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Paper 74
Entered: January 19, 2021

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*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64

Entering Stipulated Protective Order and
Denying Motions to Seal Without Prejudice
37 C.F.R. §§ 42.1 and 42.54

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–5, 7, 9, and 11–17 of U.S. Patent No. 7,496,404 B2 ("the '404 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of a claim by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that the challenged claims are unpatentable.

A. Procedural Background

Nevro Corp. ("Petitioner") filed a Petition for *inter partes* review of claims 1–5, 7, 9, and 11–17 of the '404 patent. Paper 1 ("Pet."). Boston Scientific Neuromodulation Corp. ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). In view of the then-available, preliminary record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a) (2018)), and in accordance with *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) and the Office's Guidance on the Impact of SAS on AIA Trial Proceedings (Apr. 24, 2018),[1] we instituted an *inter partes* review of claims 1–5, 7, 9, and 11–17 on all the asserted grounds. Paper 10 ("Inst. Dec."), 47.

[1] https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

After institution, Patent Owner filed a Response. Paper 28 ("PO Resp."). Petitioner filed a Reply. Paper 47 ("Reply"). Patent Owner filed an authorized Sur-reply. Paper 55 ("Sur-reply"). Also with our authorization, Petitioner subsequently filed a Sur-sur-reply. Paper 65 ("Sur-sur-reply").

In Paper 52, and pursuant to 37 C.F.R. § 42.123(b), Patent Owner filed a motion to submit supplemental information consisting of a Declaration of Mr. Carbunaru, which Petitioner opposed (Paper 53). We granted that motion on condition that the Declarant was timely made available for deposition. Paper 57, 4. In light of Patent Owner's Notice that Mr. Carbunaru was made available for a deposition on October 15, 2020, and that Petitioner declined to depose him, we consider our condition satisfied. Paper 62.

Patent Owner also filed a motion to exclude Exhibits 1020, 1023, 1032, 1044, and 1045. Paper 63. Petitioner opposed (Paper 69) and Patent Owner submitted a reply in support of its motion (Paper 72). Also before us are Petitioner's first and second motions to seal. Papers 48, 68.

On November 9, 2020, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 73 ("Tr.").

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 4, 2.

C. Related Proceedings

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, which was consolidated into IPR2017-01812. 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 not unpatentable. Ex. 1008, 152. The Federal Circuit affirmed the unpatentability of claims 8, 18, 22–24, and 27 of the ’280 patent in *Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, No. 19-1582 (Fed. Cir. 2020).

Petitioner separately filed IPR2019-01216 challenging claims 1–10 and 32–38 of the ’690 patent. Paper 8, 3. On July 13, 2020, this panel granted Patent Owner’s request for adverse judgment and cancelled all challenged claims. IPR2019-01216, Paper 23.

The ’404, ’280, and ’690 patents are, or have been, at issue in *Boston Scientific Corp. et al. v. Nevro Corp.*, Civil Action No. 1:18-cv-00644 (D. Del.). *See* Paper 8, 3.

D. 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)[2]	Holsheimer,[3] Munshi,[4] Schulman,[5] Wang[6]
2	7, 9, 13–17	103(a)	Holsheimer, Munshi, Schulman
3	11, 12	103(a)	Holsheimer, Munshi, Schulman, Rutecki[7]

In support of its patentability challenges, Petitioner relies on, *inter alia*, the Declarations of Mr. Ben Pless. Exs. 1003, 1041. Patent Owner relies, *inter alia*, on the Declaration of Darrin Young, Ph.D. (Ex. 2021).

E. 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

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[2] 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.

[3] U.S. Patent No. 5,501,703, issued Mar. 26, 1996. Ex. 1004.

[4] U.S. Patent No. 5,411,537, issued May 2, 1995. Ex. 1005.

[5] U.S. Patent No. 4,197,850, issued Apr. 15, 1980. Ex. 1006.

[6] U.S. Patent No. 5,702,431, issued Dec. 30, 1997. Ex. 1007.

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

"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.

Figure 1 of the '404 patent is reproduced below:

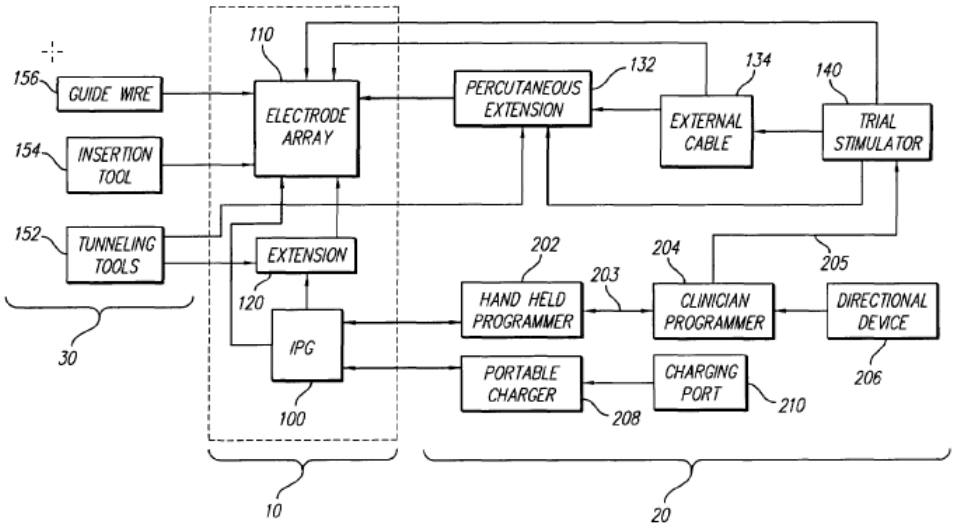


FIG. 1

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:

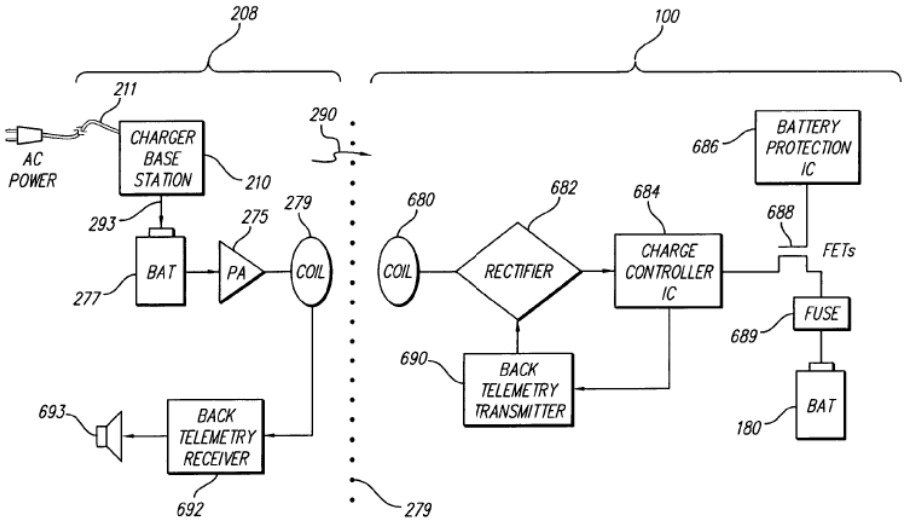


FIG. 9A

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:

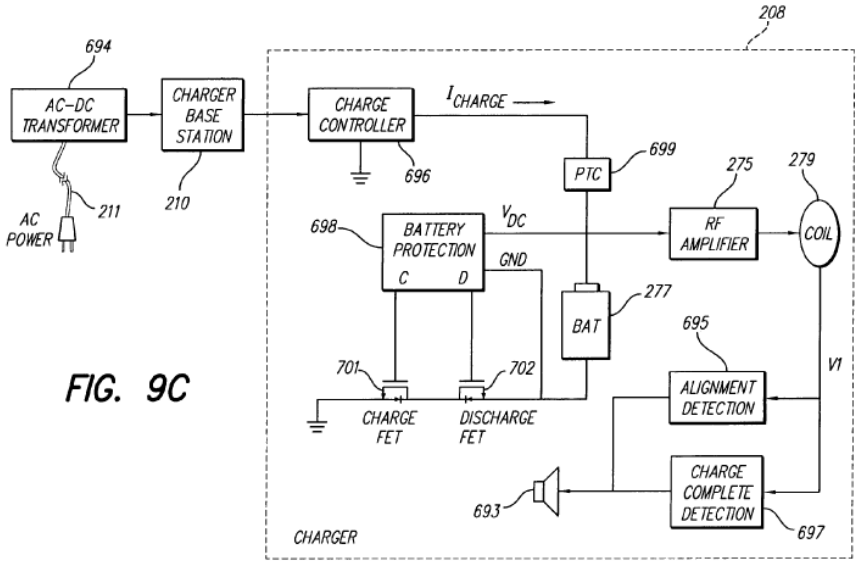


FIG. 9C

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. Ex. 1001, 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.[8] *Id.* at 298–299. The Examiner similarly rejected then-pending claim 8 (now claim 5) as obvious over the same 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.* at 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,*

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

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 applies that definition in this proceeding. PO Resp. 6.

