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Paper No. 79
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

Case IPR2017-01812[1]
Patent 6,895,280 B2

Before HUBERT C. LORIN, MICHAEL W. KIM, and AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] Case IPR2017-01920 has been consolidated with the instant proceeding.

I. INTRODUCTION

A. Procedural Background

In IPR2017-01812, Nevro Corp. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 22–24 and 26–30 of U.S. Patent No. 6,895,280 B2 (Ex. 1001, "the '280 patent"), on five asserted grounds of unpatentability. Paper 1 ("Pet."). Boston Scientific Neuromodulation Corp. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

In IPR2017-01920, Petitioner filed a Petition requesting an *inter partes* review of claims 8, 18, 22–24, and 27 of the '280 patent, on three asserted grounds of unpatentability. IPR2017-01920, Paper 1 ("–1920 Pet."). Patent Owner filed a Preliminary Response. Paper 10 ("–1920 Prelim. Resp.").

On February 5, 2018, we instituted an *inter partes* review in both proceedings, pursuant to 35 U.S.C. § 314. Specifically, in IPR2017-01812, we instituted an *inter partes* review of claim 27 on two asserted grounds of unpatentability. Paper 11 ("DI").[2] We also instituted an *inter partes* review of claim 27 in IPR2017-01920, on one asserted ground of unpatentability. IPR2017-01920, Paper 12 ("–1920 DI"). Also on the same day, we consolidated both proceedings into IPR2017-01812. Paper 13, 3 (terminating IPR2017-01920 as a separate proceeding).[3] In this consolidated proceeding, however, we denied institution of an *inter partes* review of

[2] Petitioner filed a request for rehearing of this Decision (Paper 14, "Req. Reh'g"), which we denied (Paper 17, "Dec. on Req. Reh'g").

[3] All citations to papers and exhibits in this Decision refer to those submitted into the record of IPR2017-01812, unless indicated by the prefix "–1920." *See* Paper 13, 3; Paper 21; Paper 25.

challenged claims 8, 18, 22–24, 26, and 28–30, and certain asserted grounds of unpatentability. DI 2; –1920 DI 2.

Before the Patent Owner Response was due, the U.S. Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*. 138 S. Ct. 1348 (2018). Pursuant to *SAS*, a decision to institute an *inter partes* review under 35 U.S.C. § 314 may not institute trial on fewer than all challenged claims. *Id.* at 1355–56, 1358. Accordingly, we modified our Decisions on Institution to institute review of all challenged claims, on all grounds presented in the Petitions. Paper 22, 3; *see also* Paper 24, 4 (extending due dates and enlarging word limits).

Thereafter, Patent Owner filed its Patent Owner Response ("Response") to the Petitions (Papers 31–32 (confidential and public versions),[4] "PO Resp."), and Petitioner filed its Reply (Paper 48, "Pet. Reply"). Upon request, we authorized Patent Owner to file a Sur-Reply (Paper 59, "PO Sur-Reply"), and Petitioner to file a Sur-Sur-Reply (Paper 64, "Pet. Sur-Sur-Reply").

Additionally, Petitioner filed a Motion to Exclude certain evidence submitted by Patent Owner (Paper 56, "Pet. MTE"), Patent Owner filed an Opposition (Paper 65, "PO Opp. MTE"), and Petitioner filed a Reply (Paper 66, "Pet. Reply MTE"). Likewise, Patent Owner filed a Motion to Exclude certain evidence submitted by Petitioner (Paper 60, "PO MTE"), Petitioner filed an Opposition (Paper 63, "Pet. Opp. MTE"), and Patent Owner filed a Reply (Paper 67, "PO Reply MTE").

[4] We granted Patent Owner's Second Motion to Seal, and Petitioner's Motion to Seal. Paper 62 (sealing, e.g., the Patent Owner Response).

An oral hearing was held on November 1, 2018, and a transcript of the hearing is included in the record. Paper 78 ("Tr."). Prior to the hearing, the parties filed Demonstrative Exhibits (Papers 76, 77) and Joint Objections to Demonstratives (Paper 75).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner *has* shown by a preponderance of the evidence that challenged claims 8, 18, 22–24, and 27 of the '280 patent are unpatentable, but Petitioner *has not* shown by a preponderance of the evidence that challenged claims 26 and 28–30 are unpatentable.

B. Related Proceedings

The parties represent that the '280 patent is at issue in *Boston Scientific Corp. v. Nevro Corp.*, Case No. 1:16-cv-01163-GMS (D. Del). Pet. 72; Paper 5, ii; –1920 Pet. 80; –1920 Paper 6, 2.

Also, the '280 patent was the subject of IPR2017-01811, between the same parties (institution denied on February 5, 2018). Pet. 72; Paper 5, ii; –1920 Pet. 80; –1920 Paper 6, 2.

C. The '280 Patent

The '280 patent is titled "Rechargeable Spinal Cord Stimulator System," and issued on May 17, 2005, from U.S. Application No. 10/307,098, filed Nov. 27, 2002. Ex. 1001, (21), (22), (45), (54). The '280 patent presents a priority claim to a July 27, 1999, provisional application. *Id.* at (60). Thus, we refer to July 27, 1999, as the "critical date" of the '280 patent. *Cf.* Pet. 4–5 (treating July 27, 1999, as the priority date).

The ’280 patent explains that spinal cord stimulation is used to reduce a patient’s pain by providing electrical pulses to electrodes implanted at the patient’s spinal cord. *Id.* at 1:23–32. Figure 1 of the ’280 patent is reproduced below.

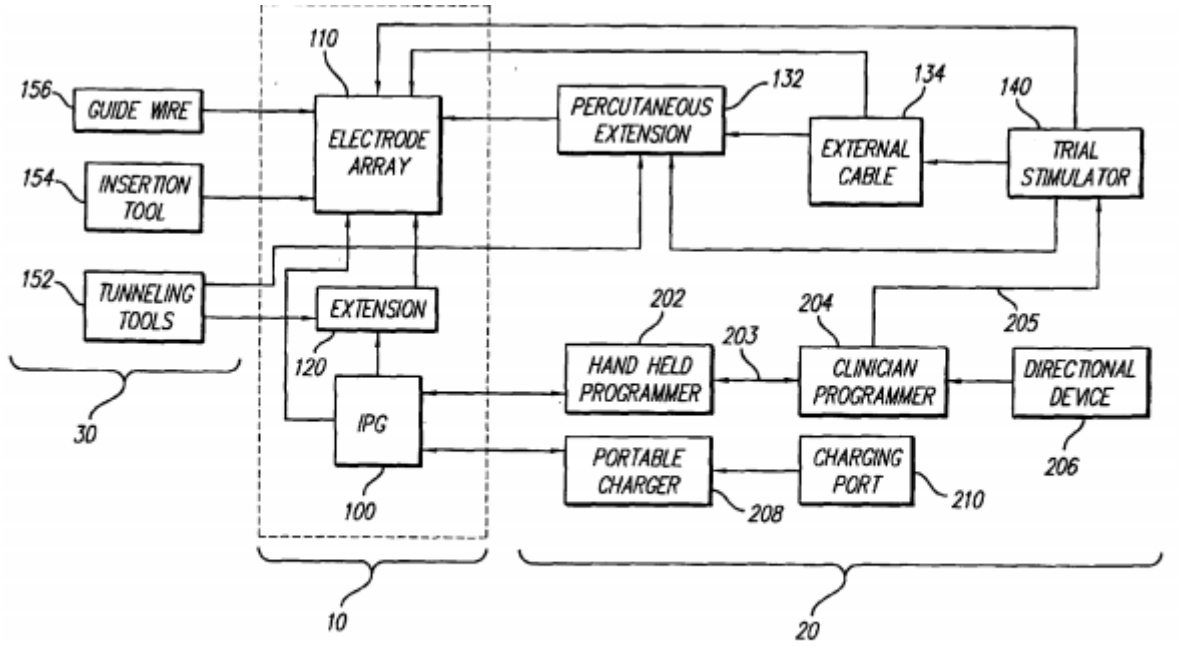

FIG. 1

Figure 1 depicts a block diagram of a spinal cord stimulation system, and identifies its implantable 10, external 20, and surgical 30 components. *Id.* at 7:3–5, 8:33–37. Implantable components 10 of the system include implantable pulse generator (“IPG”) 100, electrode array 110, and lead extension 120. *Id.* at 4:13–18, 8:37–41. These elements are implanted in the patient through use of surgical components 30. *Id.* at 8:34–37; 11:25–28. External components 20 include, for example, various programmers 202, 204, external battery charger 208, and external trial stimulator (“ETS”) 140. *Id.* at Fig. 1, 4:18–21, 11:62–11:5, 17:3–9, 40:64–66.

The spinal cord stimulation system disclosed in the ’280 patent purports to provide several advantages over prior art systems including, *inter*

alia, the ability to provide unique stimulation parameters across multiple channels of electrodes (*id.* at 2:47–51, 3:16–20), the ability to non-invasively recharge the power source of the implanted components with charger 208 (*id.* at 2:54–58, 3:30–58), and the ability to perform a temporary evaluation of stimulus levels, through use of external trial stimulator 140, prior to permanent implantation of the IPG (*id.* at 6:6–16). The disclosed system also "offers a simple connection scheme for detachably connecting a lead system thereto." *Id.* at 2:62–64. The '280 patent explains that although "the lead system [(comprising lead extension 120 and electrode array 110)] is intended to be permanent, the IPG may be replaced should its power source fail, or for other reasons." *Id.* at 27:26–38. Accordingly, a detachable connection is beneficial. *Id.* at 8:46–52, 27:31–33.

D. Illustrative Claims

Of the challenged claims, claims 8, 18, 22, 26, and 27 are independent, with claims 23 and 24 depending directly or indirectly from claim 22, and claims 28–30 depending directly or indirectly from claim 27. Claims 8, 22, 26, and 27 are illustrative and are reproduced below.

8. A spinal cord stimulation system comprising:

a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry;

an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon;

a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is

independently programmable with different stimulation parameters,

wherein m is equal to or less than n, and m is 2 or greater;

an external trial stimulator (ETS); and

a percutaneous extension which temporarily couples the ETS with the implantable electrode array.

22. A spinal cord stimulation system comprising:

an implantable, multi-channel implantable pulse generator (IPG) having a replenishable power source;

an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon;

a secondary, implanted coil coupled electrically to the replenishable power source;

an external battery charger including:

a primary coil;

a rechargeable battery contained in the charger, electrically coupled to the primary coil; and

a power amplifier for applying alternating current derived from the rechargeable battery in the charger to the primary coil,

whereby the alternating current in the primary coil is transcutaneously transferred to the secondary implanted coil to the replenishable power source contained in the IPG; and

alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil as applied by the power amplifier,

wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored.

26. A method for implanting a spinal cord stimulator system into a patient for stimulation therapy, the method comprising:

(a) implanting a nerve stimulation lead with a distally located, multi-electrode array placed near target tissue, said lead having a lead connector on the proximal end;

(b) connecting the lead connector to a percutaneous extension;

(c) externalizing the percutaneous extension through the skin;

(d) connecting an external trial stimulator (ETS) to the externalized lead extension;

(e) programming the stimulation parameters at first optimal values;

(f) waiting a specified period of time and re-programming the stimulation parameters to second optimal values;

(g) disconnecting the percutaneous extension from the lead connector;

(h) connecting a multi-channel, implantable pulse generator to the lead connector;

(i) implanting the implantable pulse generator, while programmed to the second, optimal stimulation parameters.

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

(a) charging the rechargeable battery in the external battery charger using an external power source;

(b) aligning the primary antenna coil with the implanted secondary coil;

(c) broadcasting electromagnetic energy through the primary antenna coil;

(d) receiving the broadcast electromagnetic energy through the secondary antenna coil, whereby an alternating current is produced in the secondary coil;

(e) rectifying the induced, alternating current received by the secondary coil;

(f) charging the rechargeable battery carried within the IPG, while monitoring the charging current or voltage across the battery as the battery is being charged to prevent overcharging; and

(g) stopping the charging at the battery charger when the current or voltage at the battery in the IPG reaches a prescribed level.

Ex. 1001, 53:3–18, 55:62–56:21, 57:13–58:20. Independent claim 18 is similar to claim 8, and also includes a "soft ramping circuit." *Id.* at 54:55–55:3.

E. Applied References

Petitioner relies upon the following references:

Reference	Patent/Publication	Relevant Dates	Exhibit No.
Barreras	U.S. Patent 5,733,313	Filed Aug. 1, 1996 Issued Mar. 31, 1998	Ex. 1008
Wang	U.S. Patent 5,702,431	Filed Sept. 17, 1996 Issued Dec. 30, 1997	Ex. 1018
Engebretson	U.S. Patent 5,024,224	Filed Sept. 1, 1988 Issued June 18, 1991	Ex. 1019
Holsheimer	U.S. Patent 5,501,703	Filed Jan. 24, 1994 Issued Mar. 26, 1996	Ex. 1004

Reference	Patent/Publication	Relevant Dates	Exhibit No.
Alo	Kenneth M. Alo et al., *Computer Assisted & Patient Interactive Programming of Dual Octrode Spinal Cord Stimulation in the Treatment of Chronic Pain*, 1 NEUROMODULATION: J. OF THE INT'L NEUROMODULATION SOC'Y 30–45 (1998)		Ex. 1009
Munshi	U.S. Patent 5,411,537	Filed Oct. 29, 1993 Issued May 2, 1995	Ex. 1005
Rutecki	U.S. Patent 5,330,515	Filed June 17, 1992 Issued July 19, 1994	Ex. 1007
Schulman	U.S. Patent 6,185,452	Filed Feb. 25, 1998 Issued Feb. 6, 2001	Ex. 1012
Loeb	U.S. Patent 5,571,148	Filed Aug. 10, 1994 Issued Nov. 5, 1996	Ex. 1117[5]

Pet. 8–9; –1920 Pet. 1–2, 10–11.

Additionally, Petitioner relies upon the Declaration of Dr. Mark W. Kroll ("the Kroll Declaration," Ex. 1003); the Declaration of Dr. Kroll, provided in the –1920 IPR ("the –1920 Kroll Declaration," Exhibit 1103[6]); and the Reply Declaration of Dr. Kroll ("the Kroll Reply Declaration," Exhibit 1137). Petitioner also relies upon the Declaration of Christopher A. Vellturo, Ph.D. ("the Vellturo Declaration," Exhibit 1140).

