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Paper 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

IPR2019-01313
Patent 7,496,404 B2

Before ROBERT A. POLLOCK, SCOTT C. MOORE, and RICHARD J. SMITH, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Nevro Corp. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–5, 7, 9, and 11–17 of U.S. Patent No. 7,496,404 B2 ("the '404 patent," Ex. 1001). Paper 1 ("Pet."). Boston Scientific Neuromodulation Corp. ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

B. Real Parties-in-Interest

Petitioner identifies itself, Nevro Corp., as the real party-in-interest. Pet. 2. According to Patent Owner, its real parties-in-interest are Boston Scientific Neuromodulation Corp. and Boston Scientific Corp. Paper 8, 2.

C. Related Proceedings

The '404 patent is at issue in *Boston Scientific Corp. et al. v. Nevro Corp.*, Civil Action No. 1:18-cv-00644 (D. Del.). *See* Paper 8, 3.

The '404 patent is related to U.S. Patent Nos. 6,895,280 B2 ("the '280 patent") and 7,177,690 B2 ("the '690 patent"). *See* Paper 8, 2. The '404 patent, '280 patent, and '690 patent issued from a series of continuation applications first filed on July 26, 2000, and, thus, share substantially the same specification. *See* Ex. 1001, code (63); Ex. 3001, code (63).

The '280 patent was involved in IPR2017-01811, IPR2017-01812, and IPR2017-01920. IPR2017-01920 was consolidated into IPR2017-01812. *Id.* In IPR2017-01812, the Board issued a final written decision finding claims 8, 18, 22–24, and 27 unpatentable and claims 26 and 28–30 patentable. *Id.; see also* Ex. 1008, 4. The Board's Final Written Decision on IPR2017-01812 is currently on appeal to the Federal Circuit. *Id., see*

Boston Scientific Neuromodulation Corp. v. Nevro Corp., No. 19-1582 (Fed. Cir.). The '280 patent is also at issue in the district court case: *Boston Scientific Corp. et al. v. Nevro Corp.,* Case No. 1:16-cv-01163 (D. Del.). *Id.*

Petitioner has separately filed an IPR petition on the '690 patent (IPR2019-01216). Paper 8, 3. The '690 patent is also at issue in the district court case *Boston Scientific Corp. et al. v. Nevro Corp.*, Civil Action No. 1:18-cv-00644 (D. Del.). *Id.*

D. Summary of the Institution Decision

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '404 patent is unpatentable, we institute an *inter partes* review of the challenged claims.

E. Asserted Grounds of Unpatentability

Petitioner asserts three grounds of unpatentability (Pet. 5):

Ground	Claims Challenged	35 U.S.C §	Asserted References
1	1–5	103(a)[1]	Holsheimer,[2] Munshi,[3] Schulman,[4] Wang[5]
2	7, 9, 13–17	103(a)	Holsheimer, Munshi, Schulman

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '404 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.
[2] U.S. Patent No. 5,501,703, issued Mar. 26, 1996. Ex. 1004.
[3] U.S. Patent No. 5,411,537, issued May 2, 1995. Ex. 1005.
[4] U.S. Patent No. 4,197,850, issued Apr. 15, 1980. Ex. 1006.
[5] U.S. Patent No. 5,702,431, issued Dec. 30, 1997. Ex. 1007.

Ground	Claims Challenged	35 U.S.C §	Asserted References
3	11, 12	103(a)	Holsheimer, Munshi, Schulman, Rutecki[6]

In support of its patentability challenges, Petitioner relies on, *inter alia*, the Declaration of Mr. Ben Pless. Ex. 1003.

F. The '404 Patent and Relevant Background

1) *Specification*

According to the '404 patent's Specification, "[s]pinal cord stimulation (SCS) is a well-accepted clinical method for reducing pain." Ex. 1001, 1:29–30. "SCS systems typically include an implanted pulse generator, lead wires, and electrodes connected to the lead wires." *Id.* at 1:31–32. The '404 patent's Specification states that prior art SCS systems "suffer[] from one or more short comings, e.g., no internal power storage capability, a short operating life, none or limited programming features, large physical size, the need to always wear an external power source and controller, the need to use difficult or unwieldy surgical techniques and/or tools, [and] unreliable connections." *Id.* at 2:31–38.

The Specification discloses an SCS system that addresses these problems, by including, *inter alia*, an implantable pulse generator ("IPG") with "a rechargeable power source, e.g., a rechargeable battery, that allows the patient to go about his or her daily business unfettered by an external power source and controller." *Id.* at 2:60–65. The Specification states that "the SCS system offers a simple connection scheme for detachably connecting a lead system thereto." *Id.* at 3:2–4.

[6] U.S. Patent No. 5,330,515, issued July 19, 1994. Ex. 1009.

Figure 1 of the '404 patent is reproduced below:

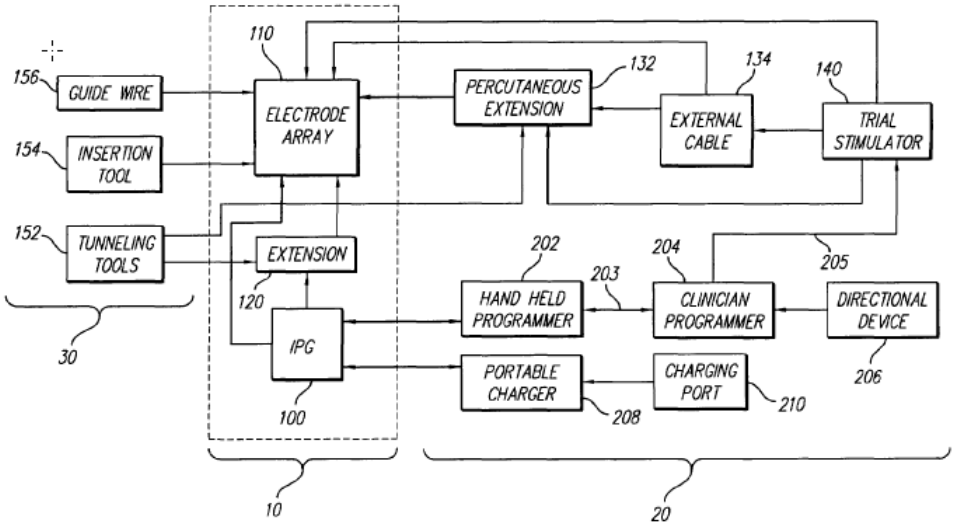


FIG. 1

Figure 1 depicts a block diagram of a spinal cord stimulation system and identifies its implantable, external, and surgical components. Ex. 1001, 7:3–5.

As illustrated in Figure 1, the Specification discloses a "connector that forms an integral part of IPG 100 [and] allows [] electrode array 110 or extension 120 to be detachably secured, i.e., electrically connected, to [] IPG 100." *Id.* at 8:40–43. Because the electrode array is detachable, "IPG 100 may be replaced when its power source fails or is no longer rechargeable." *Id.* at 8:58–65. The Specification further explains that "[i]n use, [] IPG 100 is typically placed in a surgically-made pocket either in the abdomen, or just at the top of the buttocks, and detachably connected to the lead system (comprising lead extension 120 and electrode array 110)." *Id.* at 26:59–63.

Figure 9A of the '404 patent is reproduced below:

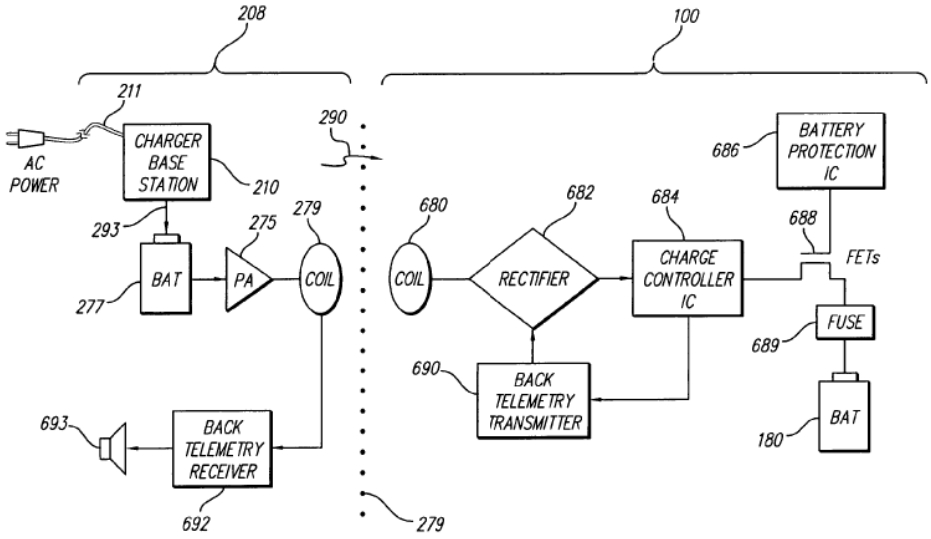


FIG. 9A

Figure 9A depicts a block diagram of a battery charging system comprising a portable external charger 208 in communication with IPG 100, implanted under a patient's skin 279. Ex. 1001, 7:63–64; *id.* at 40:51–54. According to the Specification, IPG 100 includes power source 180, such as a rechargeable battery, which may be recharged using portable external charger 208. *Id.* at 40: 40:51–55, 64–67.