Because the proposed definition is neither disputed, nor 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 the challenged claims "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)." *See* 37 C.F.R. § 42.100(b) (2019). Under that standard, we presume that a claim term carries its "ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention. *In re*

Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)); *see also 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))).

In our Institution Decision we provided the construction of "*means for using household AC*," "*means for non-invasively recharging the replenishable power source through the skin*," and "back telemetry receiver." Inst. Dec. 16–18. As the parties have not further argued these terms, we apply these constructions here for clarity and consistency.

We address below the construction of contested terms (1) "*power-up sequence*" and "*power on reset*," (2) "*powered-down IPG*," and (3) "*external trial stimulator*."

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

Patent Owner argues that the terms "power-up sequence," recited in claim 1, and "power-on-reset," recited claims 7 and 17, mean the same thing. Tr. 28:18–29:13, 41:8–43:2. In its Preliminary Response, Patent Owner argued that these terms "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. For the reasons set forth in our Institution

Decision, we did not find Patent Owner's argument persuasive, and provisionally construed "power-up sequence" and "power-on-reset" as "a process for restoring power to a device." *See* Inst. Dec. 19–20.

Patent Owner now argues that "the plain and ordinary meaning of 'power-reset' and 'reset' require restoring the device to a prescribed configuration after power has been restored," and seeks to interpret the claims in light of these definitions. PO Resp. 11–12 (citing Ex. 2021 ¶ 49; Ex. 2018, 807; Ex. 2019, 384; Ex. 2020, 642–643). Accordingly, Patent Owner argues that the disputed terms of the '404 patent "require more than simply restoring power to the IPG and resuming stimulation." PO Resp. 12 (citing Ex. 2021 ¶ 50); *see* Tr. 29:20–30:4. Rather, Patent Owner argues that we should construe "power-up sequence" and "power-on-reset" to require an initialization event, comprising "two or more steps to start or re-start the device such that it will be configured to safely and effectively function for its intended purpose." PO Resp. 11–12, 13 (citing Ex. 2021 ¶ 51).

As support, Patent Owner points to a "representative power-up reset sequence" in the '404 patent Specification. PO Resp. 10 (citing Ex. 2021 ¶ 48). According to this representative embodiment:

> when the analog IC receives the battery voltage, the analog IC asserts the HEXTRESET line and starts generation of the supply voltage VDD. (EX1001, 24:11-12, 24:19-23; EX2016, 67:15-68:20, 72:18-73:2.) After the VBAT rises above 3.0V and VDD is 2.7V, all registers affected by the HEXTRESET signal are reset. (EX1001, 24:24-29; EX2016, 73:3-74:11.) When the battery voltage rises above 3.0V, the battery monitor circuit releases the HEXTRESET signal, and the processor initiates a reset routine, in which data is read from an external memory circuit. (EX1001, 24:29-40; EX2016, 74:12-77:24.) In response to the data, the processor starts a system application code, and initializes all the registers in the integrated circuit to a safe state. (EX1001, 24:40-44; EX2016, 78:1-15.) The

> processor then verifies the system resources and sets the integrated circuit to default conditions. The hardware resources are also reset to normal operating conditions. (EX1001, 24:44-50; EX2016, 78:16-79:14.) Finally, the processor executes the commands in the main idle and diagnostic loops. (EX1001, 24:51-52; EX2016, 79:15-20.)

PO Resp. 10–11. Referencing the Intel 8086 microprocessor recited at column 20, lines 62–67 of the Specification, Patent Owner further states:

> "The 8086/8088 RESET provides an orderly way to start or restart an executing system." (EX2012, 52; EX2016, 60:14-61:3.) When the processor detects the RESET signal, "it terminates all activities until the signal goes low, at which time it initializes the system" which entails clearing flags, setting the code segment register to FFFFH, and setting the DS, SS, and ES registers to 0000H. (EX2012, 52; EX2016, 53:2-11; 55:20-56:13; 56:23-57:23; 62:8-14.)

Id. at 11; *see also* Tr. 33:22–34:11 (confirming that Patent Owner's proposed construction does not require "that the exact steps must be performed as recited in the Specification").

As an initial matter, we agree with Patent Owner insofar as the plain language of the disputed terms, specifically the words "reset" and "sequence," suggest that they require something more than the single step of restoring power to the IPG. As discussed below, however, we do not agree with the totality of Patent Owner's proposed construction.

Petitioner reasonably contends that, in considering "power-up sequence" and "power-on-reset" as equivalent, Patent Owner "improperly injects a 'reset' requirement into 'power-up sequence,'" and "a 'sequence' requirement into 'power-on reset.'" Reply 2–4, n.2 (citations omitted); Tr. 9:11–14. With respect to the latter, we agree with Petitioner that "power-on reset" does not require a sequence, i.e., two or more steps carried out in a

fixed order. Reply 11–12 (citing *e.g.*, Ex. 1042, 134:25–135:5; Ex. 1041 ¶ 10; Ex. 2018, 807, Ex. 2019, 384, Ex. 2020, 642). As such, Patent Owner's proposed construction is overly restrictive with respect to "power-on-reset." Moreover, because "power-up sequence" *expressly* invokes a sequence limitation, further construction is not necessary.

Whereas Petitioner's arguments with respect to improperly importing a reset requirement into "power-up sequence" would also appear to have merit, this distinction does not appear to affect our obviousness analysis and we need not consider it further. Indeed, Petitioner appeared to concede this point at oral argument. *See* Tr. 9:18–23 ("In terms of defining them similarly, and the way that the prior art applies to them, it doesn't, but the fact there is some differences between the two, I don't think that it matters.").

We do, however, take issue with Patent Owner's inclusion of "safe[] and effective[]" language in its proposed construction, as this language appears to imply conformance with FDA regulatory standards—a construction nowhere supported in the intrinsic evidence. *See* Tr. 36:4–38:22. As we understand Patent Owner's counsel, however, the proposed language is intended to indicate that a "power-up sequence" or "power-on-reset" configures an IPG such that it does not apply electrical stimulation "in a way that is going to cause pain or could result in a potentially dangerous situation. . . . [And] that's what a person of ordinary skill in the art would understand to be the reason that you're doing this." Tr. 31:5–32:17, 36:17–24. In accord with this explanation, we understand Patent Owner's reference to "safe and effective" to mean that the device is configured to provide the intended stimulation.

Considering the record as a whole, we agree with Patent Owner that the contested terms require something "more than simply restoring power to the IPG and resuming stimulation." *See* PO Resp. 12 (citing Ex. 2021 ¶ 50). In accord with the above, we construe "power-up sequence" and "power-on-reset" to mean "two or more steps to start or re-start the device such that the IPG may provide the intended stimulation."

2) *"powered-down IPG"*

Independent claim 1 specifies that "alternating current in the secondary coil initiates a power-up sequence for a powered-down IPG and recharges the replenishable power source." With respect to the claim term "powered-down IPG," Patent Owner focuses on *the process* by which an IPG reaches a powered-down state, contending that we should construe "powered-down IPG" in this claim phrase to mean an "IPG that is placed into a shutdown state by performing shutdown procedures prior to power supply failure." PO Resp. 13, 15 (citing Ex. 2021 ¶¶ 52, 56). Patent Owner contrasts this definition with "merely disconnecting the stimulation circuits and allowing battery voltage to drop to 0V." *Id.* at 13. In support, Patent Owner points to the Figure 4E and accompanying portions of the Specification, which describe a detailed procedure "involv[ing] multiple intermediate steps for shutting down the IPG in a controlled manner" that "avoids data loss." *Id.* at 13–15 (citing Ex. 2021 ¶¶ 53–55, Ex. 1001, 24:53–56, 24:65–25:17; Ex. 2016, 23:14–24:20, 25:7–26:18, 37:22–39:4).[9]

[9] Although Patent Owner cites Mr. Pless's testimony as support for its construction, we agree with Petitioner that Mr. Pless was testifying about an embodiment in the Specification, and not to the meaning one of ordinary skill in the art would ascribe to any claim term. *See* Reply 8 n.8.

Petitioner, in contrast, seeks to apply the plain and ordinary meaning of "powered-down IPG" and argues that Patent Owner's proposed definition improperly imports limitations from an embodiment in the Specification. *See* Reply 7–8. As noted in Petitioner's Reply, Patent Owner does not argue that the relied-upon statements in the Specification are definitional or constitute a disclaimer. *Id.* at 8. "Moreover," Petitioner notes,

> claim 17, which is directed to a "method for controlling shutdown" of an IPG, merely requires "issuing commands to stop all stimulation pulses" and "electrically disconnecting the rechargeable power source from the at least one IC" to "shutdown" the IPG. Ex.1001, 52:66-67, 53:6-11. There is thus no basis for limiting "powered-down IPG" [of claim 1] to the specific embodiments in the specification. Ex.1041¶¶14, 25.

Id.

We find Petitioner's arguments persuasive. 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 this term proposed by Patent Owner. *See Phillips*, 415 F.3d at 1323 ("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"). We disagree with Patent Owner's interpretation of "powered-down IPG" as invoking a product by process limitation. Neither the plain language of claim 1, nor the Specification as a whole, requires that a powered-down IPG reach that state by a particular process. Accordingly, we apply the plain and ordinary meaning of a "powered-down IPG" to mean an IPG that is in a shut-down state.

