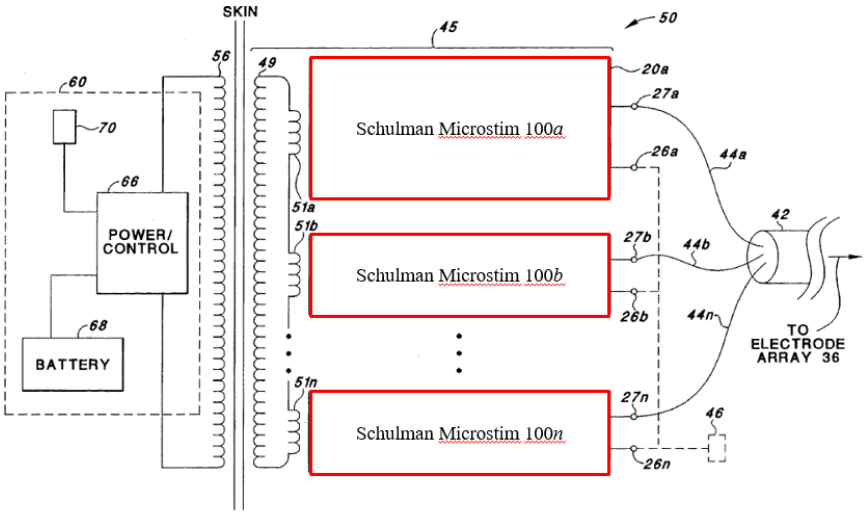

FIG. 4B

And it would have been advantageous to ensure external coil 56 and focusing coil 49 are properly aligned to optimize inductive coupling, as taught by Loeb and Wang. Ex.1017, 9:28-32; Ex.1018, 5:13-15; Ex.1003¶165. Doing so would also beneficially preserve battery 68 in the external charger as it would take less energy

to charge the microstimulators. Ex.1003¶165.

Accordingly, a POSA would have been motivated to incorporate Wang's beneficial alignment detection circuitry in Schulman's external charger in implementing Schulman's system as modified by Loeb to provide a mechanism that indicates to the patient or user when the coils are properly aligned and charging efficiency is maximized. Ex.1003¶¶165-66.

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

Wang teaches that its system "can be tuned so that the amplitude of the AC current through the primary coil 9 decreases when the primary coil 9 is not properly aligned with secondary coil 10." Ex.1018, 11:30-34. As Wang explains, the magnitude of the current through the primary coil "***depends on the power draw of the load on the secondary coil*** and the proximity and orientation of the primary coil 9 to the secondary or receiving coil 10" Ex.1018, 11:24-27, 11:34-37, Fig. 5. Thus, if the primary and secondary coils are misaligned, the amplitude of the current on the primary coil decreases due in part to the reflected impedance from the secondary coil. Ex.1003¶129. And, as discussed (*see* §V.D.4.j), the alignment indicator 40 uses the current flow through primary coil 9 to generate a voltage at resistor 42 and compare it with a "peak voltage." Accordingly, by monitoring the current through the primary coil, the alignment indicator is effectively monitoring

the reflected impedance from the secondary coil. Ex.1003¶¶129, 167.

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¶167.

5. Claim 23

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

Although Schulman discloses that its external charger 118 has a "visual or audio annunciator 152," that indicator is used to notify the patient or clinician that all of the microstimulators are fully charged—not "in response to changes sensed in the reflected impedance monitored by the back telemetry receiver," as claimed. Ex.1012, 6:14-17, Fig.3A. As discussed (§V.D.4.j), however, Wang discloses "a back telemetry receiver" (*e.g.*, resistor 42, low-pass amplifier 43, peak detector 45, differential amplifier 46 and/or comparator 47 in alignment indictor 40) to compare the voltage derived from the current through the primary coil 9 and the "peak voltage" to determine whether the coils are properly aligned. If the voltage derived from the AC current through the primary coil 9 is greater than the "peak voltage"

value, then an LED circuit (or audible signal) is turned on. Ex.1018, 12:21-24. Wang teaches that an "output device" other than an LED circuit, such as one that produces an "audible signal," can instead be used to indicate alignment. Ex.1018, 5:20-23 ("visual and/or ***audible signal***…indicat[es] proper alignment"), 11:28-31 ("…LED circuit 48 or ***other output device***...indicate[s] proper positioning"), 11:56-63, 11:63-67, 12:21-24, 14:20-24.