Portable external charger 208 includes charger base station 210, which transfers power from AC power line 211 to battery 277. *Id.* at 41:1–6. Portable external charger 208 also includes power amplifier 275, which "essentially comprises DC-to-AC conversion circuitry . . . converts dc power from [] battery 277 to an ac signal that may be inductively coupled through [] coil 279 . . . with another coil 680 included within IPG 100, as is known in the art." *Id.* at 41:6–12. More specifically, power amplifier 275 drives primary coil 279 at a resonant frequency which is tuned to the same resonant

frequency as secondary coil 680 in IPG 100, thereby inducing AC voltage which is converted to a DC voltage by rectifier circuit 682. *Id.* at 41:25–31.

Battery protection integrated circuit ("IC") 686 of the IPG "monitors the voltage and current of [] implant battery 180 to ensure safe operation." *Id.* at 42:13–17. Battery protection IC opens [field-effect transistor] FET switch 688, thereby disconnecting the battery, when: 1) the battery voltage rises above a safe maximum voltage during charging; 2) the battery voltage drops below a safe minimum voltage; or 3) the charging current exceeds a safe maximum charging current. *Id.* at 42:17–27.

Figure 9C of the '404 patent is reproduced below:

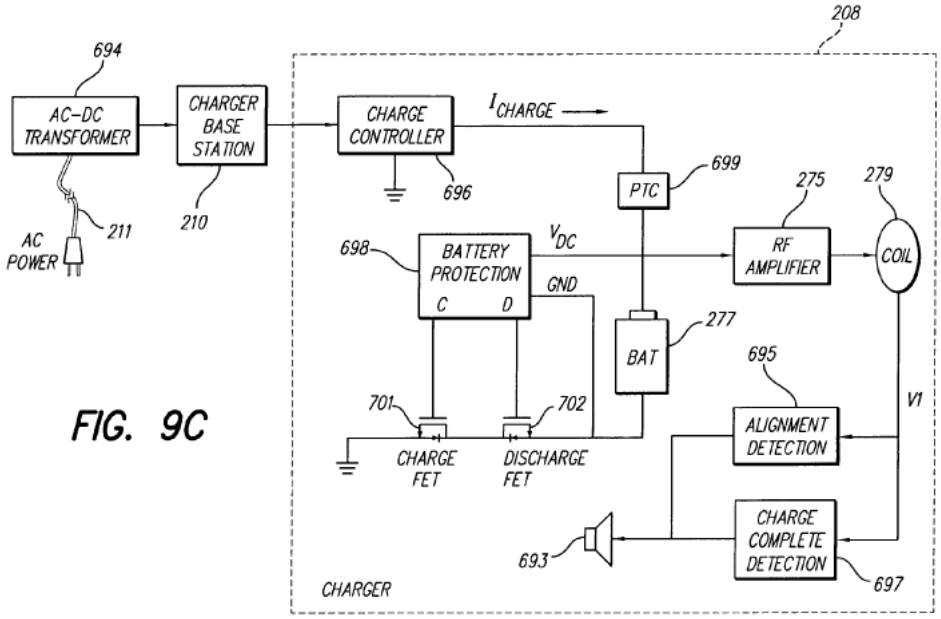


FIG. 9C

Figure 9C depicts a block diagram of battery charger/protection circuity within external charging station 208. Ex. 1001, 8:1–3. This circuitry includes "alignment detection circuit 695 [that] detects the presence of [] IPG 100 through changes in the reflected impedance on [] coil 279." *Id.* at 43:24–26. Minimum reflected impedance, i.e., when voltage V1 is at a minimum, corresponds to maximum coupling. *See id.* at 43:26–30. A first audible alarm may sound when maximum coupling is detected. *Id.* at

43:30–42. "Similarly, [] charge complete detection circuit 697 alerts the user through generation of a second audible tone (preferably an ON-OFF beeping sound) when [] IPG battery 180 is fully charged." *Id.* at 43:37–40. More specifically, when charging is completed in IPG 100, back-telemetry transmitter 690 modulates a secondary load by switching rectifier circuit 682 from a full-wave rectifier circuit to a half-wave rectifier circuit. *Id.* at 40:40–51, 43:37–52. Rectifier switching suddenly increases the amount of reflected energy, causing a sudden increase in Voltage (V1). *Id.* at 43:45–52. "This sudden increase in V1 is detected by [] charge complete detection circuit 697, and once detected causes the second audible tone, or tone sequence, to be broadcast via [] speaker 693." *Id.*

The SCS system may include various modes that initiate a reset sequence or hibernation state. *Id.* at 24:1–10. For example, a first mode includes a power-up reset that occurs at initial turn on. *Id.* at 24:2–3. The power-up reset sequence starts when an external charger is placed over the IPG. *Id.* at 24:11–15. The IPG detects a charging current, e.g., 2.6 volts, from the charger and the battery protection circuit connects the battery to the main circuit. *Id.* at 24:15–25. When the battery voltage rises above 3.0 volts, processor 160 starts a reset sequence, verifies system resources, and sets hardware resources to normal operating conditions, among other steps. *See id.* at 24:26–52.

A second mode may power down the system to protect a patient when the IPG experiences battery depletion that may result in erroneous communication between the modules. *Id.* at 24:3–7. For example, "[i]f the battery voltage falls below a first prescribed level . . . then all systems in the IPG are halted." *Id.* at 25:11–13. "Should the battery voltage fall below a second prescribed level, designated as the battery protection cutoff (2.5 V)

. . . then the battery protection circuitry disconnects the battery from the main circuit." *Id.* at 25:14–17. A third "re-awake mode [is] triggered from the depletion or hibernation state, which re-awake mode requires that the system perform self-check and validation states." *Id.* at 24:7–10. For example, "[w]hen the battery voltage rises above 2.6 V, the protection circuitry reconnects the battery . . . and the process goes through the power-on-reset process" when the voltage rises above 3.0 V. *Id.* at 25:25–35.

2) *Challenged Claims*

Petitioner challenges claims 1–5, 7, 9, and 11–17 of the '404 patent. Pet. 5. Of these, claims 1, 7, and 17 are independent:

1. A spinal cord stimulation system comprising:

an implantable pulse generator (IPG) including at least one integrated circuit (IC) that when powered allows the IPG to generate electrical stimuli, the IPG having a housing;

a replenishable power source contained within the IPG housing;

an implantable electrode array detachably connected to the IPG, the electrode array having at least two electrodes thereon;

wherein the electrical stimuli generated by the IPG are selectively delivered to at least one of the electrodes on the electrode array as controlled, at least in part, by electrical circuitry contained within the IC;

an implantable secondary coil coupled electrically to the replenishable power source;

an external power source charger including:

a primary coil;

an external power source contained in the charger, electrically coupled to the primary coil; and

a power amplifier that applies alternating current derived from the external power source to the primary coil,

whereby the alternating current in the primary coil induces a magnetic field that is transcutaneously coupled to the implantable secondary coil, thereby inducing a corresponding alternating current in the secondary coil, which alternating current in the secondary coil initiates a power-up sequence for a powered-down IPG and recharges the replenishable power source contained in the IPG;

a power source replenishing system housed within the IPG, including:

a rectifier circuit that converts the alternating current induced in the secondary coil to a dc current that is applied to the replenishable power source;

power source protection circuitry for controlling electrical connection and disconnection between the replenishable power source and the at least one IC included within the IPG; whereby the power source protection circuitry allows connection between the replenishable power source and the at least one IC upon transcutaneous transfer of power from the external power source to the replenishable power source;

alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of an ac voltage at the primary coil as applied by the power amplifier, wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored; and

an alarm generator that generates an audible alarm signal in response to a sensed change in the reflected impedance monitored by the back telemetry receiver.

7. A spinal cord stimulation system comprising:

an implantable pulse generator (IPG), the IPG having a housing;

an implantable electrode array detachably connected to the IPG, the electrode array having at least two electrodes thereon; a

rechargeable power source contained within the IPG housing;

monitoring circuitry contained in the IPG housing that monitors the voltage of the rechargeable power source and any charging current flowing to the rechargeable power source;

at least one integrated circuit (IC) within the IPG housing and electrically couplable to the rechargeable power source, said at least one IC, when coupled to the rechargeable power source, providing essential control functions that allow the IPG to operate;

a processor electrically coupled to the at least one IC and contained within the IPG housing which issues commands to stop all stimulation if the voltage of the rechargeable power source falls below a minimum level for stimulation;

power source protection circuitry within the IPG housing that controls electrical connection and disconnection between the rechargeable power source and the at least one IC, wherein the power source protection circuitry disconnects the rechargeable power source from the at least one IC if the voltage of the rechargeable power source falls below a power disconnect level, and reconnects the rechargeable power source and the at least one IC if the voltage of the rechargeable power source rises above a power reconnect level, wherein the processor initiates a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold; and

wherein the processor reinitiates stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation.

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

monitoring the voltage of the rechargeable power source and any charging current flowing to the rechargeable power source;

> issuing commands to stop all stimulation pulses if the voltage of the rechargeable power source falls below a minimum level for stimulation;
>
> electrically disconnecting the rechargeable power source from the at least one IC if the voltage of the rechargeable power source falls below a power disconnect level electrically reconnecting the rechargeable power source to the at least one IC if the voltage of the rechargeable power source rises above a power reconnect level;
>
> initiating a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold; and
>
> reinitiating stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation.