Patent Owner relies upon the Declaration of Ronald D. Berger, M.D., Ph.D. ("the Berger Declaration," Ex. 2033); the Declaration of Adam Lipson, M.D. ("the Lipson Declaration," Ex. 2034); and the Declaration of John R. Bone, CPA, CFF ("the Bone Declaration," Ex. 2035).

[5] In IPR2017-01920, Loeb was provided as Exhibit 1017.

[6] In IPR2017-01920, this declaration was provided as Exhibit 1003.

The parties also rely upon deposition transcripts of the aforementioned declarants: the April 12, 2018, deposition of Dr. Kroll (Ex. 2013); the September 7, 2018, deposition of Dr. Kroll (Ex. 2039); the July 13, 2018, deposition of Dr. Berger (Ex. 1124); the July 26, 2018, deposition of Dr. Lipson (Ex. 1125); and the June 5, 2018, deposition of Mr. Bone (Ex. 1133).

F. Asserted Grounds of Unpatentability

We instituted *inter partes* review on the following grounds. DI 33; –1920 DI 26; Paper 22, 2; *see also* Paper 24, 2.

IPR	Ground	Basis	Claim(s)
–1812	Barreras	§ 103	27
–1812	Barreras and Wang	§ 103	27
–1812	Barreras, with or without Wang, and Engebretson	§ 103	28–30
–1812	Holsheimer and Alo	§ 103	26
–1812	Holsheimer, Munshi, and Wang	§ 103	22–24
–1920	Schulman and Loeb	§ 103	18 and 27
–1920	Schulman, Loeb, and Rutecki	§ 103	8
–1920	Schulman, Loeb, Munshi, and Wang	§ 103	22–24

II. LEGAL BACKGROUND

A. Claim Construction

In this *inter partes* review, claim terms in the unexpired patent are given their broadest reasonable interpretation in light of the specification of

the patent in which they appear.[7] 37 C.F.R. § 42.100(b) (2016). Under that standard, we generally give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

1. "alignment between the primary and secondary coils"; "aligning the primary antenna coil with the implanted secondary coil"

In our Decisions on Institution, we considered the claim phrases "alignment between the primary and secondary coils" and "aligning the primary antenna coil with the implanted secondary coil," which appear in claims 22 and 27, respectively. We preliminarily determined that this language "does not require that reflected impedance be at a minimum, as Patent Owner proposes." DI 8–9; –1920 DI 7–8.

In its Response, Patent Owner contends that this language should be construed as: "achieving a spatial arrangement of the primary and secondary coils such that charging efficiency is optimized based on measurement of an electrical parameter." PO Resp. 20–21 (citing Ex. 2033 ¶ 29); *see also id.* at 19–23. According to Patent Owner, "alignment" requires "more than the bare minimum positioning for inductive charging," and instead requires positioning that achieves optimal charging efficiency. *Id.* at 20. Patent Owner contends that the '280 patent specification "consistently explains that

[7] A recent amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 100(b) effective November 13, 2018).

alignment is for efficient energy transfer," and discloses measuring an electrical parameter of charging efficiency. *Id.* at 21–22 (citing Ex. 1001, 5:4–9, 41:14–17, 42:40–42, 44:19–25, claim 22; Ex. 2033 ¶¶ 28, 30–33; Ex. 2013, 10:12–11:3, 11:7–19, 13:4–15). According to Patent Owner, this is consistent with dictionary definitions of "align." *Id.* at 22–23 (citing Ex. 2006, 28 ("to be in or come into precise adjustment of correct relative position"); Ex. 2007, 176 ("alignment of the coils has a significant effect on their mutual inductance"). Moreover, in discussing the prior art, Patent Owner argues that a broad reading of "aligning" would conflate the "aligning" step of claim 27 with the separate step of "charging the rechargeable battery." *Id.* at 30.

Petitioner replies that this language "need[s] no specific construction." Pet. Reply 10. Petitioner also argues that "optimized," as used in Patent Owner's proposed construction, is ambiguous. *Id.* (citing Ex.1124, 113:5–116:5; Ex. 1137 ¶ 5).

We have considered the parties' arguments and cited evidence, and we determine that, in light of the intrinsic and extrinsic evidence of record, the broadest reasonable interpretation of this language is "achieving a relative position between the primary and secondary coils to permit energy transfer." *See, e.g.*, Ex. 1001, 5:9, 41:15; Ex. 2006, 28.

We begin with the claim language itself. Neither claim 22 nor claim 27 further defines "alignment" or "aligning" beyond identifying the items to be aligned, i.e., the primary and secondary coils. Dependent claim 24, however, recites that an "alarm generator" produces an audible alarm "when the primary coil is *misaligned* with the secondary coil." Ex. 1001, 56:27–31 (emphasis added). Claim 24, therefore, suggests that the

"alignment" recited in independent claim 22 is broad enough to include "misalign[ment]."

The '280 patent specification does not define "aligning" or "alignment" expressly. *See generally* Ex. 1001. The specification describes "alignment" in terms of a relative position between two elements, for example, between electrodes or between inductive coils. *See, e.g.*, Ex. 1001, 1:51–55 (describing "five aligned electrodes which are positioned longitudinally on the spinal cord and transversely to the nerves entering the spinal cord"), 10:58–61 (describing electrodes as "aligned horizontally, offset horizontally, or randomly or systematically arranged in some other pattern"), 41:12–17 ("The charging head 272 is then simply slid into the pouch . . . so that it is within 2–3 cm of the IPG. In order for efficient transfer of energy to the IPG, it is important that the head 272 (or more particularly, the coil within the head 272) be properly aligned with the IPG."). The specification's use of "alignment" to describe relative positioning of elements is consistent with one dictionary definition provided by Patent Owner. Ex. 2006, 28 ("to be in or come into precise adjustment of correct relative position").

We recognize that the '280 patent specification discusses the relationship between alignment and efficient charging, as reflected in Patent Owner's proposed construction. *See, e.g.*, PO Resp. 21. This discussion, however, explains that the most efficient charging of the implanted battery occurs when there is *proper* alignment between the coils. Claims 22 and 27, however, do not recite any variation of "proper," "efficient," or "optimal" alignment. *Compare* Ex. 1001, 5:6–9 (detecting when the coils are "*properly* aligned . . . for maximum power transfer" (emphasis added)),

41:14–17 (similar), *with id.* at 44:27–28, claim 24 (indicating *improper* alignment (emphasis added)). Accordingly, these portions of the specification are less helpful in construing the broader term "alignment" or "aligning."

Similarly, the specification discusses mechanisms by which optimal charging efficiency may be measured, as a proxy for determining *proper* alignment. For example, the '280 patent specification indicates that "[r]eflected impedance is at a minimum when proper alignment has been obtained." Ex. 1001, 44:19–23; *see also id.* at 42:40–43; PO Resp. 21–22. Similarly, the '280 patent specification explains that steady-state voltage is at a minimum, and coupling is at a maximum, when proper alignment is achieved. Ex. 1001, 44:21–26. However, these descriptions do not define "alignment" or "aligning" generally.[8]

Patent Owner relies upon Dr. Berger's testimony to support its proposed construction. Ex. 2033 ¶¶ 28–33. However, Dr. Berger relies upon portions of the specification that discuss *proper* alignment, not alignment generally. *See id.* ¶ 30 (citing Ex. 1001, 5:4–9, 41:14–17). Likewise, Patent Owner and Dr. Berger rely upon the HANDBOOK OF BIOMEDICAL TELEMETRY to support the proposed construction, however, this publication discusses the alignment that is necessary to achieve "optimal inductance," i.e., *proper* alignment, which is not instructive as to the

[8] Patent Owner has not explained why a "measurement" or detection step should be imported into the "aligning" step. Patent Owner does not argue that other claim limitations, e.g., "rectifying" as recited in claim 27, should be construed as requiring "measurement" or detection that the rectification has occurred properly, efficiently, or optimally.

meaning of "alignment" or "aligning" generally. Ex. 2007, 177 (describing "perfectly aligned coaxial coils").

We have considered the other dictionary definition cited by Patent Owner, and determine that it is consistent with understanding the broadest reasonable interpretation of this language as "achieving a relative position between the primary and secondary coils to permit energy transfer." Merriam-Webster's Collegiate Dictionary defines "align" as "to be in or come into precise adjustment or correct relative position," which is consistent with our interpretation that the coils are placed in "relative position" to permit energy transfer. Ex. 2006, 28; Ex. 1001, 5:9, 41:15. Contrary to Patent Owner's argument, our construction does not permit "any relative positioning," but rather requires positioning that "permit[s] energy transfer." PO Resp. 20; Ex. 2033 ¶ 32; *see*, *e.g.*, Ex. 1001, 41:12–17 (permitting a range of positions, e.g., "within 2–3 cm").

Finally, we do not agree with Patent Owner's argument that this interpretation conflates the "aligning" step with the separate step of "charging the rechargeable battery," in claim 27. PO Resp. 30. Under our construction of this language, step (b) of claim 27 requires placing the primary and secondary coils in relative position *to permit* energy transfer; it does not require *actually transferring* energy. It is steps (c)–(f) that require the actual transfer of energy to charge the battery, i.e., (c) "broadcasting electromagnetic energy," (d) "receiving" that energy, (e) "rectifying" the induced current, and (f) "charging the rechargeable battery." Ex. 1001, 58:3–17.

2. "back telemetry receiver"

Claim 22 recites "alignment circuitry" that includes a "back telemetry receiver for monitoring the magnitude of the ac voltage" and "reflected impedance." *Id.* at 56:15–21. We did not construe this phrase in our Decisions on Institution.

In its Response, Patent Owner contends that the broadest reasonable interpretation of "telemetry" is "transmission of data or information." PO Resp. 26. Patent Owner contends this is consistent with the '280 patent specification (Ex. 1001, 5:43–49, 17:28–31, 42:33–43) and extrinsic evidence (Ex. 2001, 845; Ex. 2002, 1845; Ex. 2003, 1289; Ex. 2004, 1767; Ex. 2005, 1263; Ex. 2033 ¶¶ 41–51). Later in its Response, Patent Owner argues, apparently based on the above interpretation of "telemetry," that "[t]he 'back telemetry receiver' thus must, at a minimum, receive transmitted data or information." PO Resp. 27 (citing Ex. 2033 ¶ 51). In its Sur-Reply, Patent Owner appears to confirm this argument. PO Sur-Reply 25–26 n.6. In its assertions concerning the prior art, however, Patent Owner appears to be asserting that "monitor[ing] the magnitude of the current" cannot correspond properly to "receiv[ing] transmitted data or information." PO Resp. 70.

Petitioner replies that "'[b]ack telemetry receiver' needs no specific construction, as the claims' plain language recites its functionality: monitor 'the magnitude of the ac voltage at the primary coil' . . . and 'reflected impedance.'" Pet. Reply 21. Petitioner also contends that Patent Owner's construction is improperly narrow. *Id.* (citing Ex. 1124, 152:21–153:9; Ex. 1137 ¶¶ 11–12). For example, according to Petitioner, "telemetry" may

refer to transmission of power, which is not "data or information." *Id.* at 22 (citing Ex. 1135, Abstract; Ex. 1136, 4:5–10; Ex. 1137 ¶ 13).

Patent Owner responds that "the same modality used to transmit or receive telemetry may have other functions," such as monitoring voltage or impedance or transmitting power, but "telemetry" "requires the transmission and receipt of data or information." PO Sur-Reply 25–26, n.6.

As best as we can tell, Patent Owner is making several arguments, some of which could be seen as contradictory. In an abundance of caution, we address them all. One argument is that "back telemetry receiver . . . must, at a minimum, receive transmitted data or information." PO Resp. 27. A related argument is that monitoring voltage or impedance, or transmitting power, is not receiving transmitted data or information. *Id.* at 70; PO Sur-Reply 26 n.6, 27. The final argument is that "back telemetry receiver" "requires the transmission and receipt of data or information." PO Sur-Reply 26 n.6.

In short, we do not agree with any of Patent Owner's arguments, and are persuaded that Petitioner's overall position is correct. Beginning with the first two related arguments, even if we agree that "back telemetry receiver . . . must, at a minimum, receive transmitted data or information," we disagree in light of Patent Owner's argument that monitoring voltage or impedance, or transmitting power, is not "receiv[ing] transmitted data or information." Claim 22 recites a "back telemetry receiver," which is part of the claimed "alignment circuitry," and which explicitly recites that it monitors voltage and reflected impedance. Thus, claim 22 already specifies what the "back telemetry receiver" *is* and what it *does*— it is circuitry that monitors voltage and impedance.

The ’280 patent specification is consistent with the claim language. The specification explains that the back telemetry receiver “monitor[s] the magnitude of the ac power . . . thereby monitoring reflected impedance.” Ex. 1001, 4:64–5:1, 42:36–43. Further, Figure 9A depicts that charger 208 includes back telemetry *receiver* 692, and IPG 100 includes back telemetry *transmitter* 690. *Id.* at Fig. 9A, 42:33–43. The specification explains that back telemetry transmitter 690 transmits information regarding changes in rectification, while back telemetry *receiver* 692 monitors voltage and reflected impedance, precisely as reflected in claim 22. *Id.* at 42:33–43 (“This [rectification] modulation is, in turn, sensed in the charger 208 as a change in the coil *voltage* due to the change in the *reflected impedance*. When detected, an audible alarm is generated through a back telemetry receiver 692 and speaker 693.”) (emphasis added). Thus, we agree with Petitioner that Patent Owner’s argument that the “back telemetry receiver” must receive transmitted data or information—other than monitoring voltage or impedance, or transmitting power—is erroneous.

Moreover, the argument that “back telemetry receiver” must transmit *and* receive data or information is not consistent with Figure 9A, which depicts separate structures for *transmitting* (690) and *receiving* (692), as explained above. *See, e.g.*, PO Sur-Reply 26 n.6 (“[T]elemetry requires the transmission and receipt of data or information.”); PO Resp. 70 (“Wang, however, does not disclose receiving telemetry—the transmission of data or information—at the external charger.”).