3) *"external trial stimulator"*

The District Court in *Boston Scientific Corp. v. Nevro Corp.*, Case No. 1:16-cv-1163 (D. Del.) construed "external trial stimulator" to mean 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 this same definition in IPR2017-01812, and we adopted it in the Institution Decision for this proceeding. Ex. 1008, 21–22; Inst. Dec. 16. Neither party objects to this definition and we apply it here. *See* Pet. 13–14; PO Resp. 7–8.

D. Overview of Asserted References

1) *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:

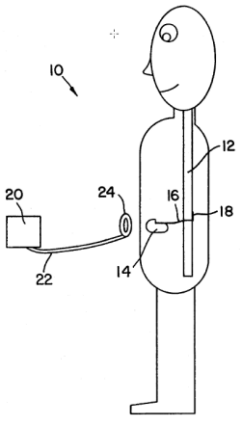


FIG. 1

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) *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:

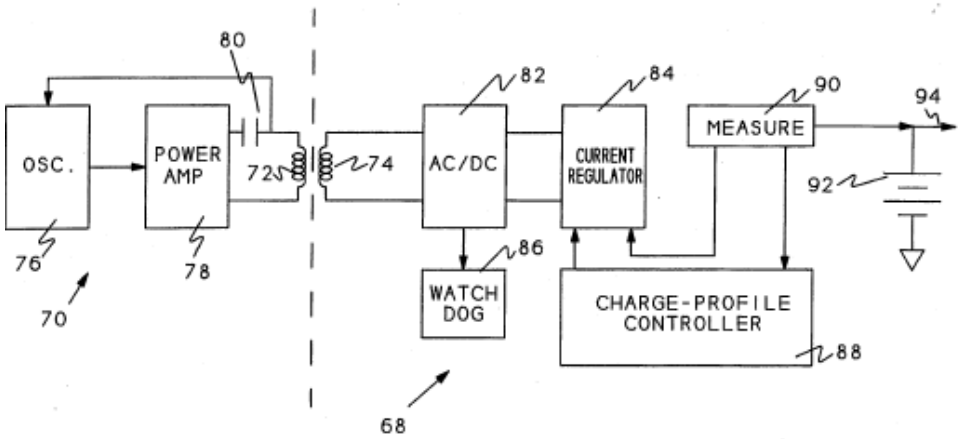


FIG. 2

Figure 2 depicts a block diagram of rechargeable power supply 68 and external charger 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 that power to its external charger

> may be supplied . . . from any suitable source, such as an AC source or a DC source or battery pack. 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. . . . [C]urrent 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) *Schulman (Ex. 1006)*

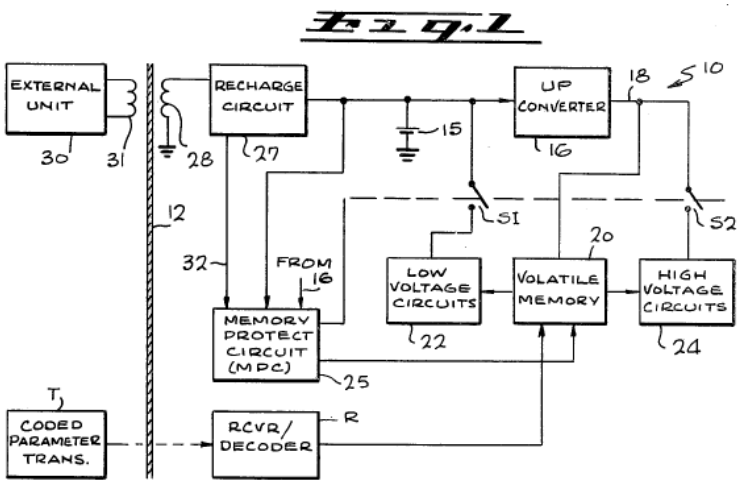
Schulman discloses an implantable human tissue stimulator ("HTS") having a volatile memory and a circuit to prevent "stimulating circuitry producing pulses as a function of unknown parameters in the memory, as a result of inadequate power to the memory from a rechargeable power source, e.g. a rechargeable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

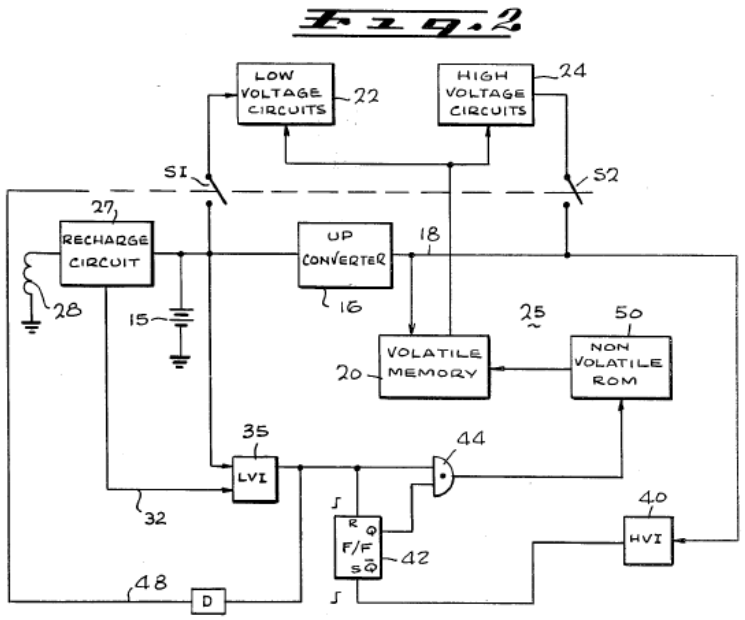
Id.

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's Figure 1 is reproduced below:



Schulman's 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:



Schulman'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) *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, code (57) (Abstract). 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.

FIG. 2

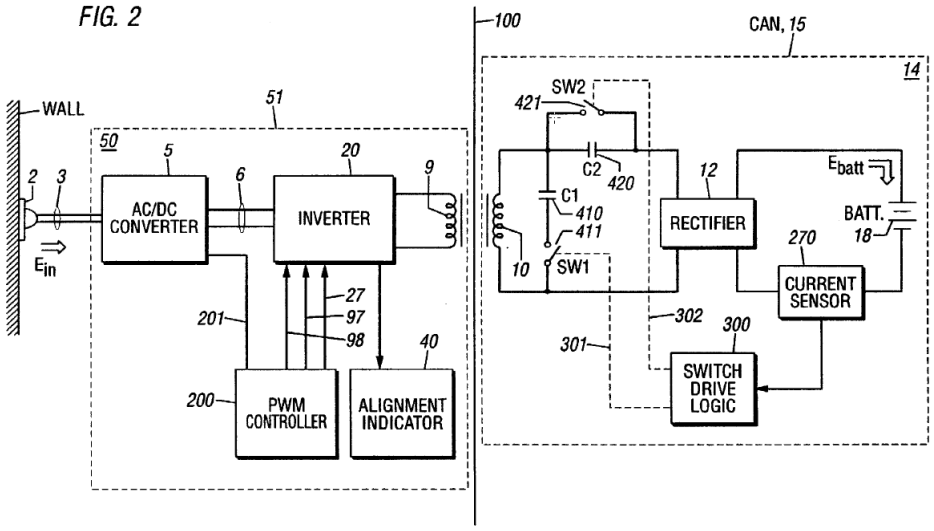


Figure 2 shows transcutaneous energy transmission device (TET) 50 containing alignment indicator 40 in communication with implanted device 14 via primary and secondary coils 9 and 10, respectively, across patient's skin 100. *See, generally, id.* at 7:13–23.

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

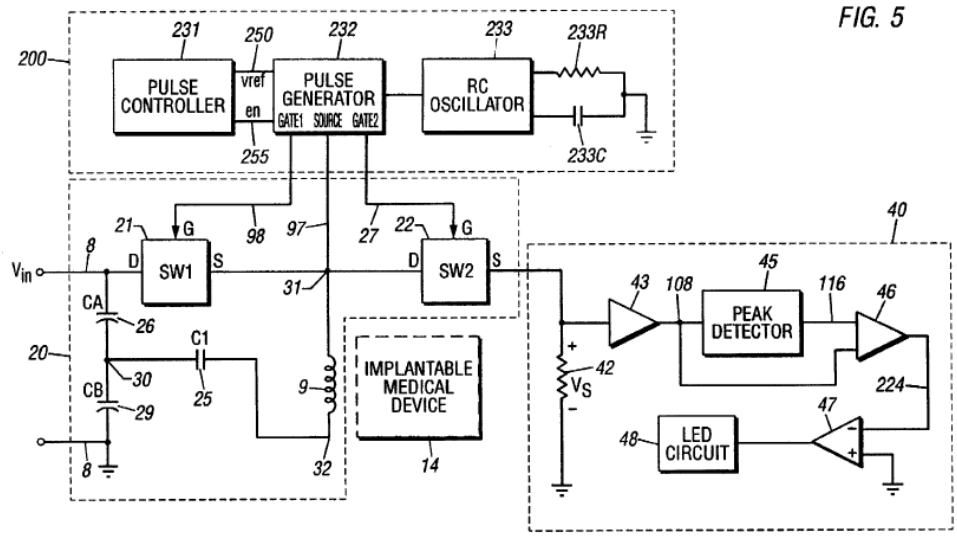


Figure 5 depicts a schematic block diagram of an alignment indicator for a transcutaneous energy transmission device, wherein "[a]lignment indicator 40 provides a light emitting diode (LED) in LED circuit 48 or other output device to indicate proper positioning . . . with respect to implanted device 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) *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.