Ex. 1001, 49:2–54, 51:9–45, 52:66-54:5.

3) *Relevant Prosecution History*

During the prosecution leading to the issuance of the '404 patent, the Examiner allowed claims 9–20 (now claims 7–18) without rejection. *Id.* at 299–300. As for the reasons for allowance, the Examiner stated:

> Initiating a power-on-reset if the voltage of a rechargeable power source rises above a reset threshold and reinitiating stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation in a spinal cord stimulation system, or a method for controlling shutdown and restart of an implantable pulse generator containing a rechargeable power source are not shown nor suggested by the prior art of record.

Id. at 300; *see id.* at 375.

In the same Office Action, however, the Examiner rejected claims 1–4 as anticipated by Mann.[7] Ex. 1002, 298–299. The Examiner similarly rejected then-pending claim 8 (now claim 5) as obvious over the same

[7] U.S. Patent No. 4,082,097, issued Apr. 4, 1978. Ex. 1030.

reference. *Id.* at 299. The Examiner found that Mann disclosed a rechargeable tissue system including an external power source with a primary coil for charging an implanted device with a secondary coil. *See id.* 298–299. The Examiner found that Mann disclosed a feedback signal so that when the power source was "properly aligned against the skin with respect to the implanted [device] the charging current is at a desired amplitude." *See id.* at 299. In response, Applicant amended claim 1 to incorporate the claimed elements of "alignment circuitry . . ." and "an alarm generator . . ." resulting in allowance of claims 1–5 of the '404 patent. *Id.* at 342–354, 374–375.

II. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406

(2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom*

Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person of ordinary skill in the art as of the relevant date "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." Pet. 11. Patent Owner does not presently dispute Petitioner's proposed definition of the skilled artisan. Prelim. Resp. 8. And as Petitioner's proposed definition is not inconsistent with the cited prior art, we adopt it for the purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the

extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner and Patent Owner both state that the claim phrase "alignment between the primary and secondary coils," of claim 1, need not be construed at this time. *See* Pet. 12; *see also* Prelim. Resp. 14. Both parties, however, propose constructions for the claim phrases: "external trial stimulator" (claim 12), "means for using household AC" (claim 3), and "means for non-invasively recharging the replenishable power source through the skin" (claim 15). *See* Pet. 13–15; *see also* Prelim. Resp. 11–12, 14–15. Patent Owner also proposes claim constructions for the claim phrases "back telemetry receiver" (claim 1), "power-up sequence" (claim 1), and "power-on-reset" (claims 7, 17). *See* Prelim. Resp. 9–11, 12–14. We address each of these constructions below.

1) *"external trial stimulator"*

As noted at page 11 of the Preliminary Response, the district court construed "external trial stimulator" to mean as a "pulse generator externally-worn by a patient capable of being used outside of the operating room that is used temporarily for evaluation purposes before implantation of the IPG." *See* Ex. 2005, 1 (construing terms of the '280 patent). The Board applied the same definition in IPR2017-01812. Ex. 1008, 21–22. For consistency, and absent argument to the contrary, we apply the same definition here.

2) *"means for using household AC"*

Petitioner reasonably construes this term as a mean-plus-function term under section 112(6) wherein "the claimed function is 'using household AC power to charge up the rechargeable power source in the power source charger' and the corresponding structure includes (1) a charging base station

that is either separate from or incorporated in an external charger, (2) an AC power line, and (3) their literal equivalents." Pet. 13 (citing Ex. 1001, 4:62–65, 40:64–41:4, Figs. 8, 9A, 9C (elements 210, 211)). Patent Owner does not presently oppose this construction but argues that construction of this term is not necessary at this stage of the proceeding. *See* Prelim. Resp. 15.

Consistent with Petitioner's arguments, we construe the recited function as "using household AC power to recharge the rechargeable power source in the power source charger," and the corresponding structures as "a recharging base station that recharges the second rechargeable battery from energy obtained from line ac power" (Ex. 1001, 4:53–65) and a "charging base station 210" (*id.* at 41:2–4).

3) *"means for non-invasively recharging the replenishable power source through the skin"*

Petitioner reasonably construes this term as a mean-plus-function term under section 112(6) wherein "The claimed function is 'non-invasively charging the replenishable power source' and the corresponding structure is an external power source (Ex. 1001, Fig. 9A, 277), power amplifier (*id*., Fig. 9A, 275), an external coil (*id*., Fig. 9A, 279), an internal coil (*id*., Fig. 9A, 680) and their literal equivalents. *Id*., 41:6-12." Pet. 14. Because Petitioner's presently unopposed construction is supported by the Specification, we adopt it for the purpose of institution, with the caveat that we further define the claimed function as "non-invasively charging the replenishable power source *through the skin*." *See* Prelim. Resp. 15 (arguing that construction of this term is not necessary at this stage of the proceeding).

4) *"back telemetry receiver"*

Patent Owner argues that "[t]he ordinary and customary meaning of a 'back telemetry receiver' is a receiver in the external device that listens for data or information (*i.e.*, telemetry) transmitted from a telemetry transmitter, not circuitry that directly measures a current (or voltage) and then compares that measured property to a reference." *Id.* at 9. Patent Owner contends the '404 patent's Specification supports this interpretation by disclosing that "other information, data or commands [is] sent by a back telemetry transmitter within the IPG, such as charge complete indication, delivered current values, temperature and the impedance of electrodes." *Id.* at 10 (citing Ex. 1001, 17:2–5, 19:53–56, 27:14–29, 32:24–27, 36:60–66, 41:40–51, 43:53–67, 48:29–62).

The Board previously addressed this term in IPR2017-01812, concluding that a back telemetry receiver does not require "the transmission and receipt of data or information" but also encompasses "circuitry that monitors voltage and impedance." Ex. 1008, 18–21. For the purpose of institution, we do not find it necessary to determine whether the term requires location "in the external device" as Patent Owner proposes. Further, Patent Owner's proposed exclusion of "circuitry that directly measures a current (or voltage)" is contrary to the Board's prior construction, against which Patent Owner presently offers no persuasive argument or evidence. Thus, in accord with Final Written Decision in IPR2017-01812, and in light of the record before us, we interpret "back telemetry receiver" as "a device for the transmission and receipt of data or information" and/or "circuitry that monitors voltage and impedance."

5) *"power-up sequence" and "power-on-reset"*

Patent Owner argues that the terms "power-up sequence" and "power-on-reset" recited in claims 7 and 17, respectively, "should be construed as the 'process by which the internal registers of the integrated circuit of the IPG are reset to a safe state.'" Prelim. Resp. 12–13. Patent Owner supports this argument with reference to Figure 4D of the Specification, which "depicts a 'representative power-up reset sequence.'" *Id.* (citing Ex. 1001, 24:11–12, 26–29, 35–50). The sequence includes steps wherein the processor starts a system application code, "initializes all the registers . . . to a safe state," and sets various resources "to default conditions" or "to normal operating conditions." *Id.* at Ex. 1001, 24:42–53.

With respect to the "power-up-reset" of claims 7 and 17, Patent Owner similarly points to the '404 patent's recitation that "[w]hen the battery voltage rises above 2.6 V, the protection circuitry reconnects the battery, and HEXTRESET is asserted (block 4E14). When the battery voltage rises above the VBAT threshold (3.0±0.1V) (block 4E15), then HEXTRESET is released, and the process goes through the power-on-reset process (block 4E16)", as illustrated in Figure 4E. *Id.* at 13–14 (citing Ex. 1001, 25:25–30).[8] According to Patent Owner, this comprises "one of the instances in which the power-up reset sequence can occur is when the voltage of the rechargeable power source rises above a reset threshold." *Id.*

We do not find Patent Owner's argument persuasive. On the present record, Patent Owner provides no expert testimony indicating that one of ordinary skill in the art would interpret "power-up sequence" and "power-

[8] Patent Owner does not explain, nor do we clearly discern, the meaning or relevance of HEXTRESET. Further explanation is suggested.

on-reset" as requiring internal registers of the integrated circuit of the IPG to be reset to a safe state. The challenged claims, moreover, make no mention of internal registers, and the '404 patent Specification expressly describes the evidence Patent Owner relies on as "representative." Ex. 1001, 7:32–35, 24:11–12. Absent a clear teaching in the Specification, or persuasive evidence regarding the understanding of one of ordinary skill in the art, we decline to apply the narrow reading of these terms proposed by Patent Owner. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms").

In light of the above, and for the purpose of institution only, we provisionally construe "power-up sequence" and "power-on-reset" as "a process for restoring power to a device," and invite the parties to further discuss the meaning of these terms at trial.

D. Obviousness over the combined teachings Holsheimer, Munshi, Schulman, and Wang (Ground 1)

As Ground 1, Petitioner challenges claims 1–5 as obvious over Holsheimer, Munshi, Schulman, and Wang. Pet. 16–49. Petitioner's challenge includes a detailed mapping of the teachings of these references to each element of claim 1. *Id.* We begin our analysis with an overview of the references asserted under Ground 1.