The ’280 patent specification also describes additional types of “telemetry” circuitry, links, or devices that perform different functions, in addition to the back telemetry transmitter 690 and receiver 692, discussed

above. *See, e.g.*, Ex. 1001, 3:46–50 (a "bidirectional telemetry link" informing of system status, or transmitting requests), 5:40–41 (a "telemetry link" communicating between IPG and hand held programmer), 5:50–53 (a "telemetry link" changing stimulus parameters of the IPG or ETS with the hand held programmer), 17:14–20 ("telemetry circuitry 172" demodulating carrier signals to recover programming data), 17:17–30 ("back telemetry circuitry 176" of "monitoring circuit 174" sending sensed informational data), 25:31–34 (limiting telemetry to status and ID responses), Fig. 4A (depicting "charging and forward telemetry" 172, and "back telemetry" 176 connected to monitoring circuitry 174). None of these disclosures, however, speak to the meaning of "back telemetry receiver"—the actual language used in the challenged '280 patent claims.

We likewise find the cited extrinsic evidence, related to "telemetry" generally, to be less helpful in determining the meaning of the "back telemetry receiver" that is part of the "alignment circuitry," as recited in claim 22. Patent Owner's briefing focuses on the term "telemetry," divorced from the larger claim phrase "back telemetry receiver," but this approach is misguided. As explained above, the claims do not require the *transmission and receipt of data or information*, as reflected in Patent Owner's proposed construction and arguments. *See, e.g.*, PO Resp. 26, 70. We will not read into the claims a narrowing limitation, the requirement of transmission in addition to receipt, that that is not recited in the claims, or clearly associated with the "back telemetry receiver" in the specification.

In light of the foregoing, we determine that "back telemetry receiver" need not be construed expressly, other than to note that the broadest reasonable interpretation of this phrase is not limited to the transmission and

receipt of data or information, as advocated by Patent Owner. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). We interpret this claim language consistent with its usage in the claims.

3. "external trial stimulator"

Claims 8 and 26 recite an "external trial stimulator." Ex. 1001, 53:15, 57:24–25. We did not construe this phrase in our Decisions on Institution.

In its Response, Patent Owner contends that this phrase should be construed as a "pulse generator externally-worn by a patient capable of being used outside of the operating room that is used temporarily for evaluation purposes before implantation of the IPG," which is the construction adopted in co-pending litigation in the District of Delaware. PO Resp. 23–24; Ex. 3001, 1. Patent Owner contends this is consistent with the '280 patent specification. Ex. 1001, 6:6–8 ("The external trial stimulator (ETS) is an externally-worn pulse generator that is used for seven to ten days for evaluation purposes before implantation of the IPG."), 6:8–12 ("[ETS is] typically applied with an adhesive patch to the skin of the patient, but may also be carried by the patient through the use of a belt clip or other form of convenient carrying pouch."), 29:44–49 (describing testing in the operating room, followed patient use during a 2–7 day trial period, with limited programming options), 28:6–9 (providing a 2–7 day trial period before permanent implantation); Ex. 2033 ¶¶ 36–37.

Petitioner contends that this phrase need not be construed specifically, and that the specification does not provide a definition or disclaimer. Pet. Reply 19. Petitioner also argues that the proposed construction is improper because, as Dr. Berger admitted, "there are ETS not capable of use outside

of the operating room" and too big or too heavy to be externally-worn. *Id.* (citing Ex. 1124, 194:6–21, 195:5–25; Ex. 1137 ¶¶ 6–8).

Because we determine that Petitioner has shown that the prior art teaches this limitation even under Patent Owner's proposed construction, *see infra* Section V.F., we apply Patent Owner's construction in this Decision.

B. Principles of Law

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 said 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 skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

"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). The burden of persuasion never shifts to Patent Owner.

Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

In our Decisions on Institution, we preliminarily determined that a person of ordinary skill in the art ("POSITA") "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." DI 10 (citing Pet. 9; Ex. 1003 ¶¶ 12–18); –1920 DI 9.

In their post-institution briefing, neither party provides additional argument or evidence regarding the appropriate level of skill in the art. PO Resp. 18; *see generally* Pet. Reply. We maintain that our determination of the relevant skill level is appropriate, in light of the evidence of record. DI 10 (citing Pet. 9; Ex. 1003 ¶¶ 12–18); –1920 DI 9.

III. MOTIONS TO EXCLUDE

In *inter partes* reviews, exhibits are admitted into evidence subject to an opposing party asserting objections to the evidence and moving to exclude the evidence. 37 C.F.R. § 42.64. The movant has the burden of showing that an exhibit is not admissible. *Id.* § 42.20(c).

A. Petitioner's Motion to Exclude

Petitioner seeks to exclude Exhibits 2009–2012, 2017–2020, 2022–2029, 2031, 2032, 2037, and 2038 in their entirety, and Exhibit 2034 in part

(i.e., Ex. 2034 ¶¶ 29–34, 36–42, 61, Ex. C). Pet. MTE 1–3; Pet. MTE Reply 1–5. Petitioner argues that these exhibits, or the cited portions thereof, are irrelevant, under Federal Rule of Evidence ("FRE") 402, because they are not discussed in Patent Owner's Response. Pet. MTE 1–3 (also citing FRE 401, 403).

Patent Owner responds that Exhibits 2009–2012, 2017–2020, 2022–2029, 2031, 2032, 2037, and 2038 are relied upon by its declarants, Dr. Lipson (Ex. 2034) and Mr. Bone (Ex. 2035). Pet. Opp. MTE 1–3. Patent Owner also argues that the cited portions of the Lipson Declaration provide support for other portions of the Declaration, as well as for arguments made in the Patent Owner Response. *Id.* at 3–6.

As an initial matter, Exhibits 2009–2012, 2017–2020, 2022–2024, 2027, 2031, 2032, 2037, 2038, and Exhibit 2034 ¶¶ 29–34, 36–42, 61, Ex. C, are not relied upon as the basis for our Decision, rendering Petitioner's Motion largely moot. Furthermore, to the extent Patent Owner's declarants rely upon these exhibits in performing, or supporting, their analyses, we determine that such reliance is permissible. *See* 37 C.F.R. § 42.65(a). Accordingly, Petitioner's Motion is *denied*.

Petitioner's arguments, especially regarding Exhibit 2034, Ex. C, are directed to the weight to be afforded to Patent Owner's contentions that rely upon this evidence, rather than whether the evidence itself is admissible. *See* Pet. MTE 3; *see infra* Section V.A.4.

B. Patent Owner's Motion to Exclude

Patent Owner seeks to exclude Exhibits 1020, 1122–1123, 1126–1128, 1130–1132, 1133, 1134, and 1139 in their entirety, and Exhibits 1124,

1125, and 1137 in part. PO MTE 1; PO MTE Reply. Petitioner opposes. Pet. Opp. MTE.

1. Exhibit 1020 – U.S. Patent No. 7,319,901

Patent Owner argues that Exhibit 1020 is irrelevant, under FRE 402. PO MTE 1. Exhibit 1020 is not relied upon in this Decision. Accordingly, this portion of Patent Owner's Motion to Exclude is *dismissed* as moot.

2. Exhibits 1122–1128, 1130–1132, and 1139 – Reply Exhibits Regarding Detachability

Patent Owner seeks to exclude evidence, which Petitioner submitted with its Reply, directed to Petitioner's contentions that the prior art teaches or suggests a detachable electrode array. PO MTE 3 (Ex. 1122), 4–5 (Ex. 1123), 6–7 (Ex. 1124), 8–9 (Ex. 1125), 10 (Exs. 1126–1128, 1130–1132), 14 (Ex. 1139); *see also* PO Sur-Reply 12–15 (same reasoning).[9] According to Patent Owner, when "the Board previously rejected Petitioner's request to submit supplemental evidence" on this issue, the Board informed the parties that Petitioner may respond to arguments made in the Patent Owner Response about detachable leads. *See*, *e.g.*, PO MTE 3; *see also* Paper 30, 6. However, Patent Owner contends that, "Dr. Berger did not address whether Holsheimer discloses detachable leads. Dr. Berger observed that Petitioner did not contend that Holsheimer explicitly discloses detachable leads and that Figures 19 and 20 show the leads reaching individual attachment points within the IPG." PO MTE 3 (citing Ex. 2033

[9] This request normally is not one properly in a motion to exclude, as it does not concern the admissibility of the evidence itself. Nevertheless, as this issue was also brought up in Patent Owner's Sur-Reply, we exercise our discretion by addressing it here.

¶¶ 108–109); Tr. 43:16–45:4. Thus, Patent Owner contends that the Reply evidence is not responsive to arguments made in the Response. *Id.*

We disagree. Patent Owner devotes ten pages of its Response to the issue of detachable leads. PO Resp. 45–50 (arguing, e.g., that "Petitioner's citation to other prior art references does not establish that 'this particular arrangement disclosed by Holsheimer is detachable'"), 51–55 (arguing, e.g., that the proposed modification to utilize detachable leads "is at odds with the teachings of both Loeb and the '280 Patent"). We do not agree with Patent Owner that the Response concerns Petitioner's failure to meet its burden, rather than the underlying issue of whether the prior art teaches or suggests detachable leads. Tr. 44:9–45:4. This is an artificial distinction; Patent Owner's Response plainly disputes Petitioner's contentions regarding detachable leads. PO Resp. 45–55. Thus, Petitioner is permitted to respond to these arguments in its Reply. *Anacor Pharmas., Inc. v. Iancu*, 889 F.3d 1372, 1380–1381 (Fed. Cir. 2018) (explaining that a petitioner "may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner, or if it is used 'to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness'").

"[T]he introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA." *Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharma. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016); *see also id.* at 1367 ("The purpose of the trial in an *inter partes* review proceeding is to give the parties an

opportunity to build a record by introducing evidence—not simply to weigh evidence of which the Board is already aware."). In this case, Patent Owner received adequate notice and had ample opportunity to respond to the evidence submitted with Petitioner's Reply. *See*, *e.g.*, Paper 30, 6 (providing notice that this evidence may be submitted in the Reply). Indeed, after the Reply evidence was filed, Patent Owner requested authorization to file a Sur-Reply, which the Board granted. PO Sur-Reply 1. In that Sur-Reply, Patent Owner presented substantive argument about the newly submitted evidence. *Id.* at 15–20; *see also id.* at 13–15 (also arguing that the evidence should be stricken). Moreover, as Patent Owner's counsel stated during the oral argument, "[i]n this particular IPR," Patent Owner did not "ask[] for the opportunity to add evidence in the sur-reply." Tr. 40:14–21.

Accordingly, because this evidence is responsive to Patent Owner's arguments, and because Patent Owner received appropriate notice and had an opportunity to respond to the evidence, this portion of Patent Owner's Motion is *denied.*

i. Exhibit 1122 – Photograph of Medtronic Itrel II

Patent Owner argues that Exhibit 1122 is irrelevant, under FRE 402. PO MTE 2. According to Patent Owner, "Petitioner failed to submit evidence that the device depicted is an ITREL II device and further that it was in existence as of the date of the invention." *Id.* Patent Owner notes that the URL at the bottom of the exhibit "suggests that the website was created or made available in May 2012." *Id.* (citing Ex. 2039, 115:9–116:12 (Dr. Kroll's testimony that the device "wasn't made in 1990")). Patent Owner also argues that even if Exhibit 1122 depicts an ITREL II, it is not

relevant because Holsheimer discloses an "ITREL IIR." *Id.* at 2–3 (emphasis added); PO Reply MTE 1–2.

Evidence is relevant if it has *any tendency* to make a fact of consequence more or less probable than it would be without the evidence. FRE 401; *Biery v. U.S.*, 2012 WL 4497656, at *4 (Fed. Cir. 2012) ("The Federal Circuit has recognized that there is a 'low threshold' for determining relevancy as defined in FRE 401.") (citing *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1406 (Fed. Cir. 1997)).

The device shown in Exhibit 1122 includes etching indicating it is an "ITREL II" from "Medtronic Inc." Ex. 1122. Whether this device includes a detachable connection is relevant to whether the "ITREL IIR available from Medtronic, Inc.," as disclosed by Holsheimer, also includes a detachable connection, i.e., it has *at least some tendency* to make that fact more probable than it would be without the evidence. Patent Owner's arguments speak more to weight than admissibility.

Accordingly, this portion of Patent Owner's Motion is *denied.* We admit Exhibit 1122 and afford it appropriate weight.

ii. Exhibit 1123 – Video of SCS Implant Procedure

Patent Owner argues that Exhibit 1123 is irrelevant, under FRE 402. PO MTE 3. Patent Owner argues that this video is undated and Petitioner failed to present evidence that Holsheimer's system was implanted according to this process. *Id.* at 3–4 (also arguing that Holsheimer's system may not have been commercialized); PO MTE Reply 3–4.

The video in Exhibit 1123 depicts a process for implanting spinal cord stimulation ("SCS") systems, wherein the process utilizes detachable leads. Ex. 1123. Whether SCS systems require detachable leads for implantation is

relevant to whether the prior art SCS systems also would have included detachable connections for implantation, i.e., it has *at least some tendency* to make those facts more probable. *See* FRE 401; *Biery*, 2012 WL 4497656, at *4. Patent Owner's arguments speak more to weight than admissibility.

Accordingly, this portion of Patent Owner's Motion is *denied*. We admit Exhibit 1123 and afford it appropriate weight.

iii. Exhibit 1124 – Berger Deposition Transcript

Patent Owner argues that cited portions of Exhibit 1124 are irrelevant, under FRE 402. PO MTE 5 (citing Ex. 1124, 56:8–61:25, 64:20–67:9, 68:25–69:13). According to Patent Owner, testimony regarding the shape of the ITREL II is not relevant because Holsheimer discloses an ITREL II<u>R</u>. *Id.* at 5–6. Patent Owner also argues that Dr. Berger's failure to consider testimony from the '280 patent inventors is irrelevant because the inventors did not speak to whether Holsheimer's leads were detachable. *Id.* at 6.

Whether Dr. Berger believes the ITREL II is similar to Holsheimer's Figure 1 is relevant to whether Holsheimer's depicted IPG also includes a detachable connection, and whether Dr. Berger considered inventor testimony regarding the prevalence of detachable connections in SCS systems is relevant to whether a POSITA would have expected other SCS systems to include detachable connections, i.e., this evidence has *at least some tendency* to make these facts more probable. *See* FRE 401; *Biery*, 2012 WL 4497656, at *4. Patent Owner's arguments speak more to weight than admissibility.