E. Obviousness of claims 1–5 over the Combined Teachings of Holsheimer, Munshi, Schulman, and Wang (Ground 1)

As to 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 these references to each element of

claim 1. *Id.* at 21–53. At pages 29–44 of our Institution Decision, we review Petitioner's support for each element of independent claim 1, from which claims 2–5 depend. Patent Owner does not address claims 2–5 independently. PO Resp. 32. We find that Petitioner has demonstrated that the cited references teach or suggest each of the undisputed limitations. We address below only the presently disputed limitations of claim 1, motivation to combine, and Patent Owner's evidence of secondary considerations.

1) *"power-up sequence"*

Under Ground 1, Petitioner relies on Munshi and Schulman as disclosing or rendering obvious the language of claim 1: "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." Pet. 34–37. Petitioner contends, in part, that

> Although Munshi expressly discloses "inducing a corresponding alternating current in the secondary coil," it does not expressly disclose that doing so "initiates a power-up sequence for a powered-down IPG." This limitation, however, would have been obvious to a POSA in view of Schulman. Ex.1003¶114.

Id. at 35–36. Petitioner explains that 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.*

Applying its proposed construction, Patent Owner argues that Schulman fails to disclose or suggest "initiat[ing] a power up sequence." PO Resp. 23. According to Patent Owner, Schulman discloses, at best, "a *single* step of loading the memory with preselected safe parameters," whereas, "the 'power-up sequence' claimed in the '404 patent is more complex than the simple step of loading the memory with preselected parameters." PO Resp. 23 (citing Ex. 1006, 7:20–26, 7:34–41; Ex. 2021 ¶¶ 78, 80). Patent Owner argues that "Schulman does not," for example, "disclose asserting any reset signal, resetting registers to a safe state, starting a system application code, verifying system resources, setting the integrated circuits to default conditions, or resetting hardware resources to normal operating conditions." *Id.* (citing Ex. 2021 ¶¶ 78, 80).

We do not find Patent Owner's arguments persuasive for the reasons set forth on pages 4–7 of the Reply, which we adopt. In short, in applying our construction of "power-up sequence" as requiring "two or more steps to start or re-start the device such that it will be configured to safely and effectively function for its intended purpose," we agree with Petitioner that Schulman teaches "numerous steps before resuming stimulation" and provides no suggestion that the resumed stimulation is not as intended.[10] No further complexity is required. We highlight several representative steps in the following passage from Schulman:

> **As the battery is being recharged** and its voltage starts to rise from 0 v the output of the up converter 16 also rises . . . to be the minimum voltage needed to power the memory. At this point in time **the output of the HVI 40 goes high**. **The low to**

[10] Our conclusion does not depend on whether we apply Patent Owner's proposed construction or the similar construction set forth in section II.C.1, above.

> **high transition of the output of HVI 40 is assumed to set FF [flip flop] 42, and therefore its Q output goes high.** However, since at this point in time the LVI output is low, And gate 44 is not enabled, and therefore its output remains low. . . . . At time t_{10} the battery voltage is assumed to reach 1.1 v. . . . **Since at this point in time the Q output of FF 42 is high, both inputs to And gate 44 are high. Therefore, the gate's output goes high.** The low to high transition of the output of And gate 44 may be used in different ways to load the memory 20 with preselected parameters. These parameters are chosen so that when subsequently the various circuits are re-enabled the parameters in the memory are of such values so that the pulse generator produces only safe stimulating pulses for the patient. . . . Another way that **the low to high transition of the output of And gate 44 may be used is to activate a non-volatile ROM 50** which stores preselected safe parameters. **When ROM 50 is activated the safe parameters, stored therein, are loaded into memory 20**. . . . [D]elay D in line 48 provides sufficient delay to insure that **switches S1 and S2 are closed only after memory 20 is reset with safe parameters.**

Ex. 1006, 6:60–7:55 (bolding added).

In light of the above language in Schulman, we are persuaded that Petitioner, relying on the testimony of Mr. Pless, has sufficiently established that Schulman discloses at least the following steps as the IPG's battery recharges and before stimulation resumes: "(1) set FF 42, (2) LVI output goes high, so output of gate 44 goes high, (3) activate ROM 50, (4) reset memory 20 with preselected safe parameters from ROM 50, (5) connect stimulation circuitry, and (6) enable circuitry." Reply 5–7 (citing Ex. 1041 ¶¶ 16–21, 23; Ex. 1042, 138:7–18, 150:20–152:13); Ex. 1042, 155:16–156:5 (Mr. Pless testifying that in one embodiment, setting FF 42 is a prerequisite to activating ROM 50).

Patent Owner responds that the above evidence is not a series of discrete steps but "a description of the underlying logic of the memory

protection circuit." Sur-reply 6–8. We are not convinced that Patent Owner's premise is correct because, at a minimum, charging the battery, activating ROM 50, and resetting memory 20 with safe parameters, would seem to involve multiple distinct locations and, thus, discrete steps, in the device. Nevertheless, to the extent Patent Owner is correct that all of steps identified by the Petitioner are contained within a single memory protection circuit, neither the express language of the challenged claims, nor any of the constructions raised in the course of these proceedings, require that different steps are performed by different circuits and/or in discrete physical locations. In sum, the distinct steps identified by Petitioner comprise "more than simply restoring power to the IPG and resuming stimulation," and satisfy our construction of a "power-up sequence." *See* PO Resp. 12; section II.C.1, above.

2) *"powered-down IPG"*

As noted above, Petitioner contends that Munshi does not expressly disclose inducing an alternating current in the second coil to "initiate[] a power-up sequence for a powered-down IPG," but that 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 then points to Schulman's disclosure of reconnecting the battery and enabling the stimulating circuitry after the battery level rises to a sufficiently high level as "initiat[ing] a power-up sequence for a powered-down IPG." *Id.* at 37; Reply 18–19.

Patent Owner responds that Schulman does not disclose a "a powered-down IPG" because "disconnecting stimulating circuits from the battery when the battery falls below a certain level" as disclosed in Schulman "is not a controlled shutdown procedure," and does not entail steps, "such as making copies of the working registers or current stimulation parameters, as in the '404 patent, to prevent data loss when the battery is completely discharged." Sur-reply 10. We do not find Patent Owner's argument persuasive in light of our construction of "a powered-down IPG" as meaning that the IPR is in a shut-down state. Claim 1 does not require the performance of any particular steps to achieve this state and we find no evidence that one of ordinary skill in the art would impute the steps suggested by Patent Owner into the claim term, or require that the IPG employs any particular method of data loss protection. Accordingly, the "powered-down IPG" limitation is satisfied by Schulman's disclosure that under certain conditions, the stimulating circuits are disconnected from the battery.

Further, were we to credit Patent Owner's implication that a "powered down IPG" must be protected from data loss, Schulman's disclosure that "[w]hen ROM 50 is activated . . . safe parameters, stored therein, are loaded into memory 20 . . . [and] memory 20 is reset with safe parameters," indicates that Schulman's powered-down IPG *is* so protected. We likewise credit Dr. Pless's undisputed testimony that

> although Schulman does not expressly state that the memory is ever disconnected from the battery due to the battery's low voltage, a POSA would have been motivated and found it obvious to disconnect Schulman's memory from the battery once the battery voltage fell to a level at which the parameters stored therein can no longer be trusted to avoid unnecessarily further draining the battery. Ex. 1003 ¶¶ 151–153. Accordingly,

> Schulman at least renders obvious the steps of (1) disconnecting stimulation circuitry, and (2) further disconnecting the memory at a lower battery threshold, when powering down the IPG.

Ex. 1041 ¶ 28; *see* Reply 28; Pet. 55–58.

Considering the totality of the record, and for the reasons set forth above, Schulman teaches or suggests "a powered-down IPG."

3) *"external power source contained in the charger"*

Claim 1 recites an "an external power source charger including . . . an external power source contained in the charger." Noting that in IPR2017-01812, the Board found that Munshi discloses this element, Petitioner further relies on Mr. Pless's testimony that Munshi, at a minimum, renders the element obvious. Pet. 31 (citing Ex. 1008, 88; Ex. 1003 ¶ 110); Ex. 1041 ¶¶ 29–32. Addressing the benefits of a charger having an integrated rechargeable battery, Mr. Pless states:

> Although Munshi does not specify whether the "rechargeable external battery pack" is "contained" within its external charger 70, it would have been obvious to include the rechargeable battery within the external charger 70. Munshi's stated motivation for using a rechargeable external battery pack is to "allow portability of the external unit." Ex.1005, 10:45-47. Including the rechargeable battery inside of the external unit would further improve its portability because it would require the patient to carry only one device rather than two separate components.

Ex. 1003 ¶ 110.