1) *Overview of Holsheimer (Ex. 1004)*

Holsheimer is directed to a neurological stimulation system for stimulating the spinal cord using an implantable pulse generator ("IPG"). Ex. 1004, 3:53–62. The preferred IPG "is an ITREL IIR implantable pulse

generator available from Medtronic Inc." *Id.* at 3:60–62. Holsheimer's Figure 1 is reproduced below:

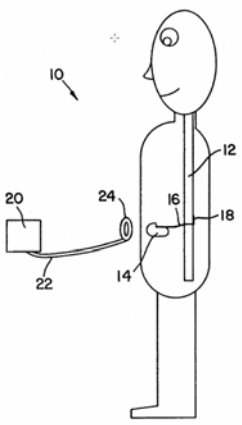


FIG. 1

Figure 1 depicts a schematic view of a patient with an implanted neurological system, including IPG 14, which produces "a number of independent stimulation pulses which are sent to spinal cord 12 by insulated lead 16 and coupled to the spinal cord by electrodes located at point 18." *Id.* at 2:45–47, 3:56–59.

2) *Overview of Munshi (Ex. 1005)*

Munshi is directed to "a pacemaker or a defibrillator or any other bioimplantable battery-powered device incorporating . . . [a] rechargeable power source" that is recharged through the patient's skin by electromagnetic induction from either an AC or DC source. Ex. 1005, Abstract, 4:3–10. Munshi's Figure 2 is reproduced below:

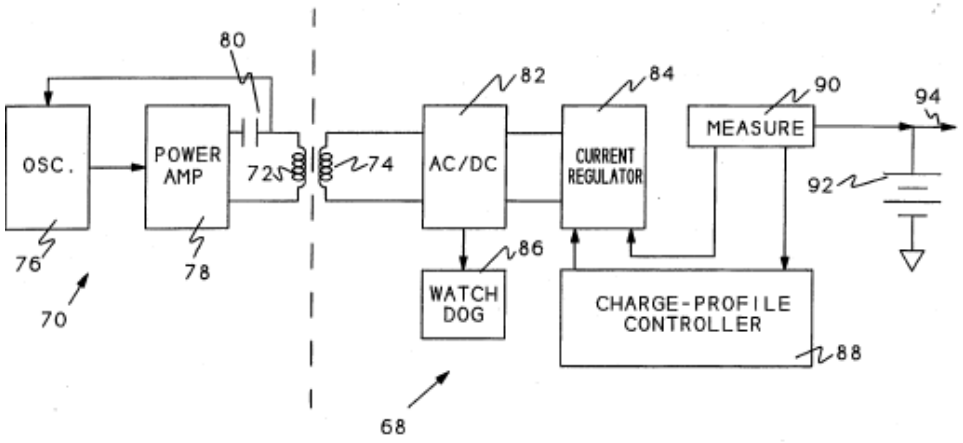


FIG. 2

Figure 2 depicts a block diagram of rechargeable power supply 68 and external charge 70. *Id.* at 5:12–13. Connection 94 connects rechargeable battery 92 to the other circuits of implantable device 10. *Id.* at 10:64–66.

Munshi discloses an interface between external charger 70 and implanted power supply 68 including mutually coupled external charging coil 72 and input coil 74. *Id.* at 10:21–26, 32–37. The coils are used to transfer energy from external transmitting coil 72 through the body tissue to implanted receiving (input) coil 74 by mutual induction. *Id.* Munshi discloses "[a] rechargeable external battery pack with its own charging system could be provided to allow portability of the external unit. If desired, an AC-to-DC converter and regulator, together with a local charging controller could allow a user to recharge the external battery pack by connecting the system to a standard AC line outlet." *Id.* at 10:43–51.

Munshi further discloses that implanted power supply 68 may include AC-to-DC converter 82 and current regulator 84 that regulates the charging current supplied to implantable rechargeable battery 92. *Id.* at 10:52–56. Munshi's IPG may further include "watch dog circuit 86 to detect the effective presence of the external charger 70 . . . charge-profile controller 68 that dynamically adjusts the implantable charging system to ensure optimal

and efficient charging of the battery . . . [and] means for measuring the battery voltage." *Id.* at 10:56–64.

According to Munshi a "user initiates the battery charging operation by placing the energy transmitting coil of the external charging unit in close proximity to the implanted coil and by turning on the excitation to the transmitting coil." *Id.* at 12:54–57. The watchdog circuit in the implanted device subsequently "detects the presence of the activated external charging unit by detecting the induced voltage in the implanted receiver coil, and then activates all implanted circuitry related to battery charging." *Id.* at 12:58–62. In addition:

> [t]he external charger has a means for measuring the transmitted power (e.g., measuring the current through the transmitting coil) and this value is continuously displayed to the user. . . . current through the transmitting coil is maximized when the coupling between the two coils is the strongest. This enables the user to adjust the position of the external coil and find the optimum position of maximum energy transfer.

Id. at 12:63–13:3.

3) *Overview of Schulman (Ex. 1006)*

Schulman discloses an implantable human tissue stimulator ("HTS") having a volatile memory and a circuit to prevent "stimulating circuitry producing pulses as a function of unknown parameters in the memory, as a result of inadequate power to the memory from a rechargeable power source, e.g. a rechargeable battery." Ex. 1006, code (57) (Abstract).

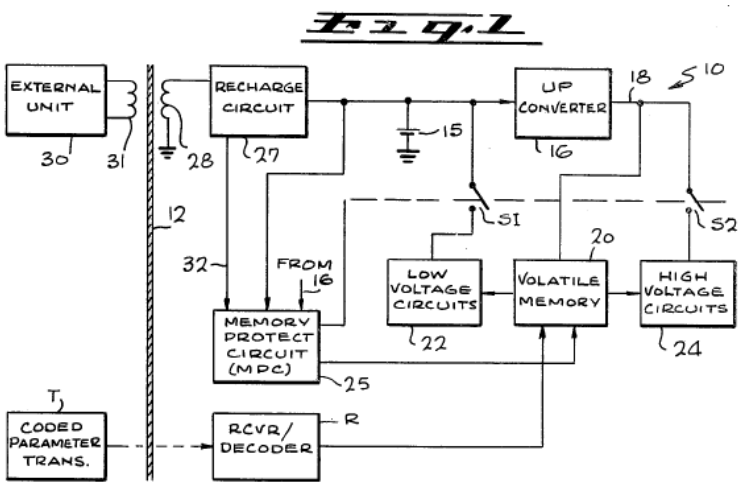
> The arrangement includes voltage sensors, so that when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery and only the memory is powered. If the voltage from the battery first drops, so that insufficient power is supplied to the memory and thereafter rises, as a result of recharging, to a level sufficient to power the memory, the memory is first reset with known

> parameter values. Only thereafter when the voltage level reaches the selected level, is the rest of the circuitry, including the stimulating circuitry, reconnected to the battery.

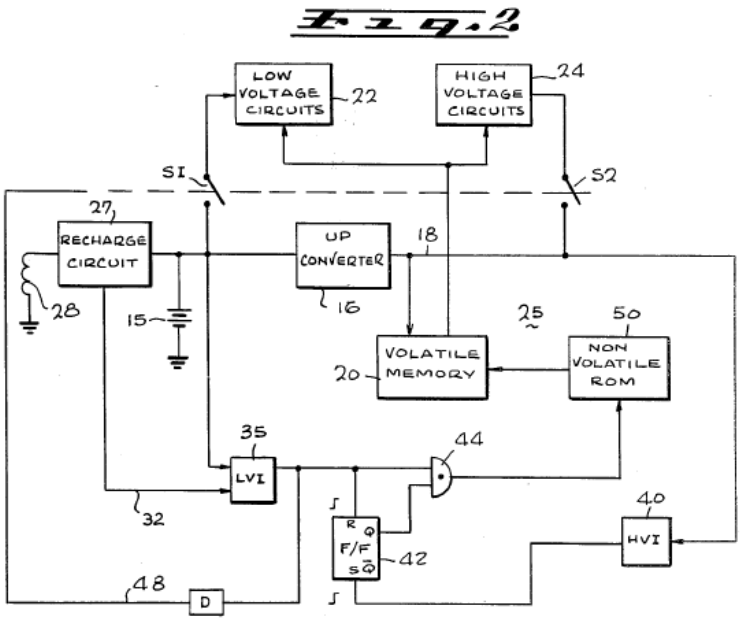
Id.

According to Schulman, preserving stored parameters in an HTS's memory is paramount for patient safety. *Id.* at 2:31–37. Particularly, "[i]f the parameters are to be stored in a volatile memory, some means must be provided to either protect the memory power supply and/or, if this cannot be done, to reset the memory to prevent dangerous stimulating regimes." *Id.* at 2:40–46.

Schulman Figure 1 is reproduced below:



Schulman Figure 1 "is a general block diagram of an HTS with a rechargeable battery, a parameter-storing memory and the memory protect circuit [MPC 25] of the present invention." *Id.* at 3:31–33. Schulman's Figure 2 is reproduced below:



Shulman's Figure 2 also depicts a block diagram of the HTS but shows MPC 25 in greater detail. *Id.* at 3:34–35. According to Schulman, "MPC 25 is supplied with the voltages from battery 15 and converter 16. In addition it is shown connected to [] battery charging circuit 27, whose function is to recharge the battery when recharging energy is received from" energy receiving coil 28. *Id.* at 4:10–15. MPC 25 further includes low voltage indicator ("LVI") 35 and high voltage indicator ("HVI") 40. *Id.* at 4:48–64. LVI 35 monitors the voltage across battery 15 at a first threshold, and HVI monitors the voltage of up converter 16 at a second threshold. *See id.* at 4:48–5:5.