Much of the cited testimony is not relied upon in this Decision. Accordingly, to the extent not relied upon, this portion of Patent Owner's

Motion is *dismissed* as moot; otherwise, this portion of the Motion is *denied*, and we admit Exhibit 1124 and afford it appropriate weight.

iv. Exhibit 1125 – Lipson Deposition Transcript

Patent Owner argues that cited portions of Exhibit 1125 are irrelevant, under FRE 402. PO MTE 7 (citing Ex. 1125, 27:18–28:22, 29:10–14, 29:19–33:9, 34:22–39:10, 41:4–14, 45:15–50:17, 52:4–9, 55:5–10). According to Patent Owner, testimony regarding SCS implantation procedures is irrelevant to Holsheimer because (1) much of the testimony concerns an undated video (Ex. 1123), (2) Holsheimer discloses paddle leads, which are not implanted with a cannulated needle, and (3) Petitioner has not shown that Holsheimer's device was reduced to practice. *Id.* at 7–8. Patent Owner also argues that testimony regarding the ITREL II is irrelevant because Holsheimer discloses an ITREL IIR. *Id.* at 8.

Petitioner responds that Patent Owner's declarant testified that both paddle and percutaneous leads must be detachable. Pet. Opp. MTE 7.

As above regarding Exhibit 1123, whether SCS systems require detachable leads for implantation (whether percutaneous or paddle) is relevant to whether prior art SCS systems also would have included detachable leads, i.e., it has *at least some tendency* to make those facts more probable. *See* FRE 401; *Biery*, 2012 WL 4497656, at *4. Patent Owner's arguments speak more to weight than admissibility.

Much of the cited testimony is not relied upon in this Decision. Accordingly, to the extent not relied upon, the portion of Patent Owner's Motion is *dismissed* as moot; otherwise, this portion of the Motion is *denied*, and we admit Exhibit 1125 and afford it appropriate weight.

v. Exhibit 1126–1128 and 1130–1131 – Chen, Woods, Meadows, and Peterson Deposition Transcripts

FRE 402

a) Exhibits 1126–1128, 1130, and 1131

Patent Owner argues that Exhibits 1126–1128, 1130, and 1131 are irrelevant, under FRE 402. PO MTE 9. According to Patent Owner, "[t]he prevalence of detachable leads is not relevant to the question of whether Holsheimer discloses detachable leads." *Id.*

Testimony as to the state of the art of SCS systems is relevant to whether the asserted prior art teaches or suggests detachable leads, whether a POSITA would have recognized the Holsheimer system to include detachable leads, and/or whether it would have been obvious to modify Schulman and Loeb to include detachable leads. The testimony of the '280 patent inventors speaks directly to what a POSITA would have understood at the critical date. Accordingly, this portion of Patent Owner's Motion is *denied.*

b) Exhibit 1131

Patent Owner also argues that Exhibit 1131 is irrelevant because it concerns an ITREL II, not an ITREL IIR. *Id.* at 9. As discussed above regarding Exhibit 1122, we will not exclude Exhibit 1131 on this basis. This portion of Patent Owner's Motion is *denied.*

c) Exhibits 1126–1128 and 1130

Patent Owner also argues that Exhibits 1126, 1127, 1128, and 1130 are irrelevant because the prevalence of rechargeable pacemakers is not relevant to the non-obviousness of rechargeable IPGs. *Id.* at 9–10. Whether

rechargeable pacemakers—a type of rechargeable implantable stimulator (Ex. 1103 ¶ 21)—existed at the critical date is relevant to whether rechargeable IPG were known, as Petitioner notes in response (Pet. Opp. MTE 8), i.e., it has *at least some tendency* to make this fact more probable. *See* FRE 401; *Biery*, 2012 WL 4497656, at *4. Accordingly, this portion of Patent Owner's Motion is *denied.*

FRE 106

Patent Owner argues that Exhibits 1130–1132 should be excluded under FRE 106 because they are incomplete deposition transcripts. PO MTE 11. However, Patent Owner does not identify "any other part – or any other writing or recorded statement – that in fairness ought to be considered at the same time." FRE 106. As such, Patent Owner has not persuaded us that these exhibits should be excluded. Accordingly, this portion of Patent Owner's Motion is *denied.*

FRE 801 and 802

Patent Owner also argues that Exhibits 1128, 1130, and 1131 should be excluded under FRE 801 and 802, arguing that they constitute inadmissible hearsay. PO MTE 10. Petitioner responds that the exceptions of FRE 801(d)(2)(C), 801(d)(2)(D), and/or 807 apply. Pet. MTE Opp. 8–11. Patent Owner disagrees. PO MTE Reply 4–5.

FRE 807 provides a residual exception to the exclusion of evidence that constitutes hearsay:

> (a) In General. Under the following circumstances, a hearsay statement is not excluded by the rule against hearsay even if the statement is not specifically covered by a hearsay exception in Rule 803 or 804:

> (1) the statement has equivalent circumstantial guarantees of trustworthiness;
>
> (2) it is offered as evidence of a material fact;
>
> (3) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts; and
>
> (4) admitting it will best serve the purposes of these rules and the interests of justice.
>
> (b) Notice. The statement is admissible only if, before the trial or hearing, the proponent gives an adverse party reasonable notice of the intent to offer the statement and its particulars, including the declarant's name and address, so that the party has a fair opportunity to meet it.

We determine that at least FRE 807 fairly applies to this circumstance.

Although these deponents are former employees of Patent Owner, they were retained as consultants by Patent Owner in litigation between the parties. PO MTE 10; Pet. Opp. 8; Ex. 1128, 290:11–25; Ex. 1130, 226:16–227:2; Ex. 1131, 31:25–33:3. During their depositions, these deponents were defended by Patent Owner's counsel. Ex. 1128, 220:3–7; Ex. 1130, 3:4–8; Ex. 1131, 3:4–12. Accordingly, this evidence has circumstantial guarantees of trustworthiness, in that Patent Owner engaged these deponents in related litigation and defended their depositions, providing Patent Owner's counsel the opportunity to examine these witnesses. *See Apple Inc. v. VirnetX Inc.*, IPR2015-00871, Paper 39, 75–76 (PTAB Sept. 28, 2016). We are not persuaded by Patent Owner's argument that it had no need to further examine these witnesses. PO MTE Reply 5. If Patent Owner's counsel had any reason to doubt the veracity or completeness of the testimony of their retained consultants, Patent Owner had ample opportunity to explore that concern during the depositions.

We agree with Petitioner that this testimony concerns evidence of a material fact (FRE 807(a)(2)), i.e., the state of the art of detachable connections for SCS systems. Pet. Opp. MTE 10. We do not agree with Patent Owner that more probative evidence, e.g., declarations, could have been obtained by Petitioner with reasonable efforts (FRE 807(a)(3)). PO Reply MTE 4–5. In this case, whether this testimony was obtained by declaration or deposition, Patent Owner had an opportunity to examine the witnesses regarding their testimony. We do not agree that it would have been more probative to provide the same testimony by declaration instead. *Contra* PO MTE Reply 5; *US Endodontics v. Gold Std.*, 2016 WL 7985423, at *17-18 (PTAB Dec. 28, 2016) (determining that "[a] declaration from Dr. Luebke in this proceeding would have been more probative than the declaration from ex parte prosecution in Exhibit 2034 because a declaration in this proceeding *would have subjected Dr. Luebke to cross-examination* by Petitioner," which differs from the present case in which Patent Owner had an opportunity to examine these witnesses) (emphasis added). Moreover, we determine that inclusion of this evidence is in the interests of justice (FRE 807(a)(4)), because this testimony is relevant to issues in this proceeding, was obtained during related litigation between the same parties, and was obtained in a manner that allowed both parties the opportunity to examine the witnesses. Finally, Patent Owner had reasonable notice that Petitioner sought to introduce this evidence (FRE 807(b)). *See* Paper 30, 2.

Accordingly, this portion of Patent Owner's Motion is *denied.*

Summary

This portion of Patent Owner's Motion is *denied.* We admit Exhibits 1126–1128 and 1130–1131, and afford them appropriate weight.

vi. Exhibit 1139 – Werder Deposition Transcript

FRE 402

Patent Owner argues that Exhibit 1139 is irrelevant, under FRE 402, because Mr. Werder's testimony concerns the ITREL II, not the ITREL IIR. PO MTE 14. For the same reasons discussed above regarding Exhibit 1122, we determine that it is permissible for Mr. Werder to provide testimony regarding the ITREL II and, accordingly, Patent Owner's Motion is *denied.*

FRE 106

Patent Owner argues that Exhibit 1139 should be excluded under FRE 106 because it is an incomplete deposition transcript that excludes portions of the transcript no longer deemed confidential. PO MTE 15 (citing Ex. 1139, 89:23–24, 90:6–7). Subsequent to Patent Owner's Motion and pursuant to the Board's request, Petitioner filed an updated version of Exhibit 1139, which includes the portions cited by Patent Owner in their Motion. *See* Ex. 1139; *see also* Pet. Opp. MTE 3–4 n.3. Patent Owner does not identify "any other part – or any other writing or recorded statement – that in fairness ought to be considered at the same time." FRE 106. As such, Patent Owner has not persuaded us that this exhibit should be excluded. Accordingly, this portion of Patent Owner's Motion is *denied.*

FRE 801 and 802

Patent Owner also argues that Exhibit 1139 should be excluded under FRE 801 and 802, arguing that it constitutes inadmissible hearsay. PO MTE 14. Petitioner responds that the exception of FRE 807 applies. Pet. MTE Opp. 12–13. Patent Owner disagrees. PO MTE Reply 4–5.

We determine that at least FRE 807 fairly applies to this circumstance. Mr. Werder, the "the director of electrical engineering for implantables for the . . . Restorative Therapies Group of Medtronic," was deposed as a corporate witness of Medtronic, Inc., under Federal Rule of Civil Procedure ("FRCP") 30(b)(6). Ex. 1139, 5:2–7, 8:25–9:6. Patent Owner's counsel was present at this deposition, taken in conjunction with district court litigation between the parties. *Id.* at 2:3–5, 5:11–16. We agree with Petitioner that this evidence has circumstantial guarantees of trustworthiness, in that it is sworn testimony of a third party witness who lacks a direct interest in the outcome of this proceeding. Pet. MTE Opp. 12. We recognize that Medtronic, Inc. is a competitor of Patent Owner. PO MTE Reply 5. However, Patent Owner's counsel had—and took advantage of—the opportunity to examine this witness during the deposition. *See* Ex. 1139, 112:24–157:18. Accordingly, if Patent Owner's counsel had any reason to doubt the veracity, bias, or completeness of Mr. Werder's testimony, Patent Owner had ample opportunity to explore that concern during the deposition.

We agree with Petitioner that this testimony concerns evidence of a material fact (FRE 807(a)(2)), i.e., the state of the art of detachable connections for SCS systems. Pet. Opp. MTE 12. We do not agree with Patent Owner that more probative evidence, e.g., a declaration, could have been obtained by Petitioner with reasonable efforts (FRE 807(a)(3)). PO Reply MTE 4–5. Whether this testimony was offered by declaration or deposition, Patent Owner had an opportunity to examine the witness regarding his testimony. We do not agree that it would have been more probative to provide the same testimony by declaration instead. *Contra* PO MTE Reply 5; *US Endodontics*, 2016 WL 7985423, at *17–18. Moreover,

we determine that inclusion of this evidence is in the interests of justice (FRE 807(a)(4)), because this testimony is relevant to issues in this proceeding, was obtained during related litigation between the same parties, and was obtained in a manner that allowed both parties the opportunity to examine the witnesses. Finally, Patent Owner had reasonable notice that Petitioner sought to introduce this evidence (FRE 807(b)). *See* Paper 30, 2.

Accordingly, this portion of Patent Owner's Motion is *denied.* We admit Exhibit 1139 and afford it appropriate weight.

3. Exhibit 1133 – Bone Deposition Transcript

Patent Owner argues that Exhibit 1133 should be excluded, under FRE 106, 402, 801, and 802. PO MTE 11–12. Exhibit 1133 is not relied upon in this Decision. Accordingly, this portion of Patent Owner's Motion to Exclude is *dismissed* as moot.

4. Exhibit 1134 – U.S. Patent No. 5,807,397

Patent Owner argues that Exhibit 1134 is irrelevant, under FRE 402. PO MTE 12–13. Patent Owner argues that this patent concerns an "implantable stimulator with a replenishable, high value capacitive power source." *Id.* Thus, Patent Owner argues that this exhibit is not relevant to IPGs with rechargeable batteries, as claimed in the '280 patent. *Id.*

Exhibit 1134 describes that rechargable implantable stimulators are used in SCS systems. Ex. 1134, [57], 1:16–24. Whether SCS systems utilized rechargeable IPG technology, even if only capacitive power sources, is relevant to whether a long-felt need existed for rechargeable IPG technology for SCS systems, i.e., it has *at least some tendency* to make that fact more probable. *See* FRE 401; *Biery*, 2012 WL 4497656, at *4. Patent Owner's arguments speak more to weight than admissibility.

Accordingly, this portion of Patent Owner's Motion is *denied.* We admit Exhibit 1134 and afford it appropriate weight.

5. Exhibit 1137 - Kroll Reply Declaration

Patent Owner argues that cited portions of Exhibit 1137 are irrelevant, under FRE 402. PO MTE 13 (citing Ex. 1137 ¶¶ 37–43, 45, 49, 50). Patent Owner incorporates its arguments regarding Exhibits 1122, 1125–1128, 1130–1132, 1139. *Id.* For the same reasons discussed above in Sections III.B.2.i., III.B.2.iv.–vi., we determine that it is permissible for Dr. Kroll to provide testimony on these topics, or rely upon these exhibits and, accordingly, Patent Owner's Motion is *denied.* We admit Exhibit 1137 and afford it appropriate weight.

6. Summary

Patent Owner's Motion to Exclude is *dismissed-in-part* as moot, and *denied-in-part*, for the reasons detailed above.