Patent Owner responds that Munshi fails to disclose or render obvious this element. PO Resp. 25–26; Sur-reply 11–12. According to Patent Owner, Munshi's reference to "[a] rechargeable **external** battery pack with its own charging system," indicates that the battery pack is not contained within the external charger and, in fact, teaches away from its integration. PO Resp.

25–26 (citing Ex. 1005 10:45–51; Ex. 2021 ¶¶ 87–88). But Munshi's statement does not specify whether "external" indicates that the battery pack is external to external charger 70 or external to the patient's body. In context, we think the latter more likely. In any event, to the extent one of ordinary skill in the art would have understood the relied-on passage to indicate a rechargeable external battery pack separate from its charging system, Munshi in no way criticizes, discredits, or otherwise discourages an integrated format. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006). ("We will not read into a reference a teaching away . . . where no such language exists."). To the contrary, the choice between the separate versus integrated designs at issue here would appear to encompass the universe of "identified, predictable solutions," known to one of ordinary skill in the art for design of an external power source and charger combination. *See KSR*, 550 U.S. 398 at 421.

Relying on Dr. Young's cross-examination testimony, Patent Owner further appears to argue that the claimed element is not obvious because there are tradeoffs involved between an external charger having an integrated battery and one comprising two separate devices. Sur-reply 11–12 (citing Ex. 1042, 161:19–163:3, 168:3–9); *see also* Ex. 1042 163:11–17, 167:23–168:9 (Dr. Young agreeing that "a trade-off . . . means that using a single device has certain advantages over carrying two devices, but that carrying a single device may also have some disadvantages compared to carrying two devices" i.e., the flexibility of being able to use different types of rechargeable batteries).

We find Petitioner has the better argument. To the extent Munshi may not expressly disclose an external power source contained in the charger as

set forth in claim 1, the benefits of doing so include convenience and enhanced portability in managing one device instead of two. Although this may limit the flexibility of the device in terms of being able to use different types of rechargeable batteries, such a tradeoff does not negate the obviousness of the claimed subject matter. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine"); *see also Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of [a] reference . . . . Instead, the benefits, both lost and gained, should be weighed against one another.").

In view of the above, Petitioner has established that Munshi, at a minimum, renders obvious the "external power source contained in the charger" recited in claim 1.

4) *Motivation to combine*

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). Moreover, a finding of obviousness does not require 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.

On pages 18–20 of the Petition, Petitioner presents arguments for why a person of ordinary skill in the art would have been motivated to combine the cited references. 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 presents three challenges to Petitioner's arguments that one of ordinary skill in the art would have been motivated to combine Holsheimer in view of Munshi, Schulman, and Wang, which we address below. PO Resp. 26–32; Sur-reply 15–20.

a. *Modifying Holsheimer to Include Munshi's Rechargeable Battery*

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 the service life of the IPG and avoid the trauma and expense of surgeries to replace the battery. Pet. 18–19, 24–25 (citing e.g., Ex. 1003 ¶¶ 78–82). Patent Owner does not dispute the recited benefits but argues that the preferred motivation "is premised on the faulty assumptions that Holsheimer is actually reduced to practice and that Holsheimer is a battery operated device." PO Resp. 27.

According to Patent Owner, absent "evidence that the Holsheimer device was ever actually reduced-to practice, commercialized, or implanted

in a patient . . . Petitioner's argument that a POSITA would have wanted to avoid further surgeries to replace the battery in an implanted device is inapplicable." *Id.* at 28 (citations omitted); *see* Sur-reply 15–16. It is, nevertheless, undisputed that one of ordinary skill in the art would have understood that Holsheimer's intent was to implement its disclosed stimulation technique into an implantable SCS system. *See* Reply 15–16 (citing Ex. 1042, 174:10–16; Ex. 1041 ¶ 36; Ex. 1004, 1:41–47, 2:33–43, 3:53–59, Fig. 1). And because we are unaware of any case law forbidding the application of prior art that has not been physically reduced to practice, we do not find Patent Owner's argument availing.

Patent Owner further argues that "Petitioner's expert failed to identify the disclosure of a battery in Holsheimer" and posits that "power for Holshimer's IPG could have been supplied through a commercially available power supply box." PO Resp. 28 (citing Ex. 1003 ¶¶ 36, 78; Ex. 2021 ¶¶ 93–95). Pointing to the specific voltages used in Holshiemer's studies and the 4.2 volts disclosed in Munshi, Patent Owner argues that "Munshi's rechargeable battery alone would not provide sufficient power to set Holshimer's voltage source at 4.52 volts." *Id.* at 28–29 (citations omitted); Sur-reply 15–16 (citations omitted). Patent Owner concludes that a person of ordinary skill in the art would not have been motivated to adjust the voltage to 4.52 volts by connecting two of Munshi's batteries in a series or using additional circuitry "because the additional battery or circuitry would add components that increase the size and complexity of the IPG." Sur-reply 16 (citing Ex. 1001, 2:31–42; Ex. 2053, 158:24–160); *see also id.* at 17 (citing Ex. 1005, 8:12–14, for the proposition that Munshi teaches away from connecting batteries in series).

In considering obviousness, "it is not necessary that the inventions of the references be physically combinable." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). Moreover, Patent Owner fails to adequately support its conclusion as to the understanding of one of ordinary skill in the art. Patent Owner's reference to column 2, lines 31–42, of the '404 Specification merely indicates a desire for "more stimulating features in a smaller package," whereas, its reference to Mr. Pless's cross-examination testimony reduces to: if you add a second battery or increase the size of a battery having the same chemistry, it will make the system bigger and heavier. *See*, Ex. 2053, 159:15–160:4. But nowhere does Patent Owner address the magnitude of the increased size or complexity under its hypothetical, or whether the alleged increased size or complexity would have dissuaded the ordinarily skilled artisan. Accordingly, Patent Owner's argument reduces to unsupported attorney argument that we do not find persuasive.

Patent Owner also quotes, as evidence of teaching away, Munshi's statement that "[in] many cases, a single cell is all that is required. This will also eliminate the problems associated with a series string of cells." Sur-reply 16–17 (quoting Ex. 1005, 8:12–14). We, however, read the cited passage to indicate that although there are benefits to using a single cell, in some cases multiple cells are required. Thus, rather than teach away, Munshi supports Petitioner's argument that one of ordinary skill would have been motivated to combine the cited references because it presents single cells and multiple cells as viable alternatives.

Because ample evidence supports the motivation and reasonable expectation of success to modify Holsheimer's IPG with a rechargeable battery as taught by Munshi, we need not consider Patent Owner's argument that the combination fails because Holsheimer is a not a battery operated

device. *See* PO Resp. 27; Reply 17 (responding that "Holsheimer explains that its "preferred system employs *fully implanted elements*" . . . [and] "its IPG is 'preferably' an 'ITREL IIR implantable pulse generator available from Medtronic, Inc.'" (citing Ex. 1004, 3:60–65, 4:2–5)).

b. *Combining Munshi with Schulman to create a "powered-up sequence for a powered-down IPG"*

As noted by Petitioner, Munshi teaches that 'the battery should not be completely discharged in a pacemaker type apparatus,'" whereas,

> Schulman teaches a technique for avoiding complete battery discharge and preserving safe functionality in low-voltage scenarios. Schulman teaches doing so via a rechargeable battery with voltage protection circuitry coupled to a "battery charging circuit . . . whose function is to recharge the battery when recharging energy is received . . . ."

Pet. 19 (citing Ex. 1005, 9:7–12; Ex. 1006, Abstract, 4:13-17). "Accordingly," Petitioner asserts, "when used in situations where the battery may be completely (or nearly completely) discharged, a POSA would have been motivated to combine the rechargeable battery of Munshi with the protection circuitry of Schulman." *Id.* (citing Ex. 1003 ¶ 80); *see also id.* at 35–37.

Patent Owner responds that because "Schulman discloses memory protection circuitry—not battery protection circuitry," "a POSITA seeking to prevent Munshi's battery from completely discharging would not find a solution in Schulman and, therefore would not be motivated to modify Munshi (or Holsheimer) with Schulman." PO Resp. 29. We do not find Patent Owner's argument persuasive and, in Petitioner's words, it "misses the point." Reply 18. In particular, "[e]ven though, like all batteries, the IPG's battery may eventually completely discharge, a POSA would have understood that it would have been advantageous to delay that occurrence

by, *e.g.*, prolonging the battery's life until the next time it is recharged." *Id.* (citing Ex. 1042, 81:17–82:3). "And, as PO's expert admitted, Schulman's technique 'prolong[s] the life of the IPG's battery.'" *Id.* at 19 (citing Ex. 1042, 143:23–144:18). Further with respect to Patent Owner's argument that "Munshi already provided a sufficient solution to guard against a completely discharged battery," we credit Petitioner's argument that that one of ordinary skill in the art would have been motivated to include Schulman's technique because it does not depend on a user response like Munshi's audible alert. PO Resp. 30; Reply 19 (citations omitted).

Patent Owner further argues that one of ordinary skill in the art would not have been motivated to modify Munshi because it is directed to a cardiac pacemaker and "disconnecting the stimulating circuitry in a pacemaker would be extremely dangerous, if not fatal, for the patient." PO Resp. 30 (citing Ex. 2021 ¶ 98). We do not find Patent Owner's position persuasive.