With respect to the operation of the MPC, Schulman discloses that when the LVI output goes low, switches L1 and L2 open thereby disconnecting circuits 22 and 24 from the battery so that the HTS does not provide stimulating pulses. *See id.* at 5:14–50. However, volatile memory 20 stays connected to the battery at the first threshold to maintain stored parameters. *See id.* at 5:41–50. If the output voltage drops below a second threshold, the output of HVI goes low indicating the "voltage applied to []

memory 20 is less than necessary for safe operation of the memory" and the stored parameters cannot be relied on. *Id.* at 6:38–44. "Thereafter, when the battery is recharged, and when the memory is again powered by sufficient voltage, the memory is loaded with preselected parameters from a memory reset source in the HTS, e.g., [] read only memory (ROM)" 50. *Id.* at 3:11–15. "Once the battery voltage exceeds the desired level, all of the rest of the circuits are again reactivated." *Id.* at 3:19–21.

4) *Overview of Wang (Ex. 1007)*

Wang is directed to a transcutaneous energy transmission device for charging rechargeable batteries in an implanted medical device that includes an alignment indicator to signal when the internal and external charging coils are optimally aligned. *See* Ex. 1007, (57) Abstr. In particular, Wang teaches that the "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." *Id.* at 5:13–17. Accordingly, Wang discloses "an alignment circuit and indicator . . . to indicate whether the coils are properly aligned." *Id.* The indicator may include "visual and/or audible signal [] provided only when the charging coil is substantially in alignment with the receiving coil in the implanted device thereby indicating proper alignment." *Id.* at 5:20–23.

Wang describes Figure 2, reproduced below, as "a schematic block diagram of the preferred circuit implementation of the present invention." *Id.* at 5:34–36.

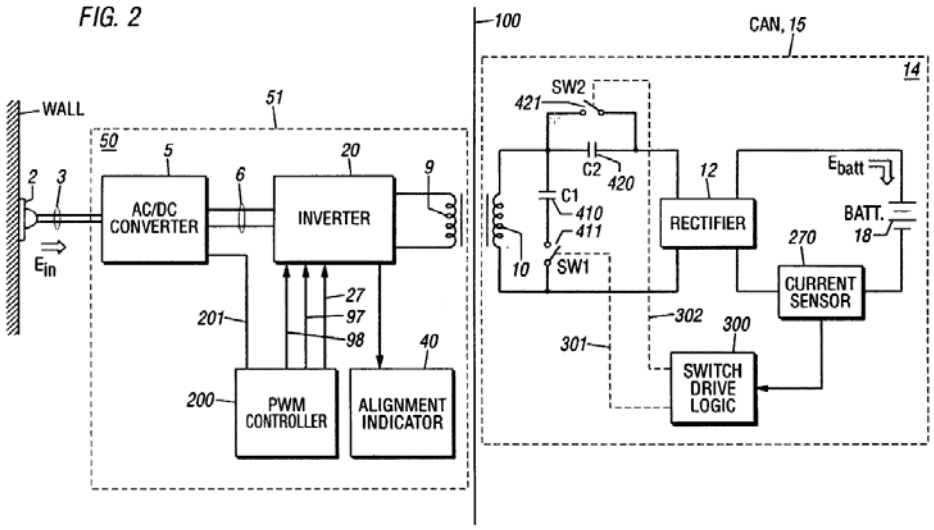


Figure 2 shows, transcutaneous energy transmission device (TET) 50 containing alignment indicator 40 in communication with implanted device 14 via primary and secondary coils 9 and 10, respectively, across patient's skin 100. *See, generally, id.* at 7:13–23.

Wang Figure 5 reproduced below, provides further details regarding alignment indicator 40 as arranged in TET 50:

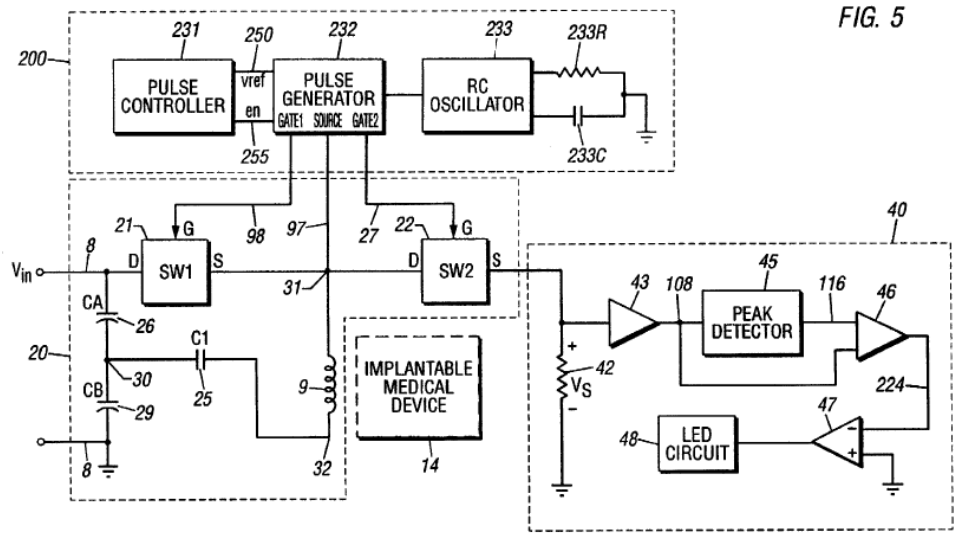


Figure 5 depicts a schematic block diagram of an alignment indicator for a transcutaneous energy transmission device, wherein "[a]lignment indicator 40 provides a light emitting diode (LED) in LED circuit 48 or other output device to indicate proper positioning . . . with respect to implanted device 14." *Id.* at 5:47–50, 11:28–31. As such, alignment indicator 40 uses the correlation between the input current and alignment to provide an output signal which indicates when energy transmission device 50 is sufficiently aligned with receiving coil 10 (see Figure 1) of implanted device 14. *Id.* at 11:42–46.

Wang discloses a charging method in which switch 22 turns on, completing a current path "from V_{in}, through capacitor 26, node 30, capacitor 25, coil 9, node 31, switch 22, and resistor 42 to ground." *Id.* at 11:11–13. Wang discloses "the purpose of resistor 42 is to sense current in the primary coil 9 and provide an output signal indicative of the current amplitude and phase shift. Accordingly, although a resistor is preferable, any current sensing device can be used in place of resistor 42." *Id.* at 11:51–55. Current flow through resistor 42 generates voltage V_s, which is amplified by low-pass amplifier 43 and sent to both peak detector 45 and differential amplifier 46. *Id.* at 12:1–18. Primary coil 9 must pass the optimal charging location at least once so that peak detector 45 records peak DC current value, and establishes a scaled peak value less than the peak value. *Id.* at 12:14–16, 26–29. Thereafter, differential amplifier 46 amplifies the difference between the scaled peak value and the current sensed value, and sends the difference to comparator 47, which turns on the LED circuit 48 when the current sensed value is greater than the scaled peak value. *Id.* at 12:19–31.

5) *Analysis of Claim 1*

Petitioner argues claims 1–5 are obvious over Holsheimer, Munshi Schulman, and Wang. Pet. 16–53. Patent Owner opposes. Prelim. Resp. 23–40. Because Patent Owner does not separately address any element of claims 2–5, we focus our analysis on the elements of claim 1, as follows.

a) "A spinal cord stimulation system comprising"

Petitioner asserts Holsheimer discloses a neurological stimulation system to stimulate spinal cord 12. Pet. 21.

Patent Owner does not respond to this assertion.

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

Petitioner asserts Holsheimer discloses an IPG in a self-contained device with a housing. Pet. 21–22. Petitioner asserts "[a]lthough Holsheimer does not expressly disclose an 'integrated circuit . . . such basic circuitry is required for the IPG to operate." *Id.* at 22. Additionally, Petitioner asserts that Munshi discloses an IPG with an integrated circuit. *See id.* at 22–23 (citing Ex. 1003 ¶¶ 86–87). According to Petitioner, it would have at least been obvious to a person of ordinary skill in the art to incorporate an integrated circuit into an IPG due to small size, low cost and ruggedness. *Id.* at 23.

Patent Owner does not respond to Petitioner's assertions.

c) "a replenishable power source contained within the IPG housing"

Petitioner asserts that Munshi discloses a replenishable power source, i.e., a rechargeable battery, contained within an IPG. Pet. 24 (citing Ex. 1003 ¶¶ 93–94). According to Petitioner, it would have at least been obvious to a person of ordinary skill in the art to incorporate Munshi's

rechargeable battery into Holsheimer's IPG to improve the service life of the device and minimize the surgical procedures required. *Id.* at 24 (citing Ex. 1003 ¶¶ 80–82).