IV. OBJECTIONS TO DEMONSTRATIVES

Patent Owner and Petitioner each filed demonstrative exhibits for use during oral argument (Papers 76, 77). The parties also filed a joint set of objections to those demonstratives. Paper 75. Patent Owner objects to Petitioner's slide numbers 10, 14–20, 23–31, 36, 40, 41, 44, 45, 56, 79, 83, 88, 98, and 105. *Id.* at 1. Petitioner objects to Petitioner's slide numbers 69 and 70. *Id.*

Demonstrative exhibits are not evidence; they are merely visual aids to assist the parties in presenting their arguments to the Board. Paper 61, 3. In this Final Written Decision, we rely only on arguments made in the parties' substantive papers and evidence of record. Because we do not rely

upon the cited slides in this Decision, we *dismiss* the parties' objections as moot.

V. ANALYSIS

A. Obviousness over Barreras or over the Combined Teachings of Barreras and Wang

Petitioner contends that claim 27 would have been obvious over Barreras or over the combined teachings of Barreras and Wang. Pet. 16–28. For reasons that follow, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Barreras (Ex. 1008)

Barreras is a U.S. patent titled "RF Coupled, Implantable Medical Device with Rechargeable Back-up Power Source," which discloses a tissue stimulator system. Ex. 1008, [54], 7:35–38. Barreras's Figure 1 is reproduced below.

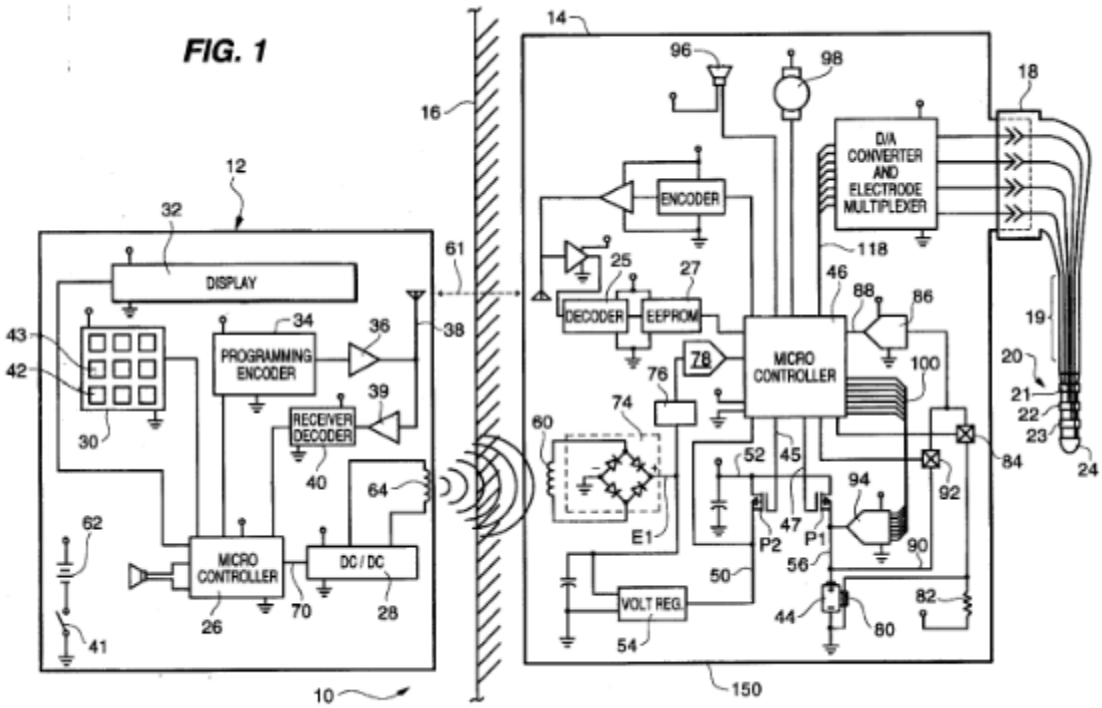

Figure 1 is a circuit diagram of the system, which includes transmitter 12 and implantable receiver 14. *Id.* at 7:6–9, 7:36–38. Receiver 14 is connected by multiple leads 19 to electrodes 21–24, which stimulate the patient's tissue in response to therapy values sent from transmitter 12. *Id.* at 7:38–47.

Barreras explains that when rechargeable power source 44 of the implanted receiver is low, "receiver 14 will transmit, via an RF communication link 61, a 'recharge' command to the transmitter 12." *Id.* at 8:35–39. In response, transmitter 12 generates—through external battery 62, DC/DC converter 28, and output inductor 64—"high energy RF waves which are coupled into the inductor 60 contained within the receiver 14" to recharge implanted power source 44. *Id.* at 8:39–43. Barreras explains that a feedback system between receiver 14 and transmitter 12 "adjust[s], as a function of distance between the inductors 64 and 60, the RF energy

required to quickly recharge the rechargeable power source 44. A close proximity requires much less RF energy to recharge the rechargeable power source 44 than a longer distance would, in the same time." *Id.* at 8:43–55.

Barreras also explains that implanted microcontroller 46 monitors the voltage level of power source 44. *Id.* at 9:7–11. When power source 44 is fully charged, the microcontroller sends "a 'stop' recharging command" to transmitter 12, and "simultaneously . . . cut[s] off the current needed to charge the rechargeable power source 44. In this manner, the power source 44 cannot be overcharged, even if the 'stop' command was not received by the transmitter 12 due to electromagnetic interference." *Id.* at 9:11–18.

2. Overview of Wang (Ex. 1018)

Wang is a U.S. patent titled "Enhanced Transcutaneous Recharging System for Battery Powered Implantable Medical Device." Ex. 1018, [54]. Wang discloses that an external inductor "forms a primary coil of a transformer in which current is induced in a secondary coil attached to an implanted medical device" to recharge the battery of the implanted device. *Id.* at 4:37–41. According to Wang, "[t]he coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." *Id.* at 5:13–15. To that end, Wang discloses an alignment circuit and alignment indicator that indicate proper alignment. *Id.* at 5:15–17.

3. Analysis of Claim 27

Petitioner contends that claim 27 would have been obvious over Barreras alone or, alternatively, over Barreras and Wang. Pet. 16–28, 25

("[T]o the extent further disclosure is required for claim element [27.b], it would have been obvious in further view of Wang.").

Patent Owner disputes Petitioner's contentions. PO Resp. 28–39. Patent Owner argues that Barreras does not "align[]" the primary and second coils, and does not "stop[] the charging at the battery charger," as claimed. *Id.* at 28–33. Patent Owner also argues that a POSITA would not have been motivated to combine Barreras and Wang. *Id.* at 33–39.

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 27 is unpatentable over Barreras alone. Accordingly, we need not reach Petitioner's alternative contention that claim 27 would have been obvious over the combined teachings of Barreras and Wang.

i. Preamble

The preamble of independent claim 27 recites "[a] method of charging a rechargeable battery contained within an implantable pulse generator (IPG), which IPG is connected to an implanted, secondary coil antenna, the method employing an external battery charger, which charger contains a rechargeable battery electrically connected to an external, primary antenna coil, the method comprising . . . ." Ex. 1001, 57:37–43. Petitioner contends that Barreras discloses this subject matter. Pet. 17–19. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 28–33.

We find that Barreras discloses implanted receiver 14 (i.e., pulse generator), which includes rechargeable power source 44 and inductor coil 60, wherein power source 44 is charged by RF energy transmitted from output inductor coil 64 of external transmitter 12. Ex. 1008, 5:34–41, 7:36–38, 8:33–35, 8:39–43, Fig. 1. Barreras discloses that external transmitter 12

includes rechargeable battery 62, connected to output inductor coil 64. *Id.* at 8:39–43; *see also* Ex. 1003 ¶¶ 71–72. Thus, we find that Barreras teaches the subject matter of the preamble of claim 27.

ii. "(a) charging the rechargeable battery in the external battery charger using an external power source"

Petitioner contends that Barreras discloses this limitation because external transmitter 12 is powered by a rechargeable battery, which must be charged from an external source before transmitter 12 can transfer power. Pet. 19. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 28–33.

We find that Barreras discloses that external transmitter 12 is "powered by either a rechargeable or non-rechargeable power source." Ex. 1008, 4:18–20, Fig. 1 (62). We credit Dr. Kroll's testimony that the rechargeable power source must be charged from an external power source, e.g., an AC outlet or external battery, to power the transmitter. Ex. 1003 ¶ 73. Thus, we find that Barreras teaches this limitation of claim 27.

iii. "(b) aligning the primary antenna coil with the implanted secondary coil"

Petitioner contends that Barreras discloses this limitation, or at least would have rendered it obvious to a POSITA. Pet. 19–21. According to Petitioner, Barreras discloses transferring RF energy from external coil 64 to implanted coil 60, wherein the distance between those coils affects the amount of energy required to recharge the implanted power source quickly, i.e., less energy being required when the coils are in close proximity. *Id.* at 19–20 (citing Ex. 1008, 8:26–32, 8:39–43, 8:49–55). Petitioner contends that "Barreras thus expressly discloses that some form of alignment between

transmitter's inductor 64 and receiver's inductor 60 is necessary to recharge the rechargeable battery in the implant. Figure 1 . . . shows coils 60 and 64 are aligned and transferring energy." *Id.* at 20. Alternatively, Petitioner contends that it would have been "obvious to align Barreras's transmitter and receiver coils because better alignment between the transmitter's and receiver's inductors would conserve the transmitter's battery power by more efficiently recharging the implanted battery." *Id.* at 21 (citing Ex. 1003 ¶¶ 74–75; Ex. 1008, 8:49–53).

Patent Owner disputes Petitioner's contention, arguing that Barreras does not satisfy its proposed construction of "alignment," because Barreras does not optimize charging efficiency based on a measurement of an electrical parameter. PO Resp. 28. Patent Owner argues that Barreras teaches away from aligning the coils, because Barreras adjusts the amount of RF energy transferred between the coils to compensate for the distance between them. *Id.* at 28–30 (analogizing to turning up a loudspeaker's volume, rather than altering its position). According to Patent Owner, because Barreras's system "is designed to adapt to any positioning" of the coils, it "obviates the need to achieve any particular spatial arrangement," i.e., alignment. *Id.* at 28–30 (citing Ex. 1008, 5:51–60, 8:43–55; Ex. 2033 ¶¶ 74–78); *see also* PO Sur-Reply 4. Thus, Patent Owner argues that "Barreras teaches no more than that inductive charging can occur . . . but not that the inductors are 'aligned.' But claim 27 requires 'aligning' as a separate step from '(f) charging the rechargeable battery carried within the IPG." PO Resp. 30.

Petitioner replies that "Barreras does not 'teach[] away' from achieving any particular spatial arrangement of the coils. Rather, Barreras

expressly teaches the advantage (e.g., less RF energy) of achieving a particular spatial arrangement (e.g., close proximity)." Pet. Reply. 11; *see also id.* at 9–10 (addressing Patent Owner's proposed construction).

We have considered the parties' arguments and evidence, and determine that the cited evidence supports Petitioner's contentions. Barreras discloses that external transmitter 12 includes output inductor coil 64 ("primary"), and implanted receiver 14 includes implanted inductor coil 60 ("secondary"). Ex. 1008, 8:39–43, Fig. 1. As shown in Figure 1, these coils are "aligned," under the broadest reasonable interpretation of this phrase, *see supra* Section II.A.1., because they are in relative position to permit energy transfer. Ex. 1008, 8:39–43 ("[H]igh energy RF waves . . . are coupled into the inductor 60.").

We recognize that Barreras adjusts the amount of energy that primary coil 64 transmits to secondary coil 60, to compensate for the distance between coils 64, 60. Ex. 1008, 8:49–55. We do not agree, however, that this teaching "obviates the need" to align the coils, as Patent Owner argues. PO Resp. 28–30. Rather, we perceive that this teaching highlights the importance of aligning the coils—Barreras explains that "[a] close proximity requires much less RF energy to recharge [quickly] the rechargeable power source 44 than a longer distance would." Ex. 1008, 8:52 ("quickly"), 8:53–55. Indeed, we note that this appears to be a principle that would have been understood by someone with even fewer qualifications than a POSITA, as defined in this proceeding—even a high school student who had taken an introductory physics course in electricity and magnetism would have been expected to possess such knowledge. Moreover, as discussed in Section II.A.1, the step of "aligning" does not require a specific relative position, or

achieving optimal or proper alignment. Nonetheless, even if it did, we determine that, in light of Barreras's teachings, a POSITA would have found it obvious to adjust the position of the coils, i.e., by moving them into "close proximity" and optimal alignment, to achieve the benefits expressly taught by Barreras, i.e., the use of less RF energy to achieve the same result. Ex. 1008, 8:53–55; *see also* Pet. 21; Pet. Reply n.6.

Dr. Kroll's testimony supports this conclusion. Dr. Kroll testifies that Barreras's Figure 1 shows that the coils are aligned, as required to transfer energy between them. Ex. 1003 ¶¶ 74–75. According to Dr. Kroll, Barreras confirms that it was known in the art that "better alignment . . . increases charging efficiency and, further, conserves the transmitter's battery." *Id.* ¶ 75 (citing Ex. 1008, 8:49–53). Dr. Kroll also testifies that "Barreras teaches that there are advantages to properly aligning the external and implanted coils even with its real-time feedback system," namely, "that it requires much less RF energy to recharge the IPG's battery than a longer distance would in the same time, thus preserving the transmitter's battery." Ex. 1137 ¶¶ 17–18. In light of Barreras's express teachings of the benefits of close alignment, and Dr. Kroll's testimony that a POSITA would have understood these teachings to suggest moving the coils into even closer proximity, we are persuaded that Petitioner has provided very strong evidence in support of its contentions.

We have considered the cited portions of Dr. Berger's testimony, but do not agree with his conclusions. Ex. 2033 ¶¶ 28, 73–76, 78. For example, Dr. Berger explains that "[o]ptimal alignment (to achieve maximum efficiency) occurs when the central axis of the two coils fall on the same line, i.e., the axes are parallel to each other with the coils centered one over

the other . . . [and] as close to each other as possible." *Id.* ¶ 74. Our construction of "aligning," however, requires neither optimal alignment, parallel axes, nor any specific level of closeness. Moreover, Dr. Berger explicitly recognize Barreras's teaching that close proximity between coils results in less RF energy being needed to complete recharging, *id.* ¶ 75, but then makes a contorted analysis, analogizing to a loudspeaker, to conclude that a POSITA would not have taken the miniscule logical step to move the coils into a closer proximity to achieve this self-evident benefit. *See, e.g.*, *id.* ¶¶ 76–78. Although Barreras discloses adjusting the level of energy output to compensate for distance, we determine that a POSITA, who is "a person of ordinary creativity, not an automaton," also would have recognized that moving the coils into "close proximity" would have achieved the benefits expressly taught by Barreras, i.e., the use of less RF energy to achieve the same result. *See, e.g.*, Ex. 1137 ¶¶ 17–18; *KSR*, 550 U.S. at 421.