As an initial matter, we note that a person of ordinary skill is not an automaton compelled to blindly follow the teaching of a prior art reference absent the exercise of independent judgment (*see Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984)), but "a person of ordinary creativity" (KSR, 550 U.S. 398 at 421). Moreover, the overwhelming thrust of Ground 1 involves the modification of Holsheimer's IPG, and not Munshi's cardiac pacemaker. *See e.g.*, Pet. 19 ("[A] POSA would have been motivated to include Munshi's rechargeable power source in Holsheimer's IPG"); *id* at 20 (referencing "Holsheimer (as modified by Munshi)").

Nevertheless, as even Patent Owner appears to recognize, "Munshi is not limited to a cardiac pacemaker and applies to other bioimplantable battery-powered devices." PO Resp. 30. In particular, Munshi relates to

cardiac pacemakers and "any other bioimplantable battery-powered device incorporating . . . [a] rechargeable power source" that is recharged through the patient's skin by electromagnetic induction which, we understand from Munshi, encompass "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]").

c. *Adding Wang's alignment circuitry to Munshi's external charger*

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* Ex. 1003 ¶ 81.

Patent Owner contends, however, that Munshi already disclosed a solution to maximize charging efficiency such that one of ordinary skill in the art "would have had no reason to add Wang's alignment detection circuity to accomplish the same function." PO Resp. 31–32 (citing Ex. 1005, 12:63–13:5; Ex. 2021 ¶¶ 100–101). Petitioner reasonably responds that Munshi "does not provide any details regarding, *e.g.*, what circuitry to use or how such power is measured" and, accordingly, one of ordinary skill in the

art would have "looked to Wang, which provides those details." Reply 20 (citing Ex. 1018, 5:15–17; Pet. 42–44; Ex. 1041 ¶¶ 44–46).

We also find persuasive the determination of our sister panel in IPR2017-01812 that one of ordinary skill in the art

> would have found it obvious to use Wang's alignment circuitry in the external charger of the Holsheimer and Munshi combination, to indicate proper alignment of the inductive coils and to maximize charging efficiency. Pet. 53–54, 66; Ex. 1003 ¶ 162. This is supported by Munshi's express disclosure that the position of the external coil can be adjusted to "find the optimum position of maximum energy transfer." Ex. 1005, 13:1–5. We also determine that such a combination would have been expected to be successful, due to the similarities of the systems, and because Munshi and Wang are directed to solving the same problem of noninvasively recharging an implanted battery. Pet. 53–54, 66; Ex. 1003 ¶¶ 139–140, 162.

Ex. 1008, 92.

5) *Expert Opinions*

Patent Owner contends that we should accord Mr. Pless's declaration little or no weight because it "merely repeats arguments from the Petition." PO Resp. 61–62; *see* Sur-reply 25–26. Petitioner responds, *inter alia*, that Mr. Pless's testimony "is fully supported by reasoning and analysis and cites to evidence of record." Reply 26–27. Notably, Patent Owner neither challenges Mr. Pless's credentials nor moves to exclude his testimony as lacking support in the record.

While it is often helpful to the Board for an expert declaration to further explicate or support a party's assertions, we find no requirement that they do so. Irrespective of the precise relationship between the declaration and a party's assertions, we consider the clarity of the expert's opinions, the extent to which those opinions are supported in the record, the expert's

experience and qualifications, and the reputation the witness puts on the line with every submission to, and deposition before, this body. In the present case, we do not find either parties' expert wanting. Accordingly, we do not find Patent Owner's argument persuasive.

Patent Owner next alleges that, during cross-examination, Mr. Pless admitted that his obviousness analysis was "guided by the '404 patent and its claims." PO Resp. 63. Patent Owner argues that Mr. Pless's approach of starting with how the patent combines its elements, and then reviewing the prior art "epitomizes an improper motivation-to-combine analysis." *Id.* (citing *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017)).

Petitioner responds that Mr. Pless "fully explains in his declaration the specific reasons a POSA would have been motivated to make the proposed combinations and modifications and cites record evidence to support his opinions." Reply 27. We agree with Petitioner.

Moreover, it is well-established, and indeed, commonsensical that any judgment on obviousness is, in a sense, necessarily a reconstruction based upon hindsight reasoning. *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971). Petitioner, and Mr. Pless, have established a reasonable case, as we have explained in the preceding section, that a person of ordinary skill in the art, understanding the teachings of the cited prior art, would have found it obvious to combine and/or modify the teachings of the prior art to arrive at the claimed invention. Patent Owner does not point to any reliance by Mr. Pless upon information that could have been gleaned only from the disclosures of the '404 patent. *See id.* Accordingly, Patent Owner's allegation that Mr. Pless engaged in impermissible hindsight analysis is

unsupported and does not detract from our consideration of Mr. Pless's testimony.

6) *Objective Indicia of Non-obviousness*

In support of its non-obviousness contentions, Patent Owner contends that its Precision SCS systems embody the challenged claims, and offers evidence of long-felt but unmet need, industry recognition, and commercial success relating to those products.[11] PO Resp. 36–61; Sur-reply 20–25. Our reviewing court has held that such secondary considerations, or objective indicia of nonobviousness, "must be considered in every case where present." *Apple Inc. v. Samsung Elecs. Co. Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc). But "[f]or objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (quotation and emphasis omitted).

"The burden of proof as to this connection or nexus resides with the patentee." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). Nevertheless, when evaluating the import of Patent Owner's secondary considerations evidence on whether the challenged claims would have been obvious, we apply a presumption of nexus between the secondary considerations and the challenged claims "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is

[11] Because we base our analysis on the threshold issue of nexus, we presume, *without deciding*, that Patent Owner has established the factual bases of these assertions.

coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (internal citations omitted). That presumption, however, is rebuttable. *Id.* at 1373 (citing *Demaco Corp. v. F. Von Langsdorff Licensing Ltd*., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

Particularly relevant to our analysis, nexus fails where commercial success, or other secondary considerations, arise from features of a product that were readily available in the prior art. *See, e.g.*, *Ormco Corp. v. Align Tech., Inc*., 463 F.3d 1299, 1312 (Fed. Cir. 2006) (internal citation omitted) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention. . . . [I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent."); *J.T. Eaton & Co. v. Atl. Paste & Glue Co*., 106 F.3d 1563, 1571 (Fed. Cir. 1997) ("[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.").

Pages 57–61 of the Patent Owner Response detail evidence of long-felt need, industry recognition, and commercial success for Precision SCS systems. But as Petitioner correctly points out, all of the Patent Owner's evidence focuses on the "rechargeable IPG"[12] elements common to the challenged claims. Reply 22; *see e.g.*, PO Resp. 59 ("the introduction of Boston Scientific's rechargeable IPG technology in SCS systems solved the long-felt need for effective pain treatment, convenience, and more effective

[12] More specifically, independent claims 1, 7, and 17 refer to a replenishable/rechargeable power source, further identified as a battery in, e.g., claims 8, 13, and 14. Independent claims 1 and 7 recite a replenishable/rechargeable power source in the context of an SCS system, whereas claim 17 more broadly recites an implantable pulse generator.

power mechanisms"); *id.* (citing Ex. 2008, 4 as touting "unique features" of the Precision SCS including a "Rechargeable battery"); *id.* at 61 ("the commercial success of the Precision Plus provides contemporaneous evidence . . . that the rechargeable battery technology in the Challenged Claims was novel"). Petitioner argues that nexus fails because rechargeable IPGs—the focus of Patent Owner's evidence—"were known in the art, including in SCS systems, before the '404 patent." Reply 22. In support, Petitioner cites testimony taken in IPR2017-01812 from Patent Owner's then-expert, along with the testimony of several named inventors taken in the related district court litigation. *Id.* The proffered testimony evidences admissions from Patent Owner's witness that rechargeable IPGs were known in the art. *Id.* (citing, e.g., Ex. 1032, 221:14–20; Ex. 1023, 277:16–278:16; Ex. 1025, 197:7–14; Ex. 1045, 345:20–346:18; Ex. 1044, 168:4–9); *see also* section II.D.2, and II.D.4, above (Munshi and Wang disclosing IPGs with an implantable rechargeable battery).

With respect to SCS stimulators in particular, Petitioner also points to Barreras[13] as describing implantable stimulators "with a replenishable, high value capacitive power source." Reply 22 (citing Ex. 1043, 1:19–24, 27–35, 7:26–30, 10:1–2, 10:54–57). Barreras teaches that "[p]rior art implantable stimulators utilize nickel-cadmium rechargeable batteries," which rely on electrochemical reactions, whereas the disclosed capacitor's "electrical storage mechanism is a physical phenomena." *Id.* at 10:1–13; *see id.* at 10:65–11:1 ("capacitive power Source 36 is a high value, small size capacitive energy device comprising a single capacitor or a plurality of parallel connected capacitors"). Barreras discusses the use of implantable

[13] Barreras, US 5,807,397, issued Sept. 15, 1998. Ex. 1043.

tissue stimulators for, e.g., treating chronic pain by spinal cord stimulation (Ex. 1043, 1:1–34), and expressly teaches the implantation of "stimulating leads on or near targeted . . . nerves in the spinal cord" (*id.* at 10:38–57). Accordingly, we find that Barreras discloses the use of rechargeable power sources in implantable SCS stimulators.