Patent Owner does not respond to Petitioner's assertions.

d) "an implantable electrode array detachably connected to the IPG . . . having at least two electrodes thereon"

Petitioner notes that the Board previously determined in IPR2017-01812 that Holsheimer teaches an implantable electrode array detachably connected to an IPG. *Id.* at 25 (citing Ex. 1008, 87). Petitioner asserts "Holsheimer discloses an 'implantable electrode array' (*e.g.*, implanted lead with electrode array) 'connected to the IPG' (*e.g.*, connected to the pulse generator) and 'having at least two electrodes thereon' (*e.g.*, electrodes on the lead)." Pet. 25. Petitioner contends Holsheimer's Figure 1 "shows a standard connector notch commonly used to depict lead connectors for attaching and detaching leads. *Id.* (citing Ex. 1003 ¶ 96).

Petitioner contends Holsheimer's IPG is preferably a Medtronic ITREL II system which, "like all SCS systems, used detachable leads." *Id.* at 26. Petitioner submits evidence that Medtronic's ITREL systems utilized detachable leads. *See id.* (citing Ex. 1020, 9:3–6, 80:14–81:11, 141:19–143:12; Ex. 1021; 109:4–22; Ex. 1022, 53:10–55:10). Petitioner further submits evidence that "***all*** SCS systems used detachable leads" and there were no known SCS systems without detachable leads at the time of invention. *Id.* at 26–27 (citing Ex. 1021, 110:21–111:10, 279:4–12; Ex. 1022, 37:18–22; Ex. 1024, 295:19–22; Ex. 1025, 198:3–22). Moreover, Petitioner submits evidence that a person of ordinary skill in the art "would also have understood that the SCS implantation process necessitates detachable leads." *Id.* at 27–28 (citing Ex. 1022, 27:18–28:22, 29:10–14,

29:19–25; Ex. 1026 ¶¶ 20, 21, 22, 24, 25); *see* Ex. 1003 ¶¶ 96–101. Taken together, Petitioner contends "[b]ecause all known SCS systems used detachable leads and because the implantation process necessarily requires detachable leads, a POSA would have understood Holsheimer to also disclose the use of detachable leads." *Id.* at 28 (citing Ex. 1003 ¶¶ 99–101).

Patent Owner responds that "Holsheimer does not disclose a detachable electrode array [and] [i]n fact, Holsheimer teaches away from detachable leads." Prelim. Resp. 26.[9] As to the Board's prior findings in IPR2017-01812, Patent Owner argues that issue preclusion does not apply because the decision is subject to change on appeal. *Id.* at 27.

Patent Owner contends that "Holsheimer discloses an apparatus in which wires connected the outputs of [the] pulse generator to the electrodes of the array" thus disclosing "*attached* leads, not detachable leads." *Id*. at 27 (citing Ex. 1004, 7:22–27, 47–58, Figs. 19 & 20). Patent Owner contends that Holsheimer discloses "a generic representation of an IPG that does not inform a POSITA about the details of the IPG." *Id.* at 28.

As to Petitioner's evidence, Patent Owner contends that Holsheimer's IPG is an "ITREL IIR" and not an "ITREL II," so that the evidence with respect to the detachable ITREL II should be disregarded. *Id.* at 29. Patent

[9] Patent Owner does not persuasively explainthe basis for its teaching away assertion. To the extent Patent Owner intends that the alleged absence of detachable leads in Holsheimer constitutes a teaching away, we remain mindful that "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed." *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). "We will not read into a reference a teaching away . . . where no such language exists." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006).

Owner also contends that "even if commercially implanted medical devices for spinal cord stimulation tended to have a detachable lead at the time of the '404 patent's invention, that does not mean that Holsheimer necessarily or inherently disclosed detachable leads." *Id.* at 30.

We do not find Patent Owner's argument persuasive on the present record. As set forth above, Petitioner provides evidence, including the declaration testimony of its technical expert, Mr. Pless, that one of ordinary skill in the art "would have understood Holsheimer to . . . use detachable leads with its SCS system and accordingly discloses 'an implantable electrode array detachably connected to the IPG, the electrode array having at least two electrodes thereon.'" *See* Ex. 1003 ¶ 101. Petitioner's evidence appears similar to that the Board previously relied on in IPR2017-01812 in finding that Holsheimer teaches an implantable electrode array detachably connected to an IPG. *See* Ex. 1008, 86–87. With respect to this earlier case, Patent Owner points out that the panel in IPR2017-01812 did not establish that Holsheimer disclosed detachable leads when it instituted trial. Prelim. Resp. 27–28 (citing Ex. 2006, 24–25; 2007, 6). In the Final Written Decision, however, the panel stated:

> Although we maintain our conclusion that the Petition alone is insufficient to demonstrate that Holsheimer's leads are detachable, for the reasons noted above, that failure does not dictate resolution of the issue . . . . In light of the entire record before us, we find that Petitioner has carried its burden in demonstrating that a POSITA would have recognized Holsheimer's leads to be detachable.

Ex. 1008, 79. To the extent our sister panel's determination is subject to a pending appeal and not preclusive, as Patent Owner argues, we, nevertheless, give substantial weight to its findings. *See* Prelim. Resp. 26–27 & n.1.

At this stage of the proceeding, Patent Owner provides no persuasive evidence rebutting Petitioner's persuasive argument that Holsheimer discloses detachable leads, and that the use of such leads was well known in the art. To the contrary, Patent Owner appears to admit that it is "equally plausible" to read Holsheimer as teaching attached or detachable leads. *See* Prelim. Resp. 31 ("With respect to Holsheimer, it is equally plausible, if not more plausible, that Holsheimer discloses an *attached* lead given the reference's focus on modeling stimulation patterns using the particular electrode configurations disclosed."). *Id.* at 31.

In view of the above, and on the present record, Petitioner has established sufficiently that one of ordinary skill in the art would have understood Holsheimer to teach or render obvious "an implantable electrode array detachably connected to the IPG . . . having at least two electrodes thereon."

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

Petitioner asserts that Holsheimer discloses an IPG generating electrical stimuli which are selectively delivered to at least one of the electrodes on the electrode array. Pet. 29. Petitioner contends a person of ordinary skill in the art "would have understood that such stimulation is controlled by electrical circuitry within the IPG." *Id.* (citing Ex. 1003 ¶¶ 103–104). Alternatively, Petitioner contends that it would have been obvious in view of Munshi to control stimulation using circuitry within the IC. *Id.*

Patent Owner does not respond to Petitioner's assertions.

f) "an implantable secondary coil coupled electrically to the replenishable power source"

Petitioner asserts Munshi discloses a rechargeable battery with an input coil that would have been obvious to include in Holsheimer's IPG. Pet. 30.

Patent Owner does not respond to this assertion.

g) "an external power source charger including"

Petitioner asserts Munshi discloses external charger 70 which is an external power source charger. Pet. 31.

Patent Owner does not respond to this assertion.

(1) "a primary coil"

Petitioner asserts Munshi discloses external charging coil (transmitting coil) 72, which corresponds to a primary coil. Pet. 32.

Patent Owner does not respond to this assertion.

(2) "an external power source contained in the charger, electrically coupled to the primary coil"

Petitioner asserts Munshi discloses a rechargeable external battery pack coupled to external charging coil (transmitting coil) 72, which corresponds to an external power source in the charger. Pet. 32–33.

Patent Owner does not respond to this assertion.

(3) "a power amplifier that applies alternating current derived from the external power source to the primary coil"

Petitioner asserts that Munshi discloses power amplifier 78 that applies alternating current driven by oscillator 76 to transmitting coil 72, and that power amplifier corresponds to the claimed power amplifier. Pet. 33–34.

Patent Owner does not respond to this assertion.

> *(4) "whereby the alternating current in the primary coil induces a magnetic field that is transcutaneously coupled to the implantable secondary coil, thereby inducing a corresponding alternating current in the secondary coil,"*

Petitioner asserts that Munshi discloses oscillator circuit 76 drives transmitting coil 72 with an alternating current causing magnetic induction coupled between external charging coil (transmitting coil) 72 and input coil 74. Pet. 34–35.

Patent Owner does not respond to this assertion.

> *(5) "which alternating current in the secondary coil initiates a power-up sequence for a powered-down IPG and recharges the replenishable power source contained in the IPG"*

Petitioner contends that although Munshi does not expressly disclose that inducing an alternating current in the second coil "initiates a power-up sequence for a powered-down IPG," this limitation "would have been obvious to a POSA in view of Schulman." Pet. 35–36 (citing Ex. 1003 ¶ 114). Petitioner asserts Schulman discloses protection circuitry that disconnects the stimulating circuitry from the battery when voltage is below a selected threshold, thereby powering down the IPG. *Id.* at 36. Petitioner asserts that Schulman discloses reconnecting the battery to the stimulating circuitry after the battery level rises to a sufficiently high level. *Id.* at 37. Petitioner contends that reconnecting the battery and enabling the stimulating circuitry corresponds to the claimed power-up sequence. *See id.*

Patent Owner responds that Schulman does not disclose a "power-up sequence for a powered-down IPG." Prelim. Resp. 24. In particular, Patent Owner contends "Schulman's memory protection circuitry maintains power to the implanted device's volatile memory and the circuits that control the

supply of power to the volatile memory even when the voltage across the battery falls below a preselected level" and "thus does not disclose a powered-down IPG." *Id.* at 23–24. Patent Owner further contends that Petitioner has not established that "resuming stimulation constitutes 'initiat[ing] a power-up sequence.'" *Id.* at 24. Patent Owner argues that "Schulman says nothing about its human tissue stimulator including integrated circuits or resetting registers of those integrated circuits to a safe state as part of a sequence of actions to power up the powered-down IPG." *Id.*

We do not find Patent Owner's argument persuasive on the current record. With respect to its argument that Schulman fails to discloses a powered-down IPG in light of its disclosure that "'when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery and ***only the memory is powered***,'" Patent Owner fails to explain sufficiently why we should construe "powered-down IPG" to require that *all* circuitry of the IPG is disconnected from the battery. *See* Prelim. Resp. 25 (quoting Ex. 1006, 2:54–66). Absent such argument, and for the purpose of institution, we find Schulman's disclosure "that when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery," sufficiently discloses a "powered-down IPG." As such, Petitioner reasonably relies on testimonial evidence to argue that the claimed "initiat[ion] of a power-up sequence in the secondary coil" would have been obvious in view of Schulman. Pet. 35–36 (citing Ex. 1003 ¶ 114). And to the extent Patent Owner argues that "Schulman says nothing about its human tissue stimulator including integrated circuits or resetting registers of those integrated circuits to a safe state as part of a sequence of

actions to power up the powered-down IPG," our provisional construction of this term is not so limited. *See* Prelim. Resp. 24; section II(C)(5), above.