As discussed (§V.D.4.k), by monitoring the current through the primary coil—which changes based on the "power draw from the secondary coil"—Wang's "back telemetry receiver" is effectively monitoring the reflected impedance from the secondary coil. Therefore, Wang discloses "an alarm generator that generates an audible alarm signal" (*e.g.*, an "output device" provides an "audible signal") "in response to changes sensed in the reflected impedance" (*e.g.*, when the voltage derived from the current through the primary coil becomes greater than the peak value) "monitored by the back telemetry receiver" (*e.g.*, monitored by resistor 42, low-pass amplifier 43, peak detector 45, differential amplifier 46 and/or comparator 47 in alignment indictor 40). Ex.1003¶¶168-69.

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¶170. Because of the

similarities between Schulman, Loeb, and Wang, a POSA would have known the combination yielding the structure as claimed would have worked as expected. Ex.1003¶¶142, 170.

6. Claim 24

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

As explained (§V.D.5), Schulman discloses that its external charger 118 has a "visual or audio annunciator 152," but that indicator is to notify the patient or clinician that all of the microstimulators are fully charged—not to indicate misalignment or alignment, as claimed. Ex.1012, 6:14-17, Fig.3A. Wang, however, teaches an LED circuit turns a light on to indicate proper positioning between the primary coil in the external device and the secondary coil in the implanted device. Ex.1018, 11:28-31 ("Alignment indicator 40 provides a light emitting diode (LED) in LED circuit 48 or other output device to indicate proper positioning of respect to implant with respect to implanted device 14."). Wang also teaches that instead of or in addition to a visual signal, multiple "audible indications" can used to indicate alignment. Ex.1018, 14:21-24. One way of using the plurality of "audible indications" is to sound an "audible signal" when the coils

are properly aligned, as disclosed in Wang. Ex.1018, 5:20-23; *see also id*., 11:28-31, 11:63-67, 12:21-24, 14:20-24. Another obvious option would be to use a first audible signal to indicate misalignment of the coils and a second, different audible signal to indicate their alignment. Ex.1003¶172. A third option would be to use an audible signal only to indicate that the coils are misaligned. *Id*. A POSA would have considered any of these options a matter of mere design choice in implementing Wang's alignment indicator. *Id*. A POSA would have been motivated and found it obvious to combine Schulman, Loeb, and Wang for the same reasons discussed above (§V.D.5).

VI. NO SECONDARY CONSIDERATIONS EXIST

As described above, the presented grounds of unpatentability render obvious each of the Claims. No secondary indicia of non-obviousness exist having a nexus to the '280's putative invention contrary to that conclusion. Petitioner reserves its right to respond to any assertion of secondary indicia of non-obviousness advanced by PO. Ex.1003¶173.

VII. CONCLUSION

Petitioner respectfully submits the evidence presented in this Petition establishes a reasonable likelihood Petitioner will prevail in establishing the Challenged Claims are unpatentable, and requests Trial be instituted.

VIII. STANDING (§42.104(a))

Petitioner certifies the ’280 is available for IPR and Petitioner is not barred or estopped from requesting IPR of the ’280 claims. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the ’280. The ’280 is the subject of two pending IPRs—IPR2017-01811 and IPR2017-01812—filed by Petitioner on July 21, 2017.

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

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

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

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

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

B. Other Proceedings (§42.8(b)(2))

1. Patents and Applications

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

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

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

2. Related Litigation

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

3. Patent Office Proceedings

The '280 patent is the subject of IPR2017-01811 and IPR2017-01812, both filed by Petitioner on July 21, 2017.

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

Lead Counsel is Ching-Lee Fukuda (Reg. No. 44,334, clfukuda@sidley.com, 212-839-7364) at the address: Sidley Austin LLP, 787 Seventh Avenue, New York, New York 10019. Backup Counsel are Thomas A. Broughan, III (Reg. No. 66,001, tbroughan@sidley.com, 202-736-8314), Sharon Lee[10] (sharon.lee@sidley.com, 202-736-8510), both at the address: Sidley Austin LLP, 1501 K Street N.W., Washington, DC 20005. Additional back-up counsel

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

includes Jon Wright (Reg. No. 50,720, jwright-PTAB@skgf.com), and Richard D. Coller III (Reg. No. 60,390, rcoller-PTAB@skgf.com), both at STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Washington, D.C., 20005, phone number (202) 371-2600, and facsimile (202) 371-2540.

D. Service Information (§42.8(b)(4))

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

Dated: August 11, 2017

Respectfully Submitted,

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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 13,742 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: August 11, 2017

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of August, 2017, a copy of this Petition, including all attachments, appendices and exhibits, has been served in its entirety by overnight mail on the following counsel of record for patent owner:

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Seattle, WA 98104
PAIR Correspondence Address for U.S.P.N. 6,895,280

YOUNG CONAWAY STARGATT & TAYLOR LLP
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