According to Patent Owner, to the extent the claims are directed to "an *SCS system* including an IPG with a rechargeable battery," the testimony Petitioner relies on above is "irrelevant" because it involves rechargeable pacemakers rather than spinal cord stimulators. Sur-reply 22. Patent Owner further argues that Barreras is irrelevant because it relies on a capacitive power source and "the '404 Patent claims are directed to an IPG containing a rechargeable battery." *Id.*

Upon consideration of all the evidence, we find that Petitioner has the better argument. As of the critical date, it was well known to use rechargeable batteries in IPGs. As discussed above, Barreras teaches a rechargeable capacitive power source as an alternative to rechargeable batteries in IPG's, including SCS systems. Because Barreras discloses a capacitive power source for SCS systems and as an advance over rechargeable batteries, we infer that it was also known to use rechargeable batteries in SCS systems. Accordingly, we agree with Petitioner that Patent Owner has failed to establish nexus. To the extent the use of rechargeable batteries in SCS systems was not expressly known, that concept is obvious on this record, and we accord little weight to Patent Owner's evidence of secondary considerations.

Petitioner also argues that in IPR2017-01812 and before the district court, Patent Owner previously asserted that its Precision Plus[14] product "embodies claims of other patents directed to different features not claimed in the '404 [patent], including the '280 patent (multi-channel SCS systems), U.S. 8,682,447 (determining relative position and orientation of electrodes), and U.S. 6,381,496 (changing sets of operational parameters)." Reply 23 (citing Ex. 1008, 54; Ex. 1047, 10). According to Petitioner, "[t]here can be no presumption of nexus here where, as PO has admitted, the claimed invention of the '404 patent is only a component of PO's Precision Plus system." *Id.* (citing *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)).

Patent Owner tacitly concedes that it has asserted that its commercial products embody claims of three patents other than the '408 patent at issue here. *See* Sur-reply 23–24. Relying on *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991), Patent Owner argues that it is not necessary that the patented invention be *solely* responsible for the secondary indicia, where the "industry recognition and commercial success was at least partly attributable to the rechargeable battery feature." *Id*. Patent Owner, however, provides no guidance or suggestion of how credit for secondary indicia should be apportioned between the four referenced patents.

On balance, we find Petitioner's argument persuasive. Assuming, for the sake of argument that nexus is shown, we would accord little weight to

[14] We note that Patent Owner expressly references both the Precision and Precision Plus embodiments before the district court. Ex. 1047, 10.

its evidence of long-felt need, industry recognition, and commercial success, as that must be apportioned between at least four different patents.

Moreover, even were we to apportion Patent Owner's secondary considerations evidence, such evidence does not necessarily control the obviousness conclusion. *See, e.g.*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007). ("Here, the record establishes such a strong case of obviousness that Pfizer's alleged unexpectedly superior results are ultimately insufficient."); *see also Ryko Mfg. Co. v. Nu–Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991) (holding on summary judgment that "secondary considerations did not carry sufficient weight to override a determination of obviousness based on primary considerations"). Even presuming nexus, and considering the strong case of obviousness set forth in the Petition, Patent Owner's alleged secondary considerations would not carry sufficient weight to outweigh the persuasive evidence of obviousness put forth by Petitioner in this case.

7) *Conclusion as to Ground 1*

Considering all the evidence of record, Petitioner has shown by a preponderance of the evidence that claims 1–5 would have been obvious over the combined teachings of Holsheimer, Munshi, Schulman, and Wang.

F. Obviousness of claims 7, 9, 13–17 over the Combined Teachings Holsheimer, Munshi, Schulman (Ground 2)

As to Ground 2, Petitioner challenges claims 7, 9, and 13–17 as obvious over Holsheimer, Munshi, and Schulman. Pet. 53–67. Petitioner's challenge includes a detailed mapping of the teachings of these references to each element of claim 1. *Id.* With respect to elements common to claim 1, motivation to combine, and secondary considerations analyses, we refer to

section II.E, above. Patent Owner does not address claims 9 and 14–16 independently of Ground 1. PO Resp. 34–35. We find that Petitioner has demonstrated that the cited references teach or suggest each of the undisputed limitations. We address below only the presently disputed limitations of independent claims 7 and 17, and Patent Owner's additional argument with respect to motivation to combine.

1) *"initiat[ing] a power-on-reset"*

Claims 7 and 17 require "initiat[ing] a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold." Petitioner relies on Schulman for this limitation. Pet. 59–60, 67 (citing, *e.g.*, Ex. 1006, 3:11–21; 4:62–68, 7:56–8:10; Ex. 1003 ¶¶ 156–158).

Referencing its arguments with respect to sections II.E.1 and II.E.2, above, Patent Owner argues that this limitation is not satisfied because "Petitioner identifies [in Schulman] only a single step of loading the memory with preselected parameters[, whereas], the "power-on reset," requires two or more steps to start or re-start the device such that it will be configured to function safely and effectively for its intended purpose." PO Resp. 33; Sur-reply 12–14. In accord with our construction of power-up sequence, we find Patent Owner's argument unpersuasive for essentially the same reasons as set forth in section II.E.1, above

2) *"the processor initiates a power-on-reset"*

Claim 7 specifies that "the *processor* initiates a power-on-reset if the volt age of the rechargeable power source rises above a reset threshold." In its Sur-reply, Patent Owner argues that Ground 2 fails because "Petitioner relies only on Schulman for this limitation" and Petitioner's expert

"admitted that Schulman does not disclose a processor." Sur-reply 14 (citations omitted).

Petitioner, however, relies on Munshi, not Schulman, as disclosing a processor. *See* Pet. 55 (citing Ex. 1005, 6:9–15 ("it would have been obvious . . . to modify Munshi in light of Schulman such that Munshi's process issues commands to stop all stimulation if the voltage of the rechargeable battery falls below a minimum level for stimulation")). And as further explained by Mr. Pless on cross examination: "So while Schulman doesn't specifically have a microprocessor, it would have been obvious . . . to use microprocessor circuitry to achieve the functionality of Schulman. . . . Where Schulman accomplishes that functionality without a microprocessor, it would have been obvious to a POSA in 1999 to use a microprocessor." Ex. 2053, 172:17–173:5. Accordingly, we do not find Patent Owner's argument persuasive.

3) *Combining Munshi with Schulman*

Claims 7 and 17 require "issu[ing] commands to stop all stimulation if the voltage of the rechargeable power source falls below a minimum level for stimulation." Referencing the arguments in section VIII.A.3.b of the Patent Owner response, Patent Owner contends that one of ordinary skill in the art would not have been motivated to modify Munshi with Schulman because "disconnecting the stimulating circuitry in Munshi's pacemaker would be extremely dangerous, if not fatal, for the patient," and "Munshi already provided an intermittent audio signal to alert the user to recharge the battery before the battery reaches critical levels." PO Resp. 34 (citing Ex. 2021 ¶¶ 105,106. For the reasons set forth in section II.E.4.b, above, we do not find Patent Owner's arguments persuasive.

4) *Claim 9*

Petitioner contends that Petitioner has not satisfied the "an external power source contained in the external power source charger" limitation of claim 9. As set forth in section II.E.3, above, Munshi discloses or renders obvious this limitation.

5) *Conclusion as to Ground 2*

Considering all the evidence of record, Petitioner has shown by a preponderance of the evidence that claims 7, 9, 13–17 would have been obvious over the combined teachings of Holsheimer, Munshi, and Schulman.

G. Obviousness of claims 11 and 12 over the Combined Teachings Holsheimer, Munshi, Schulman, and Rutecki (Ground 3)

As to Ground 3, Petitioner challenges claims 11 and 12 as obvious over Holsheimer, Munshi, Schulman, and Rutecki. Pet. 68–74. With respect to common claim elements, motivation to combine, and secondary considerations analyses, we find that Petitioner has demonstrated that the cited references teach or suggest each of the undisputed limitations and refer to section II.E and II.F, above. Patent Owner does not address claim 11 independently of Grounds 1 and 2. PO Resp. 35.

1) *"external trial stimulator (ETS)"*

Patent Owner contends that Ground 3 fails with respect to claim 12 because "Rutecki's external stimulus generator cannot be used outside the operating room" and, thus, does not satisfy the "external trial stimulator (ETS)" limitation, as that term is construed in section II.C.3, above. PO Resp. 35–36 (citing Ex. 1009, 14:8–18; Ex. 2021 ¶¶ 74, 108–109).

Our sister panel in IPR2017-01812, previously addressed this argument, finding that Rutecki teaches this element. Ex. 1008, 21–22, 133–137. We find this argument persuasive and we adopt it here.