Finally, we do not agree with Patent Owner's argument that this interpretation conflates the "aligning" step with the separate step of "charging the rechargeable battery." PO Resp. 30. As discussed above, *see supra* Section II.A.1., our construction of "aligning" does not collapse this step into the separate "charging" step. Rather, as properly construed, step (b) of claim 27 requires placing the primary and secondary coils in relative position *to permit* energy transfer; it does not require the step of actually transferring energy. Steps (c)–(f) do.

Accordingly, for the reasons set forth above, we determine that Petitioner has provided very strong evidence that Barreras at least renders obvious this limitation of claim 27.

iv. "(c) broadcasting electromagnetic energy through the primary antenna coil"

Petitioner contends that Barreras discloses this limitation because external transmitter 12 broadcasts RF energy through output inductor coil 64. Pet. 21–22. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 28–33.

We find that Barreras discloses that transmitter 12 "generate[s], via the battery 62, the DC/DC converter 28 and an output inductor 64, high energy RF waves which are coupled into the inductor 60 contained within the receiver 14." Ex. 1008, 8:39–43; *see also id.* at 5:34–41 (inductive RF power link); Ex. 1003 ¶ 78. Thus, we find that Barreras teaches this limitation of claim 27.

v. "(d) receiving the broadcast electromagnetic energy through the secondary antenna coil, whereby an alternating current is produced in the secondary coil"

Petitioner contends that Barreras discloses this limitation because coil inductor 60 of implanted receiver 14 receives the RF energy broadcasted by transmitter 12, which is alternating. Pet. 22–23. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 28–33.

As above, we find that Barreras discloses that transmitter 12 generates RF energy that is "coupled into the inductor 60 contained within the receiver 14." Ex. 1008, 8:39–43; Ex. 1003 ¶ 79. Barreras explains that the "RF coupled power . . . is alternating current or AC in nature." Ex. 1008, 4:62–67; Ex. 1003 ¶¶ 80–83 (opining that "the output from inductor 60 must be alternating current, otherwise there would be no need for the implanted device to include rectifier 74"). Thus, we find that Barreras teaches this limitation of claim 27.

vi. "(e) rectifying the induced, alternating current received by the secondary coil"

Petitioner contends that Barreras discloses this limitation because the RF power received by receiver 14 is rectified. Pet. 23. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 28–33.

We find that Barreras discloses that the "RF coupled power . . . is rectified, filtered and converted into a high DC voltage within the receiver." Ex. 1008, 4:64–67; Ex. 1003 ¶¶ 81–84. Thus, we find that Barreras teaches this limitation of claim 27.

vii. "(f) charging the rechargeable battery carried within the IPG, while monitoring the charging current or voltage across the battery as the battery is being charged to prevent overcharging"

Petitioner contends that Barreras discloses this limitation because microcontroller 46 monitors the voltage level of rechargeable power source 44, while it is being recharged. Pet. 24. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 28–33.

We find that Barreras discloses that "during recharging of the power source 44, micro controller 46 will monitor the voltage level of the power source 44 . . . . In this manner, the power source 44 cannot be overcharged." Ex. 1008, 9:7–17, 9:44–53; Ex. 1003 ¶ 85. Thus, we find that Barreras teaches this limitation of claim 27.

viii. "(g) stopping the charging at the battery charger when the current or voltage at the battery in the IPG reaches a prescribed level"

Petitioner contends that Barreras discloses this limitation because microcontroller 46 sends a termination command to transmitter 12, instructing it to stop recharging, when power source 44 is fully recharged.

Pet. 24. Upon receipt, Petitioner contends that transmitter 12 terminates the transmission of RF power, which stops the recharging. *Id.* at 24–25 (citing Ex. 1008, 4:34–39, 9:7–17, 9:44–53; Ex. 1003 ¶ 86).

Patent Owner argues that it is "circuitry *within the IPG* rather than 'at the battery charger'" that stops the charging of implantable power source 44. PO Resp. 31–33 (citing Ex. 1008, 9:10–17, 9:45–53; Ex. 2033 ¶¶ 80–81). Specifically, Patent Owner argues that microcontroller 46 turns off D/A converter 94 (located within implanted receiver 14), which stops the recharging. *Id.* at 31. Thus, although Barreras discloses that a "stop recharging command" is sent to the transmitter, "the critical step of 'stopping the charging' has already occurred at the implanted D/A converter, simultaneously with the *transmission* of a message to the external device." *Id.* at 31–32. According to Patent Owner, turning off the D/A converter ensures that overcharging cannot occur, even if the termination command is not received by the transmitter. *Id.* at 32.

Petitioner replies that "Barreras discloses embodiments where the charger cuts off the current and the IPG does not." Pet. Reply. 12 (citing Ex. 1008, 4:34–39, 6:15–20).

We have considered the parties' arguments and evidence, and we determine that the cited evidence supports Petitioner's contention, in that while the "preferred embodiment" may support Patent Owner's argument, other cited portions of Barreras support Petitioner. Specifically, Barreras discloses a "preferred embodiment" in which microcontroller 46 monitors the voltage of rechargeable power source 44 and, upon sensing that it is fully charged, "will telemeter to transmitter 12 . . . a 'stop' recharging command and *simultaneously will turn off a D/A converter* 94 [in the implanted

receiver] which will cut off the current needed to charge the rechargeable power source 44." Ex. 1008, 9:4–15 (emphasis added). Thus, in this embodiment, Patent Owner is correct that it is the D/A converter 94, *at the implanted receiver*, that "stop[s] the charging" at the same time a termination command is sent to the external charger. *Id.* at 9:4–15.[10] Barreras explains that this approach provides redundancy—"the power source 44 cannot be overcharged, even if the 'stop' command was not received by the transmitter 12 due to electromagnetic interference." *Id.* at 9:15–17.

Petitioner, however, relies upon additional disclosures of Barreras. For example, Barreras explains that, in a second mode of operation, the transmitter will recharge the implanted power source and "will terminate the RF transmission upon receiving from the receiver a 'termination command' which indicates that the back-up power source is fully charged." *Id.* at 4:34–39 (cited at Pet. 24; Reply 12). In this mode, Barreras does not disclose a redundant mechanism for terminating recharging, e.g., turning off the D/A converter. Patent Owner does not address these disclosures in its Response or Sur-Reply, nor does Dr. Berger address them in his Declaration. PO Resp. 31–33; PO Sur-Reply 4–5; Ex. 2033 ¶¶ 80–81; *see also* Pet. Sur-Sur-Reply 5. Thus, we determine that Petitioner has shown sufficiently that in

[10] We are not persuaded by Petitioner's argument that the "comprising" claim language allows both the implanted device and the external charger to stop the charging, because we are not persuaded that "the charging" can be stopped more than once. Pet. Reply 11–12. We agree with Patent Owner that "[i]t is axiomatic that if, as in Barreras, the D/A converter stops charging within the implanted device, 'the charging' cannot be stopped 'at the battery charger.'" PO Sur-Reply 5.

this mode of operation, charging is stopped *at the external battery charger*, "upon receiving . . . a 'termination command.'" Ex. 1008, 4:34–39, 6:15–20, claim 11, claim 28.

Thus, we find that Barreras teaches this limitation of claim 27.

4. Secondary Considerations

Patent Owner asserts that evidence of secondary considerations, i.e., objective indicia of non-obviousness, demonstrate that claims 8, 18, 22–24, 27 would not have been obvious. PO Resp. 72–80; PO Sur-Reply 30–33. Petitioner disagrees. Pet. Reply 29–35; Pet. Sur-Sur-Reply 5.

ix. Relevant Law

Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of non-obviousness, may lead to a conclusion that the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Such evidence must be considered, when present in the record. *In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011) ("[W]hen secondary considerations are present, though they are not always dispositive, it is error not to consider them.").

To be given substantial weight in the obviousness analysis, Patent Owner must demonstrate a causal relationship, i.e., a nexus, between the purported evidence of non-obviousness and the claimed invention. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). All types of objective evidence of non-obviousness must be shown to have nexus. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (nexus generally); *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (commercial

success); *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (copying); *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (long-felt need); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008) (praise).

Generally speaking, a showing of nexus is required to establish that the proffered evidence traces back to a novel element in the claim, not to something in the prior art. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). Objective evidence that results from something that is not "both claimed and novel in the claim," generally lacks a nexus to the merits of the invention. *In re Kao*, 639 F.3d at 1068. However, because the obviousness inquiry concerns the claimed invention as a whole, "[w]here the allegedly obvious patent claim is a combination of prior art elements . . . the patent owner can show that it is the claimed *combination as a whole* that serves as a nexus for the objective evidence." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016) (emphasis added).

The Federal Circuit holds that a rebuttable "presumption of nexus" applies "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *WBIP*, 829 F.3d at 1329. This presumption may be rebutted with a showing that, *inter alia*, the proffered evidence of non-obviousness was due to "extraneous features other than the patented invention," e.g., "additional unclaimed features," "external factors, such as improvements in marketing," or "non-novel" features of the device. *Id.* The stronger the showing of nexus, the greater the weight afforded to the objective evidence

of non-obviousness. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986).

x. Patent Owner's Products and Nexus

Patent Owner contends that its Precision and Spectra systems practice claims 8, 18, 22–24, and 27 of the '280 patent. PO Resp. 72, 76. Taking into account Petitioner's arguments in opposition, we find that the Precision Plus system practices claim 27. PO Resp. 72–76; Pet. Reply 30.

Claim 27

Regarding the preamble, we find that the Precision system includes an IPG with a rechargeable battery and an implanted coil, and an external battery charger with a rechargeable battery and an external coil. PO Resp. 73; Ex. 2034 ¶ 45. Regarding step (a), we find that the Precision Plus battery charger is "powered by a rechargeable battery" that is charged by an external power source, i.e., through a "universal-input, wall-mounted transformer provided with the charging base." PO Resp. 73; Ex. 2034 ¶ 46; Ex. 2014, 95.[11] Regarding step (b), we find that the coils of the external charger and implanted stimulator are aligned through an alignment indicator. PO Resp. 74; Ex. 2034 ¶ 47; Ex. 2016, 47[12] ("Place the Charger over the Stimulator. When the Charger is aligned with the Stimulator, the beeping

[11] Page numbers cited herein refer to the Advanced Bionics Corporation document page numbering, i.e., "Page [ ] of 108."

[12] Page numbers cited herein refer to the Clinical Manual page numbering, i.e., "91083273-01 Rev A [] of 69."

will stop."); Ex. 2025, 12[13] (similar).[14] Regarding steps (c) and (d), we find that the charger transcutaneously charges the implanted coil, which involves broadcasting electromagnetic energy through the primary antenna coil and receiving it through the implanted coil. PO Resp. 74; Ex. 2034 ¶¶ 48–49; Ex. 2014, 95. Regarding step (e), we find that the IPG rectifies the received energy from AC to DC constant current. PO Resp. 75; Ex. 2034 ¶ 50; Ex. 2014, 96–97. Regarding step (f), we find that the IPG's battery is charged, while being monitored to prevent overcharging. PO Resp. 75; Ex. 2034 ¶ 51; Ex. 2014, 17 ("Battery Over-Voltage Protection"). Regarding step (g), we find that the charger stops the charging at the battery charger when the battery voltage reaches a prescribed level. PO Resp. 75–76; Ex. 2034 ¶ 52; Ex. 2014, 19 ("IPG End of Charger Indication"), 95–96 ("The Recharger shall automatically shut off if the IPG back-telemetry link to indicate full charge is detected.").

Claims 8, 18, and 22–24

Patent Owner also contends that its products practice claims 8, 18, and 22–24. PO Resp. 72, 76. The Response identifies certain limitations[15] of

[13] Page numbers cited herein refer to the Charger Handbook page numbering, i.e., "90657810-01 REV D [ ] of 18."

[14] We are not persuaded by Petitioner's argument that a user is involved in the alignment step, because this is not precluded by the claim. Pet. Reply 30. Nor are we persuaded by Petitioner's argument directed to Patent Owner's proposed construction, which we do not adopt. *Id.*; Section II.A.1.

[15] The Response contends that its products are "spinal cord stimulation systems . . . [with] an implantable electrode array detachably connected to the IPG . . . an external trial stimulator . . . a multiplicity of M stimulation channels, each independently programmable with different stimulation

these claims that Patent Owner contends are practiced by its products. *Id.* at 76. Otherwise, Patent Owner refers to Exhibit C of the Lipson Declaration, which presents a detailed claim chart, addressing all limitations of these claims. *Id.* (citing Ex. 2034, Ex. C).

As referenced in Section III.A., Petitioner seeks to exclude Exhibit C of the Lipson Declaration, arguing that Patent Owner improperly attempts to incorporate it by reference, in violation of 37 C.F.R. § 42.6(a)(3). Pet. MTE 3. Section 42.6(a)(3) states that "[a]rguments must not be incorporated by reference from one document into another document."

The Patent Owner Response itself fails to discuss certain elements of claims 8, 18, and 22–24 that are not present in exemplary claim 27. *Id.* at 76. Specifically, with respect to claim 8, the Response does not address "a multi-channel implantable pulse generator having a replenishable power source, the IPG having a housing which contains IPG processing circuitry," "wherein m is equal to or less than n, and m is 2 or greater," or "a percutaneous extension." *Id.* With respect to claim 18, the Response does not address the "soft ramping circuit" limitation. *Id.* And with respect to claims 22–24, the Response does not address the "alignment circuitry" limitation. *Id.* These limitations are discussed *only* in Exhibit C of the Lipson Declaration. *See* Ex. 2034, 43–53 (claim 8), 53–57 (claim 18), 64–68 (claims 22–24). However, Patent Owner's attempt to incorporate the content of Exhibit C into its Response in this manner plainly violates Section 42.6(a)(3). *See* Pet. Opp. MTE 3 (citing *Hulu, LLC v. Intertainer,*

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parameters . . . [and] an alarm generator [that] broadcasts an audible tone when the primary and secondary coils are properly aligned." PO Resp. 76.