> *(6) "a power source replenishing system housed within the IPG"*

Petitioner asserts that Munshi discloses input coil 74 for replenishing battery 92 in the IPG. Pet. 38.

Patent Owner does not respond to this assertion.

> *(7) "a rectifier circuit that converts the alternating current induced in the secondary coil to a dc current that is applied to the replenishable power source"*

Petitioner asserts that Munshi discloses AC-to-DC converter 82 for converting induced AC voltage on the receiving (input) coil 74 to DC and current regulator 82 that regulates the charging current to the implantable rechargeable battery. Pet. 38. Mr. Pless states that "[m]ost, if not all AC-to-DC converters would have used some form of a rectifier. Accordingly, a POSA would have understood that Munshi's AC-to-DC converter could have been a rectifier circuit." Ex. 1003 ¶ 119 (citing Ex. 1011, 6:55–57).

Patent Owner does not respond to Petitioner's assertions.

> *(8) "power source protection circuitry for controlling electrical connection and disconnection between the replenishable power source and the at least one IC included within the IPG; whereby the power source protection circuitry allows connection between the replenishable power source and the at least one IC upon transcutaneous transfer of power from the external power source to the replenishable power source"*

Petitioner asserts that Munshi discloses connection 94 from rechargeable battery 92 to other circuits of the implantable device. Pet. 39. Petitioner asserts further that Munshi discloses that the implanted device watchdog circuit detects the present of the activated external charging unit

and then activates all implanted circuitry related to battery charging. *Id.* As noted by Petitioner, "Schulman describes protection circuitry that includes voltage sensors, so that 'when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery and only the memory is powered.'" *Id.* at 40 (quoting Ex. 1006, Abstract). Petitioner contends that "a POSA would have found it obvious to use Schulman's protection circuity in combination with Munshi's 'connection 94'" to control electrical connection and disconnection. *Id.* at 40.

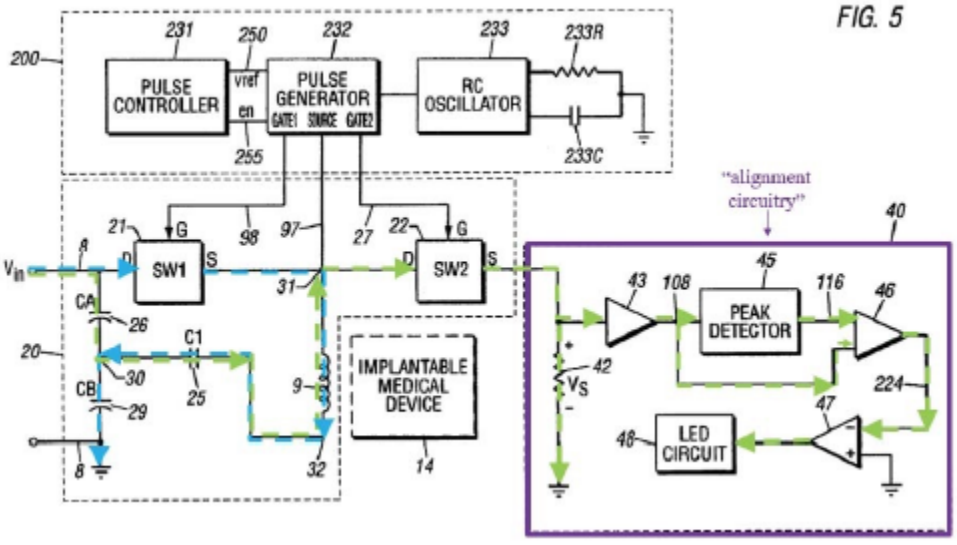
Patent Owner responds that Schulman "does not disclose complete disconnection between the replenishable power source and the at least one IC." Prelim. Resp. 25. Rather, Schulman discloses the memory remains connected to the battery and keeps draining battery power. *Id.* Patent Owner contends that because "Schulman does not expressly disclose disconnection between the replenishable power source and the at least one IC, and Petitioner failed to make any arguments to modify Schulman's protection circuitry, Petitioner fails to meet its burden." *Id.* at 25–26.

As with section II(D)(5)(g)(5), above, we do not find Patent Owner's argument persuasive because the plain language of claim 1 does not require complete disconnection between the replenishable power source and the at least one IC included within the IPG, and Patent Owner does not persuade us otherwise on the present record. Moreover, on the present record, it is not clear that the "at least one IC" recited in the claims necessarily includes memory.

Accordingly, for the purpose of institution, we find it sufficient that Schulman discloses "that 'when the voltage from the battery drops below a selected level the stimulating circuitry is disconnected from the battery.'" *See* Ex. 1006, Abstract.

> *(9) "alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of an ac voltage at the primary coil as applied by the power amplifier, wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored" "*

Petitioner notes that the Board previously determined in IPR2017-01812 that Wang discloses alignment circuitry including a back telemetry receiver. Pet. 44–45 (citing Ex. 1008, 90–92). Petitioner asserts that although Munshi discloses finding an optimum position of maximum energy transfer between the two coils, it does not expressly disclose alignment circuitry. *Id.* at 41–42. Petitioner contends that "Wang provides 'an alignment circuit and indicator . . . to indicate whether the coils are properly aligned.'" *Id.* at 42 (emphasis omitted). Petitioner refers to an annotated version of Wang's Figure 5, reproduced below:



Annotated Figure 5 highlights a blue current path when switch 21 (SW1) is on and switch 22 (SW2) is off, and a green current path when switch 21 is off and switch 22 is on. *Id.* at 42–43. Petitioner asserts "[a]s shown, the

current on [] primary coil 9 is alternating." *Id.* at 43. Petitioner asserts that "when the voltage of Wang's current sensing resistor is at its peak (the current through the primary coil is at a peak), the alignment indicator indicates that proper alignment has been achieved." *Id.* at 44. Mr. Pless states that "[t]he better the alignment between the coils, the more current that is produced from the voltage source. *Id.* Thus, according to Ohm's law (voltage = current * resistance), when the voltage across the current sensing resistor is at a peak, reflected impedance is at a minimum." Ex. 1003 ¶ 126.

Petitioner contends that according to the '404 patent's Specification, the claimed "'back telemetry receiver' senses changes in reflected impedance to indicate, *e.g.*, the IPG's battery is fully charged or charger-IPG alignment." Pet. 45 (citing Ex. 1001, 41:40–51, 43:24–52). Petitioner asserts that "Wang's alignment circuitry also monitors reflected impedance to indicate charger-IPG alignment" wherein "[t]he magnitude of the monitored current 'depends on the power draw of the load on the secondary coil.'" *Id.* Mr. Pless states that "[a] POSA would have understood that this change in current is necessarily a function of reflected impedance from the secondary coil . . . Thus, like the '404's 'back telemetry receiver,' Wang's alignment circuitry receives information indicating charger-IPG alignment by sensing changes in reflected impedance." Ex. 1003 ¶ 129.

Patent Owner responds that Wang does not disclose a "back telemetry receiver." Prelim. Resp. 32. Rather, Patent Owner contends, "Wang discloses a device for sensing an induced electromagnetic field, measuring an electrical parameter of that field, and comparing it to a reference value," as opposed to a receiver that listens for data or information (*i.e.*, telemetry). *Id.* On the present record we do not find Patent Owner's argument persuasive in light of our construction of "back telemetry receiver" as

encompassing "circuitry that monitors voltage and impedance," such as Petitioner describes in Wang. *See e.g.*, Pet. 45; section II(C)(4), above.

> *(10) "an alarm generator that generates an audible alarm signal in response to a sensed change in the reflected impedance monitored by the back telemetry receiver"*

Petitioner asserts that Wang discloses "an 'output device' other than an LED—such as one that produces an 'audible signal'—can instead be used to indicate alignment." Pet. 48.

Patent Owner does not respond to this assertion.

h) Reason to combine the references

In determining obviousness, "a reference . . . is prior art for all that it teaches." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (citation omitted). Nevertheless, in finding obviousness, it is not necessary that all features of a secondary reference are "bodily incorporated into the structure of the primary reference," *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." (*Id*. (citation omitted).) "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417.