In light of that earlier determination, Petitioner persuasively argues that Patent Owner is collaterally estopped because the Board expressly rejected the same argument in IPR2017-01812 that Patent Owner presents here. Reply 13–14 (citing Ex. 1008, 21–22, 133–137); Tr. 22:1–13. As set forth in the Reply:

> *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) ("Collateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent."); *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (estoppel applies in administrative context). Collateral estoppel applies where, as here, the prior action (i) presents an identical issue, (ii) actually litigated and adjudged the issue, (iii) necessarily required determination of the issue, and (iv) featured full representation of the estopped party. *VirnetX Inc. v. Apple, Inc.*, 909 F.3d 1375, 1377 (Fed. Cir. 2018). Collateral estoppel is not limited to identical patent claims. *Ohio Willow Wood*, 735 F.3d at 1342. "Rather, it is the identity of the *issues* that were litigated that determine whether collateral estoppel should apply." *Id*.

Reply 13–14. Patent Owner does not argue persuasively that collateral estoppel fails to attach with respect to this element. *See* Sur-reply 12 n.1, 17 n.2, 20 n.3. Nevertheless, given that we adopt the reasoned arguments of the panel in IPR2017-01812, we need not rely on Petitioner's estoppel argument.

Moreover, on pages 14–15 of its Reply, Petitioner sets forth reasons why (1) Rutecki discloses an external trial stimulator and (2), why one of ordinary skill in the art "would have found it obvious to use an ETS that is

capable of use both inside and outside of the OR." Reply 14–15 (citing Ex. 1032, 202:3–2037; Ex. 1022, 58:16–25,Ex. 1022, 58:16–25, 59:2–7; Ex. 1010, 33–34; Ex. 1041 ¶¶ 50–51). We agree with, and adopt, Petitioner's assessment.

2) *Conclusion as to Ground 3*

Considering all the evidence of record, Petitioner has shown by a preponderance of the evidence that claims 11 and 12 would have been obvious over the combined teachings of Holsheimer, Munshi, Schulman, and Rutecki.

H. Patent Owner's Motion to Exclude

Patent Owner seeks to exclude Exhibits 1020, 1023, 1032, 1044, and 1045. Paper 63; Paper 72. Because we do not rely on Exhibit 1020, we deny Patent Owner's motion as moot with respect to this exhibit.

The remaining subjects of Patent Owner's motion are deposition transcripts of named inventors of the '404 patent taken in connection with either the related district court proceeding (Exhibits 1023, 1044, and 1045) or IPR2017-01812 (Exhibit 1032). *Id.* at 3–8.[15] Petitioner relies on these exhibits as partial support for the unremarkable, and unopposed position that implantable rechargeable batteries were known in the art as of the critical date. Although this fact is adequately supported in, for example, Munshi and Wang (*see* section II.D.2 and II.D.4, above), and the testimony of Mr. Pless

[15] We note that although Petitioner and Mr. Pless cite Dr. Berger's testimony that patients can be "under observation" outside of the operating room (Reply 14; Ex. 1041 ¶ 50 (citing Ex. 1032, 202:3–203:7)), this passage is not within the scope of Patent Owner's Motion (*see* Paper 63, 5 ("Specifically, on page 22 of the Reply, Petitioner cites Exhibit 1032 to support the argument that rechargeable IPGs were known in the art before 1999.")).

(*see e.g.*, Ex. 1003 ¶¶ 38, 66–68, 72–77, 79, 106), Patent Owner does not persuade us to exclude the confirmatory testimony from the named inventors.

To the extent Patent Owner seeks to exclude Mr. Meadow's testimony that it was known that rechargeable battery technology from cardiac or cochlear systems could be used in a spinal cord stimulation system (Paper 63, 4 (citing 278:10–16)), we do not rely on that testimony and deny that portion of the motion as moot. We reach the same conclusion with respect to Mr. Peterson's testimony regarding "multiple commercial versions of the Precision system." *Id.* at 6 (citing Ex. 1044, 69:24–70:1).

Patent Owner moves to exclude Mr. Peterson's testimony as irrelevant under FRE 401–403 because it concerns rechargeable batteries in implanted pacemakers rather than spinal cord stimulation systems. Paper 63, 6 (citing Ex. 1044, 168:4–9). We, nevertheless, find Mr. Peterson's testimony relevant, and understand that it is limited to rechargeable pacemaker batteries. We deny Patent Owner' motion as it fails to explain how the cited testimony engenders unfair prejudice or confusion. We reach the same conclusion with respect to Ms. Wood's testimony with respect to "IPGs with a replenishable power source in single channel muscle stimulator." *Id.* at 7 (citing Ex. 1045, 345:20–346:18).

Patent Owner moves to exclude each of Exhibits 1023, 1032, 1044, and 1045 under FRE 801 and 802 on the ground of hearsay and under FRE 801(d)(2) because the witnesses were not 30(b)(6) witnesses and were not Patent Owner's employees at the time of the deposition. *Id.* at 3–8. Patent Owner's arguments are not persuasive for the reasons aptly set forth at pages 5–12 of Petitioner's Opposition (Paper 69), and which we adopt, to the extent not incompatible with this section.

In sum, Patent Owner's motion is denied with respect to the portions of Exhibits 1023, 1032, 1044, and 1045 cited in section II.E.6, above, and denied as moot with respect to Exhibit 1020 and the remaining portions of Exhibits 1023, 1032, 1044, and 1045.

I. Stipulated Protective Order

In Paper 27, Patent Owner submits a Stipulated Protective Order based on our Default Protective Order but having modifications regarding in-house counsel access and expert certifications. Petitioner does not oppose (*id.* at 1), and we find the proposed modifications are acceptable. Accordingly, the Stipulated Protective Order (Attachment A to Paper 27) shall apply to the confidentiality of documents submitted in this proceeding.

J. Motions to Seal

Before us are three unopposed motions to seal. Paper 27 (by Patent Owner); Papers 48 and 68 (by Petitioner). All motions involve information alleged by Patent Owner to be confidential.

"There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an *inter partes* review which determines the patentability of claims in an issued patent and therefore affects the rights of the public." *Garmin Int'l v. Cuozzo Speed Techs., LLC*, IPR2012-00001, Paper 34 (PTAB Mar. 14, 2013), 1–2. For this reason, except as otherwise ordered, the record of an *inter partes* review shall be made available to the public. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14.

The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a). That standard includes a showing that

> (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4) on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record.

Argentum Pharms. LLC v. Alcon Research, Ltd., IPR2017-01053, Paper 27 (PTAB Jan. 19, 2018) (informative), 3–4. The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c).

In Paper 27, Patent Owner moves to seal Exhibits 2026–2034, 2036–2041, and 2043 as containing highly confidential and proprietary information regarding the design and operation of Boston Scientific's products (Paper 27, 2–5); Exhibits 2045–2048 as containing highly confidential financial information (*id.* at 5–7); and portions of Patent Owner's Response and Exhibits 2021–2022, as discussing the substance of those exhibits (*id.* at 8–9). Patent Owner provides detailed explanations for why we should find good cause for sealing the recited exhibits.

In Paper 48, Petitioner moves to seal portions of Dr. Young's transcript (Ex. 1042) that Patent Owner contends disclose its highly confidential information. Petitioner includes with the motion, Patent Owner's statement for why the Board should find good cause for granting the motion. Paper 48, 2. In Paper 68, Petitioner similarly moves to seal slides 54, 55, and 57 of Petitioner's demonstratives for containing information from Exhibits 2021 and 2026 that Patent Owner contends should be sealed.

Patent Owner has set forth a reasonable case that good cause exists to seal the identified information. In order to balance the strong public interest

in having an open record, however, we deny the pending motions without prejudice.

Accordingly, Patent Owner is invited to file, jointly or with Petitioner's consent, a renewed motion to seal any document or portion thereof identified above containing confidential information. The motion shall attest that the material sought to be protected is not directly or indirectly relied on in this Decision, or, to the extent we rely on any of the material sought to be protected in this Decision, provide sufficient justification that outweighs the heightened public interest in understanding the basis for our decision on patentability. Patent Owner need not repeat its arguments for good cause with respect to information covered by the attestation. Together with the renewed motion to seal, and to the extent such documents are not presently on file, Patent Owner shall file narrowly redacted public versions of any documents sought to be sealed.

III. CONCLUSION

For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that claims 1–5, 7, 9, and 11–17 of U.S. Patent No. 7,496,404 B2 are unpatentable, as summarized in the following table:

Claims	**35 U.S.C §**	**Reference(s) /Basis**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
1–5	103(a)	Holsheimer, Munshi, Schulman, Wang	1–5	

7, 9, 13–17	103(a)	Holsheimer, Munshi, Schulman	7, 9, 13–17	
11, 12	103(a)	Holsheimer, Munshi, Schulman, Rutecki	11, 12	
Overall Outcome			1–5, 7, 9, 11–17	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 7, 9, and 11–17 of U.S. Patent No. 7,496,404 B2 are determined to be unpatentable;

ORDERED that Patent Owner's motion to exclude evidence is denied with respect to the portions of Exhibits 1023, 1032, 1044, and 1045 cited in section II.E.6, above, and denied as moot with respect to Exhibit 1020 and the remaining portions of Exhibits 1023, 1032, 1044, and 1045;

ORDERED that the Stipulated Protective Order (Attachment A to Paper 27) applies to this proceeding;

ORDERED that Petitioner's and Patent Owner's Motions to Seal are *denied without prejudice*, subject to the conditions for submitting a Renewed Motion to Seal set forth in section II.I, above; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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