Inc., IPR2014-01456, Paper 11, 8 (PTAB Oct. 15, 2015)).[16] Thus, we afford no weight to the Lipson Declaration's Exhibit C, or the exhibits cited therein, that are not set forth independently in the Patent Owner Response, when considering Patent Owner's arguments regarding claims 8, 18, and 22–24.

With this in mind, we do not agree with Patent Owner's contention that its products practice claims 8, 18, and 22–24, because Patent Owner has not shown that its products practice, *inter alia*, "a multi-channel implantable pulse generator having a replenishable power source, the IPG having a housing which contains IPG processing circuitry," "wherein m is equal to or less than n, and m is 2 or greater," "a percutaneous extension," a "soft ramping circuit," or "alignment circuitry." PO Resp. 76.

Nexus

As discussed above, Patent Owner has shown that its Precision system practices claim 27 of the '280 patent. Additionally, as discussed below, much of Patent Owner's proffered objective evidence of non-obviousness relates to this product. Accordingly, a rebuttable "presumption of nexus" applies in this case, because Patent Owner has "show[n] that the asserted objective evidence is tied to a specific product [i.e., the Precision Plus] and that product 'is the invention disclosed and claimed in [claim 27 of] the

[16] Patent Owner cites to *Unified Patents Inc. v. Olivistar, LLC*, IPR2015-01217, Paper 15, at 13 (PTAB Nov. 20, 2015) in arguing that claim charts may provide support for arguments provided in a paper. PO Opp. MTE 5–6. However, Patent Owner fails to identify where, in a substantive paper, it showed how its products practice the identified limitations of claims 8, 18, or 22–24.

patent.'" *WBIP*, 829 F.3d at 1329. Patent Owner has not established a nexus between claims 8, 18, and 22–24 and the objective evidence of non-obviousness, because Patent Owner has not shown that its products practice these claims.

The presumption of nexus for claim 27 may be rebutted if Patent Owner's evidence of secondary considerations was due to extraneous features. *WBIP*, 829 F.3d at 1329. Also, less weight will be afforded to evidence that results from something that is not "both claimed and novel in the claim." *In re Kao*, 639 F.3d at 1068. Moreover, secondary consideration evidence may be afforded less weight for claims that are considerably broader than the particular features of Patent Owner's product that practices the claim. *See ClassCo, Inc. v. Apple*, 838 F.3d 1214, 1222–1223 (Fed. Cir. 2016).

Patent Owner does not argue that it is the combination as a whole that serves as a nexus for the objective evidence (*WBIP*, 829 F.3d at 1330); rather, Patent Owner focuses on the use of rechargeable technology in SCS systems to establish nexus. *See, e.g.*, PO Sur-Reply 32. Patent Owner contends that its proffered objective evidence regarding long-felt need (PO Resp. 78), industry praise (*id.* at 78–79), and commercial success (*id.* at 79–80) demonstrates the non-obviousness of the rechargeable technology reflected in the claims. According to Patent Owner, the "rechargeable IPG . . . was a novel feature in SCS systems and therefore can establish a nexus between secondary indicia evidence and the claimed invention." PO Sur-Reply 32. Patent Owner argues that "it is sufficient that industry recognition and commercial success was at least partly attributable to the rechargeable battery feature." *Id.*

xi. Long-Felt Need

Patent Owner relies upon the Lipson Declaration in arguing that, prior to the '280 patent, a long-felt need existed for SCS systems that improved upon existing RF powered systems, and existing primary cell systems. PO Resp. 76–78. Dr. Lipson explains that these systems suffered from disadvantages, including an external unit that interfered with normal activities (in RF systems) and limitations on stimulation (in primary cell systems). *Id.* at 77; Ex. 2034 ¶¶ 54–55. According to Dr. Lipson, the Precision system addressed this need by introducing an SCS system with "rechargeable IPG technology." Ex. 2034 ¶ 56 (citing Ex. 2026). Dr. Lipson testifies that the Precision system provided appropriate stimulation, including multichannel and high frequency stimulation, without the lifestyle limitations of RF systems. *Id.* ¶ 57. Additionally, Dr. Lipson testifies that the system provided longer service life and minimized surgical battery replacements. *Id.*

Petitioner replies that the "alleged long-felt need for a rechargeable IPG was satisfied before the '280 [patent]" because, e.g., rechargeable pacemakers were well known. Pet. Reply 33 (citing Ex. 1124, 221:14–20; Ex. 1126, 197:7–14; Ex. 1127, 345:20–346:18; Ex. 1128, 277:16–278:9; Ex. 1130, 168:4–9; Ex. 1134, 1:19–24, 1:27–35, 7:26–30, 10:54–57). Petitioner introduces Dr. Lipson's testimony, from cross-examination, that it was known and intuitive that rechargeable IPGs also would be beneficial in an SCS system. *Id.* (citing Ex. 1125, 133:1–134:5). Petitioner also asserts that it was constraints of rechargeable batteries themselves that prevented use of rechargeable IPG technology in SCS systems. *Id.* (citing Ex. 1009, 43; Ex. 1124, 175:5–25 (need for long-lasting battery with quick recharge)).

Thus, Petitioner contends that if a long-felt need existed, it was for a specific type of rechargeable battery that is not claimed in the '280 patent.

Dr. Lipson's testimony, which stands unrebutted by testimony of Petitioner's declarant (*see* Pet. Reply 33–34), supports Patent Owner's contention that the Precision system addressed a long-felt need in the SCS industry by introducing a SCS system with "rechargeable IPG technology," including a rechargeable battery. Ex. 2034 ¶¶ 56–57 (explaining that the Precision system "did not need surgical replacements of the battery as frequently," and "allowed high power capabilities for complex multichannel stimulation and high frequency stimulation"). However, we agree with Petitioner that record evidence, including Dr. Lipson's testimony, shows convincingly that "IPGs with a replenishable power source"—namely, rechargeable pacemakers—were well known at the critical date. Ex. 1124, 221:14–20 (also opining, "I know there were pacemakers with rechargeable batteries prior to 1999"); Ex. 1126, 197:7–14 (similar); Ex. 1127, 345:20–346:18 (similar); Ex. 1128, 277:16–278:9 (similar); Ex. 1130, 168:4–9 (similar). Petitioner also shows that IPGs for SCS systems included rechargeable IPG technology prior to the critical date, albeit with a rechargeable *capacitive* power source, instead of a rechargeable battery, as reflected in claim 27. *See* Ex. 1134, 1:19–24, 1:27–35, 7:26–30, 10:54–57; PO MTE 12–13.

Thus, we find that Patent Owner has provided some evidence of long-felt need, although the evidence also indicates that potential solutions were well known. The weight afforded is, thus, minimal. Moreover, secondary consideration evidence may be afforded less weight for claims that are considerably broader than the particular features of the product that practices

the claim. *See ClassCo, Inc. v. Apple*, 838 F.3d at 1222–1223. Here, claim 27 is not directed to IPGs with rechargeable batteries *in SCS systems*, which is the focus of Patent Owner's evidence. Rather, claim 27 more broadly recites a "method of charging a rechargeable battery contained within an implantable pulse generator (IPG)," without further limitation to SCS systems. Accordingly, we determine that Patent Owner's evidence supports, at best, only a very weak finding of long-felt need for the invention embodied in claim 27.

xii. Industry Recognition

Petitioner contends that the Precision system received "substantial praise and industry recognition for the features enabled by the claims of the '280 patent." PO Resp. 78 (citing Ex. 2034 ¶¶ 58–59). Patent Owner identifies an article, published in 2005, discussing the "Precision™ spinal cord stimulator," which explains that "the Precision device offers a number of unique features," including a "[r]echargeable battery," and "[b]ecause the Precision battery is rechargeable, patients do not need to limit the amount of electricity they use." Ex. 2036, 1, 4. Patent Owner also identifies a 2009 book that includes a chapter discussing spinal cord stimulation, which explains that "[t]he impact of the introduction of the Precision and Bion products on the neuromodulation market has been tremendous," and, "in less than two years' time the Precision system became the number two player in the market and before its third year on the market has already over 13000

patients implanted . . . and enjoys greater than 30% market share." Ex. 2015, 39–40;[17] *id.* at 36–40 (use for spinal cord stimulation).

Petitioner contends that the 2005 article (Ex. 2036) describes numerous other "unique" features of the system, including "[p]atient control" and "[s]maller size," which are not reflected in the '280 patent claims. Pet. Reply 34. Additionally, Petitioner contends that the 2009 article (Ex. 2015) was written by an inventor of the '280 patent, Mr. Paul M. Meadows, and argues that "an inventor's praise for his own invention hardly qualifies as 'industry recognition.'" Pet. Reply 34.

Regarding Exhibit 2036, we agree with Patent Owner that the praise for the Precision system conveyed in the cited portions of the article is directed to a combination of features, including its "[r]echargeable battery" (and attendant lack of limitations on use), as well as "[p]atient control," and "[s]maller size." Ex. 2036, 4. Thus, the evidence suggests that at least some portion of the documented industry recognition is attributable to the rechargeable battery technology embodied in claim 27.

Regarding Exhibit 2015, we recognize that the chapter lauding "[t]he impact of the introduction of the Precision" system was authored by an inventor of the '280 patent. *Compare* Ex. 2015, 29, 39–40, *with* Ex. 1001, (75). We do not find this fact, however, to detract entirely from the weight to be afforded to this exhibit. This article was published as part of a compilation of works from numerous authors and, as such, bears at least some indication that its content was reviewed by the book editors or contributors, and deemed sufficiently unbiased for publication. *See, e.g.*,

[17] We note that this evidence also bears on commercial success, and is also addressed below. *See infra* V.A.4.xiii; PO Resp. 79.

Ex. 2015, xiii–xxiii. Moreover, regardless of whether Mr. Meadows is an inventor on the '280 patent, this chapter was published and made available to the SCS industry, and the cited portions of the exhibit present evidence demonstrating the success of the Precision system.

For these reasons, we find that Patent Owner has provided some evidence of industry recognition for claim 27 of the '280 patent. Again, however, secondary consideration evidence may be afforded less weight for claims that are considerably broader than the particular features of the product that practices the claim. *See ClassCo, Inc. v. Apple*, 838 F.3d at 1222–1223. Here, the evidence suggests that the improvement offered by the '280 patent was the "unique" combination of features, including the rechargeable battery noted above, as applied to a SCS system, which is notably narrower than the scope of claim 27. As discussed above, claim 27 is directed broadly to a "method of charging a rechargeable battery contained within an implantable pulse generator (IPG)," and covers non-SCS systems, such as rechargeable pacemakers. *See, e.g.*, Ex. 1124, 221:14–20 (Dr. Berger's testimony that, prior to 1999, there existed IPGs with replenishable power sources, and pacemakers with rechargeable batteries). Accordingly, we determine that Patent Owner's evidence supports, at best, a moderate finding of industry recognition for the invention embodied in claim 27.

xiii. Commercial Success

Patent Owner relies on the Lipson and Bone Declarations to support its argument that the Precision systems enjoyed commercial success, in terms of increased number of units sold, market share, and gross sales volume. Ex. 2035 ¶ 14 (market share), ¶ 15 (sales volume), ¶ 16 (gross

profit); Ex. 2008 (sales and gross profit); PO Resp. 79 (citing Ex. 2034 ¶ 60; Ex. 2035 ¶¶ 13–16; Ex. 2037; Ex. 2038; Ex. 2008; Ex. 2015, 39–40). This is consistent with the reported success of the Precision system, discussed above. Ex. 2015, 39–40.

Petitioner argues that this evidence does not demonstrate that the commercial success was due to the rechargeable IPG feature. Pet. Reply 35. Patent Owner argues, however, and we agree, that we may take into account evidence that is at least partially attributable to the merits of the invention. PO Sur-Reply 32.

Neither Dr. Lipson nor Dr. Bone opine as to the driver of the Precision's success, although Dr. Lipson provides the conclusory statement that "[a]fter Boston Scientific's Precision Plus system with the rechargeable battery became commercially available, the market began to recognize its advantages, and the rechargeable battery design was widely adopted." Ex. 2034 ¶ 60; Ex. 2035 ¶¶ 13–16. As discussed above regarding Patent Owner's evidence of industry recognition, the evidence suggests that the praise for—and commercial success of—the Precision system is directed to a combination of features, including its "[r]echargeable battery." Ex. 2036, 4. This is consistent with Dr. Lipson's testimony that many factors are considered by a physician, when selecting an SCS system. Ex. 1125, 62:7–66:4, 77:11–25 (factors other than rechargeability may drive selection). Thus, the evidence suggests that at least some portion of the documented commercial success is attributable to the rechargeable battery technology embodied in claim 27.

For these reasons, we find that Patent Owner has provided some evidence of commercial success for claim 27 of the '280 patent. Again,

however, secondary consideration evidence may be afforded less weight for claims that are considerably broader than the particular features of the product that practices the claim. *See ClassCo, Inc. v. Apple*, 838 F.3d at 1222–1223. Here, the evidence suggests that the improvement offered by the '280 patent was the "unique" combination of features, including the rechargeable battery noted above, applied to a SCS system, which is notably narrower than the scope of claim 27. Accordingly, we determine that Patent Owner's evidence supports, at best, a moderate finding of commercial success for the invention embodied in claim 27.

xiv. Weighing of Evidence

For the foregoing reasons, we find that Patent Owner has presented moderate evidence of industry recognition and commercial success, and some—but almost non-existent—evidence of long-felt need. As discussed above, the majority of Patent Owner's arguments and evidence is directed to the purportedly non-obvious use of rechargeable batteries in SCS systems, but claim 27 is not directed to a SCS system. Rather, claim 27 more broadly recites a "method of charging a rechargeable battery contained within an implantable pulse generator (IPG)." As such, even if a "rechargeable IPG . . . was a novel feature in SCS systems," as Patent Owner contends (PO Sur-Reply 32), such a feature is not recited in claim 27. Claim 27 is much broader and covers other IPGs, such as pacemakers, for which the record clearly shows that rechargeable technology was well known at the critical date. Accordingly, the weight we afford this evidence is minimal. *See ClassCo*, 838 F.3d at 1222–1223.