In the present case, Petitioner asserts that a person of ordinary skill in the art would have been motivated to modify Holsheimer's IPG with Munshi's rechargeable power source to address known problems of service life of the IPG. Pet. 18–19 (citing Ex. 1003 ¶ 79). Petitioner asserts that a person of ordinary skill in the art would have been motivated to modify

Holsheimer and Munshi to guard against complete battery discharge with Schulman's protection circuitry. *Id.* at 19 (citing Ex. 1003 ¶ 80). According to Petitioner, Munshi acknowledges that transmitting power from an external device to a rechargeable IPG requires close proximity between transmitting and receiving coils. *Id.* at 20. Petitioner asserts that a person of ordinary skill in the art would have been motivated to modify Holsheimer and Munshi with Wang's alignment circuitry to find the optimum position for maximum energy transfer. *Id.*, *see also* Ex. 1003 ¶ 81. Petitioner further asserts that because "Holsheimer (as modified by Munshi), Schulman and Wang describe analogous implantable electrical stimulation systems," "a POSA would have known that features from these references could be combined with a high degree of predictability and that the combination would work as expected." *Id.* (citing Ex. 1003 ¶ 82).

Patent Owner contends that "Petitioner has not articulated any coherent reason why a POSITA would decide to modify Holsheimer" with the "disparate references with different teachings" of Munshi, Schulman, and Wang. Prelim. Resp. 32–33. Patent Owner contends that "Munshi's external charger already provided a means for determining alignment to maximize charging current." Prelim. Resp. 39–40. Patent Owner argues, therefore, there would be no reason to modify Munshi with Wang's alignment circuitry. *Id* at 38. It is well settled, however, that it is obvious for one of ordinary skill in the art to select a particular component from among many disclosed by the prior art as long as the prior art teaches that the selection will result in the disclosed effect. *See Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("That the '813 patent discloses a multitude of effective combinations does not render any particular formulation less obvious."); *Wm. Wrigley Jr. Co. v. Cadbury*

Adams USA LLC, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (all that was required to obtain [the claimed] combination was to substitute one well-known . . . agent for another").

Patent Owner's remaining arguments appear to relate to Munschi's focus on cardiac support devices such as pacemakers and defibrillators, as opposed to spinal cord stimulators as recited in the challenged claims. In particular, Patent Owner asserts that Holsheimer could be implemented as an RF system, in which service life would not be limited by battery life, and that "Petitioner presented no evidence that Munshi's rechargeable battery would be sufficient to power Holsheimer's spinal cord stimulation." *Id.* at 34–35. Patent Owner also contends that "a POSITA who desired to prevent Munshi's battery from completely discharging would not find a solution in Schulman," as Schulman allows for complete battery discharge. *Id.* at 36–37. Moreover, Patent Owner contends that a person of ordinary skill in the art would not be motivated to disconnect the stimulating circuitry from the Munshi's pacemaker as this would be extremely dangerous for the patient. *Id.* at 37–38. Rather, Patent Owner contends that Munshi generates an audio signal alerting the user to recharge the battery. *Id.* at 38.

We do not find Patent Owner's arguments persuasive on the present record in light of Petitioner's arguments and Mr. Pless's supporting testimony. Moreover, and contrary to the thrust of Patent Owner's position, Munshi is expressly *not* limited to cardiac support devices but applies to "any other bioimplantable battery-powered device incorporating . . . [a] rechargeable power source" that is recharged through the patient's skin by electromagnetic induction which, Munshi implies, include "drug infusion and dispensing systems, defibrillators, nerve and bone growth stimulators, gut stimulators, pain suppressors, scoliosis treatment apparatus, artificial

vision apparatus, artificial hearts, artificial larynxs, bladder stimulators, brain stimulators, muscle stimulation, and implanted sensors." Ex. 1005, Abstract, 1:20–28, 4:3–10; *cf.* claim 1 (directed to "[a]n implantable medical device" having "therapy deliv[ery] means") and claims 4 and 5, respectively, ("wherein said therapy deliv[ery] means comprise a cardiac [pacemaker / defibrillator]") .

In light of the above, and on the present record, Petitioner's reasons to combine the asserted references are sufficient to support our decision to institute trial. We, nevertheless, look forward to any expert testimony and other countervailing evidence supporting Patent Owner's contentions.

Accordingly, for the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 1–5 would have been obvious under Ground 1.

E. Obviousness over the combined teachings Holsheimer, Munshi, and Schulman (Ground 2)

As Ground 2, Petitioner challenges claims 7, 9, and 13–17 as obvious over Holsheimer, Munshi, and Schulman. Pet. 53–72. Petitioner's challenge includes a detailed mapping of the teachings of these references to each element of claims 7 and 17. *Id.* Patent Owner opposes. Prelim. Resp. 40–43.

Ground 2 involves a subset of the references asserted under Ground 1, which are discussed in sections II(D)1–3, above. Claim 7 differs from claim 1 (challenged under Ground 1) in reciting "power-on reset" rather than "power-up-sequence." As our provisional construction of these terms is the same, as are the parties' arguments with respect to this term, we institute trial on claim 7 for essentially the same reasons as discussed above with respect to claim 1, Ground 1. *See* Pet. 59–60; Prelim. Resp. 41.

Patent Owner does not separately argue any of claims 9 and 13–16 and, with respect to claim 17, and relies on its earlier arguments with respect to claim 1, Ground 1. *See* Prelim. Resp. 43–44. Accordingly, we likewise institute trial on claims 9 and 13–17 for the reasons set forth with respect to Ground 1.

F. Obviousness over the combined teachings Holsheimer, Munshi, Schulman, and Rutecki (Ground 3)

As Ground 3, Petitioner challenges claims 11 and 12 as obvious over Holsheimer, Munshi, Schulman, and Rutecki. Pet. 68–74. Petitioner's challenge includes a detailed mapping of the teachings of these references to each element of claims 11 and 12. *Id.* Patent Owner opposes. Prelim. Resp. 44–45. We begin our analysis with a discussion of Rutecki in addition to the previous discussion of the references asserted in Grounds 1 and 2.

1) *Overview of Rutecki (Ex. 1009)*

Rutecki is directed to an implantable neurostimulator that includes a pulse generator which delivers therapy to a nerve electrode array implanted on the patient's vagus nerve. Ex. 1009, 6:26–35. Rutecki's system includes external components, such as "a programming wand for telemetry of parameter changes to the stimulus generator and monitoring signals from the generator, and a computer and associated software for adjustment of parameters and control of communication between the generator, the programming wand and the computer." *Id.* at 10:11–18. Rutecki discloses that "an external stimulus generator" with leads extending percutaneously to the implanted nerve electrode assembly should be used in "relatively short term tests" to determine whether the vagal stimulation is sufficient before a permanent implant is performed. *Id*. at 14:3–18.

2) *Analysis of Claims 11 and 12*

Patent Owner contends that Ground 3 fails for the same reasons as set forth with respect to claim 7. Prelim. Resp. 44.

Patent Owner further contends that Rutecki, "external stimulus generator" is not an "external trial stimulator [ETS]," as recited in claim 12. *Id.* at 44–45. In particular, Patent Owner points to the district court's construction of ETS as a "pulse generator externally-worn by a patient capable of being used outside of the operating room that is used temporarily for evaluation purposes before implantation of the IPG." *Id.* at 44 (quoting Ex. 2005, 1 (italics omitted)). According to Patent Owner, the ETS disclosed in Rutecki "is not used during a trial period "and "cannot be used outside the operating room." *Id.* at 45.

As an initial matter, we note that the district court found "an appreciable difference" between its stated construction and one proposed by Nevro lacking the words "capable of being used outside of the operating room." Ex. 2001, 1 at n.1. Thus, even if we were to adopt the district court's construction, it is not clear that Patent Owner's non-obviousness argument reflects any appreciable difference.

In any event, Patent Owner points to passages in Rutecki without, at present, any testimonial evidence as to how one of ordinary skill in the art would have interpreted them. In contrast, Petitioner relies on Dr. Pless's testimony that it was standard practice to conduct tests prior to permanent installation of an IPG, and that Rutecki teaches such trial periods for the evaluation of an ETS. Pet. 73–74 (citing Ex. 1002 ¶¶ 200–202). Consistent with this evidence, Petitioner further notes that PO's expert in a prior litigation testified that ITREL external trial stimulators were designed for

use both inside and outside of the operating room. *Id.* at 73 (citing Ex. 1022, 58:16–25, 59:2–7).

On the record before us, we find Petitioner's arguments sufficiently persuasive for the purpose of institution. We, nevertheless, invite the parties to further discuss at trial the construction of claim 12, and the disclosure of Rutecki as understood by one of ordinary skill in the art.

III. CONCLUSION

On the present record, we find Petitioner has made a sufficiently persuasive showing that the cited references would have taught or suggested each element of claims 1–5, 7, 9, and 11–17, and set forth a sufficient rationale for why a person of ordinary skill would have been motivated to combine these teachings and suggestions to arrive at the invention recited in claims 1–5, 7, 9, and 11–17. Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 1–5, 7, 9, and 11–17 would have been obvious over the asserted combinations of Holsheimer, Munshi, Schulman, Wang, and Rutecki.

IV. ORDER

ORDERED, pursuant to 35 U.S.C. § 314(a), that an *inter partes* review of claims 1–5, 7, 9, and 11–17 of the '404 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '404 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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