We weigh this evidence in conjunction with the other factors relevant to an obviousness analysis. As discussed in Section V.A.3., we find that

Barreras discloses expressly most elements of claim 27. With respect to the step of "aligning" the coils, we determine that Petitioner has demonstrated with convincing evidence that this step at least would have been obvious to a POSITA, especially in light of Barreras's explicit recognition of the benefits attendant to aligning the coils. Overall, upon weighing the factors, we determine that the moderate evidence of industry recognition and commercial success, and some, but almost non-existent, evidence of long-felt need, is insufficient to outweigh our very strong determination that Barreras accounts for every limitation of claim 27.

5. Conclusion

For the foregoing reasons, on this record, Petitioner has shown, by a preponderance of the evidence, that claim 27 would have been obvious in view of Barreras's teachings.

B. Obviousness over the Combined Teachings of Barreras and Engebretson

Petitioner contends that claims 28–30 would have been obvious over the combined teachings of Barreras and Engebretson. Pet. 28–37.[18] For reasons that follow, we determine Petitioner has not demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

[18] Petitioner's asserted ground of unpatentability relies upon "Barreras, with or without Wang," to account for the two alternative grounds including Barreras, as described in the preceding ground. Pet. 9 n.4; *see supra* V.A.3. Because we do not rely upon Wang with respect to Petitioner's challenge to claim 27, and Petitioner does not rely on Wang in the same manner that it relies on Engebretson, we do not include it here.

1. Overview of Engebretson (Ex. 1019)

Engebretson is a U.S. patent titled "Method of Readout of Implanted Hearing Aid Device And Apparatus Therefor." Ex. 1019, [54]. Engebretson's Figure 1 is reproduced below.

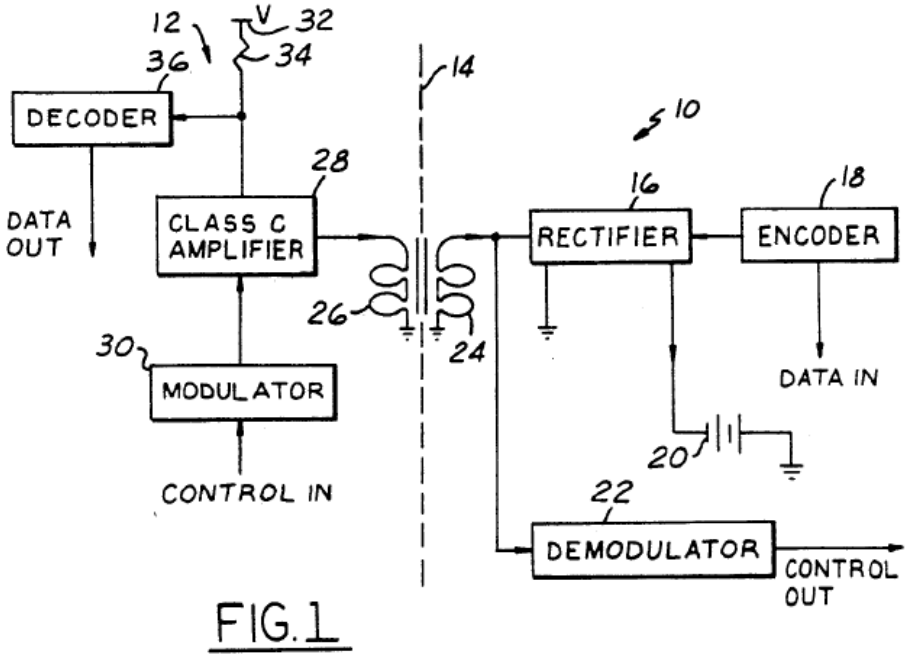

Figure 1 depicts a functional block diagram of the system, which includes implanted device 10 and external device 12. *Id.* at 2:9, 2:22–26. Implanted device 10 includes encoder circuit 18 and rectifier circuit 16, which provides an output that may be used to recharge battery 20. *Id.* at 2:28–32. Internal coil 24 and external coil 26 are inductively coupled. *Id.* at 2:37–39.

Engebretson explains that this system may be used to transmit a signal from implanted device 10 to external device 12 regarding conditions sensed beneath the skin, without requiring an internal transmitter or excessive power consumption. *Id.* at 1:33–38, 3:37–40. Specifically,

> Signals are conveyed from the implanted device [10] to the external device [12] using encoder 18. The signal to be conveyed is supplied to encoder 18 as DATA IN. Encoder 18 causes

> rectifier 16 to switch selectively between modes of half wave rectification and full wave rectification. The rectification modes may be considered as different binary states and in this fashion binary messages can be represented as changes in the impedance of the implanted device as a function of time.

Id. at 3:1–9. During this signal conveyance, whether in full or half wave rectification mode, "energy is nevertheless being delivered to the implanted device and may be used to charge . . . battery 20." *Id.* at 3:67–4:3. Therefore, "the invention makes it possible to recharge an implanted battery automatically as a benefit of obtaining a readout of conditions beneath the surface of the skin, e.g., previous settings of the implanted hearing aid." *Id.* at 4:3–7.

2. Analysis of Claims 28–30

Petitioner contends that claims 28–30 would have been obvious over the combined teachings of Barreras and Engebretson. Pet. 28–37.

Patent Owner disputes Petitioner's contentions. PO Resp. 40–42. Patent Owner argues, *inter alia*, that Engebretson fails to disclose or suggest "sensing the change in rectification . . . ," as recited in claim 28, and that a POSITA would not have been motivated to combine the references. *Id.*

After considering the parties' arguments and evidence, we determine that Petitioner has not met its burden of demonstrating that the challenged claims are unpatentable, by a preponderance of the evidence.

Analysis of Claim 28

Claim 28 depends from claim 27 and recites "[sensing][19] the change in rectification in the IPG using circuitry means located in the external battery charger, to thereby sense when the rechargeable battery in the IPG is fully charge[d]." Ex. 1001, 58:21–25.

Petitioner contends that Barreras detects when the implanted battery is fully charged, and transmits a termination command to the external charger to prevent overcharging of the battery. Pet. 29; *see supra* Section V.A.3.g. Petitioner acknowledges that Barreras does not sense a change in rectification, as claimed. Pet. 29–30. According to Petitioner, however, it would have been obvious to a POSITA to have included such a feature, in light of Engebretson's teachings. *Id.* at 30–31. Petitioner contends that a POSITA would have been motivated to modify Barreras in this manner, to provide "a low-power, low-cost communication method" that is less susceptible to the electromagnetic interference that Barreras acknowledges could prevent a termination command from being received by the external charger. *Id.* at 29, 32–33 (citing, e.g., Ex. 1003 ¶¶ 91–92, 96–97).

Patent Owner argues that "Engebretson does not teach using changes in rectification to indicate when the implanted rechargeable battery is fully charged, but rather discloses only communications about the settings of the implanted hearing aid." PO Resp. 40–41; *see also* Prelim. Resp. 38–39 (asserting the same). According to Patent Owner, Petitioner relies upon

[19] The parties agree that claim 28 includes a typographical error and should recite "sensing," as reflected herein. Pet. 15 n.6; Prelim. Resp. 38 n.1.

insufficient testimony from Petitioner's declarant to support its contention. PO Resp. 41; *see also* PO Sur-Reply 8–9 (asserting the same).

In our Decision on Institution, we were persuaded by Patent Owner's arguments, and denied institution on that basis. DI 19–22. As discussed above, we included this asserted ground of unpatentability in this proceeding as a result of the holding in *SAS Institute.* Accordingly, we revisit the evidence as further developed over the course of this proceeding.

In its Reply, Petitioner argues that "Petitioner and [Dr.] Kroll explained why and how a POSA would have modified Engebretson to sense battery status," i.e., by "replac[ing] Barreras'[s] less reliable RF system with Engebretson's more reliable inductive system to transmit Barreras'[s] ''stop' recharging command' through changes in rectification modes—the same way Engebretson conveys information about other 'conditions sensed . . . beneath the surface of the skin'" to ensure a reliable communication method. Pet. Reply 14–15 (citing Pet. 30–33; Ex. 1137 ¶¶ 29–32; Ex. 1008, 4:34–39, 9:7–17, 9:44–53).

We have considered the parties' arguments and evidence and we determine that Petitioner has not demonstrated that Engebretson teaches the limitation of "[sensing] the change in rectification in the IPG . . . to thereby sense when the rechargeable battery in the IPG is fully charge[d]." We find that Engebretson discloses implanted hearing aid device 10 with rectifier 16, and that rectifier 16 selectively switches between half and full wave rectification modes to indicate different binary states to external device 12. Ex. 1019, 3:1–9. However, Engebretson only discloses using this change in rectification to convey information about *conditions beneath the skin surface*, e.g., the previous settings of the implanted device. *Id.* at 3:37–40,

4:3–7. Moreover, although Engebretson charges its implanted battery, Engebretson does not disclose using changes in rectification to convey information about battery status. *Id.* at 2:30–32, 4:3–10. Thus, at best, the teachings of the prior art suggest modifying Barreras to utilize changes in rectification modes to convey information about sensed conditions beneath the skin, as taught by Engebretson. The Petition fails to explain adequately how this conveyed information relates to battery status information, as required by the claim.

Petitioner's citations to the original Kroll Declaration are insufficient to demonstrate that it would have been obvious to further modify Engebretson's teachings to utilize changes in rectification to convey information about battery status instead. Pet. 28–33 (citing Ex. 1003 ¶¶ 91–97); Pet. Reply 14–15 (citing Ex. 1137 ¶¶ 29–32). For example, Dr. Kroll acknowledges that Engebretson discloses using rectification changes only to convey information about conditions sensed beneath the skin surface. Ex. 1003 ¶ 92. Yet Dr. Kroll then conclusorily asserts that a POSITA "would have recognized that Engebretson's communication method *could be used* to convey the 'stop' recharging command to the transmitter in Barreras's system," but without providing any persuasive analysis or explanation bridging the gap between the finding of fact and the conclusion. *Id.* (emphasis added). Likewise, Dr. Kroll fails to explain adequately the basis for his conclusion that modifying Engebretson's teachings to sense battery status "would work as expected." *Id.* Merely touting the results associated with such a modified use alone is classic impermissible hindsight, and is inadequate to support a persuasive showing that it would have been obvious to modify the prior art as asserted. *Id.*; *see also id.* ¶ 96; 37 C.F.R.

§ 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

In the Kroll Reply Declaration, Dr. Kroll asserts that a POSITA would have been motivated to use Engebretson's communication technique to convey Barreras's "stop" recharging command because Engebretson's technique is less susceptible to interference. Ex. 1137 ¶¶ 30–31. Even if this communication technique would have been more reliable than RF transmissions, this does not explain how or why a POSITA would have found it obvious to modify Engebretson's teachings to convey *battery status information* through changes in rectification. As noted above, and admitted by Dr. Kroll, Engebretson does not suggest this use. Like the original Kroll Declaration, the Reply Declaration fails to explain persuasively why or how a POSITA would have found it obvious to modify Engebretson to convey *this particular information*, even if such a communication were more reliable.

Accordingly, we determine that Petitioner has not demonstrated the unpatentability of claim 28, by a preponderance of the evidence.

Analysis of Claims 29 and 30

Dependent claims 29 and 30 depend, directly or indirectly, from claim 28. Ex. 1001, 58:26–41. Petitioner's contentions with respect to these claims do not remedy the deficiency regarding claim 28. Pet. 33–37.

Accordingly, for the same reasons discussed regarding claim 28, we determine that Petitioner has not demonstrated the unpatentability of claims 29 or 30 by a preponderance of the evidence.

C. Obviousness over the Combined Teachings of Holsheimer, Munshi, and Wang

Petitioner contends that claims 22–24 would have been obvious over the combined teachings of Holsheimer, Munshi, and Wang. Pet. 51–71. For reasons that follow, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Holsheimer (Ex. 1004)

Holsheimer is a U.S. patent titled "Multichannel Apparatus for Epidural Spinal Cord Stimulation," and discloses a pulse generator that drives a plurality of electrodes implanted near a patient's spinal cord. Ex. 1004, [54], [57]. Holsheimer's Figure 1 is reproduced below.

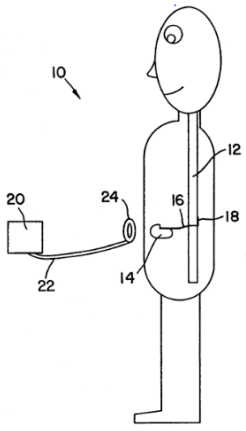

FIG. 1

Figure 1 depicts a schematic view of a patient with an implanted neurological stimulation system. *Id.* at 2:46–47. In this system, implantable pulse generator 14 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 3:56–59.

2. Overview of Munshi (Ex. 1005)

Munshi is a U.S. Patent titled "Rechargeable Biomedical Battery Powered Devices with Recharging and Control System Therefore," and discloses an implantable device with a power source that is recharged by magnetic induction. Ex. 1005, [54], [57].

3. Analysis of Claim 22

Petitioner contends that claim 22 would have been obvious over Holsheimer, Munshi, and Wang. Pet. 51–71.

Patent Owner disputes Petitioner's contentions. PO Resp. 47–50. Patent Owner argues that Holsheimer does not disclose "an implantable electrode array detachably connected to the IPG." *Id.*

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 22 is unpatentable over Holsheimer, Munshi, and Wang.

i. Preamble

The preamble of independent claim 22 recites "[a] spinal cord stimulation system . . . ." Petitioner contends that Holsheimer discloses this subject matter. Pet. 54. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

We find that Holsheimer discloses a "neurological stimulation system" for stimulating a patient's spinal cord. Ex. 1004, 3:53–55, Fig. 1. Thus, we find that Holsheimer teaches the subject matter of the preamble of claim 22.

ii. "an implantable, multi-channel implantable pulse generator (IPG) having a replenishable power source"

Petitioner contends that the combined teachings of Holsheimer and Munshi would have rendered obvious this limitation. Pet. 47–50, 52–54. Petitioner contends that Holsheimer discloses a multi-channel IPG and, although Holsheimer does not disclose a replenishable power source, this would have been obvious in view of Munshi's teachings. *Id.* at 55. Petitioner also contends that a POSITA would have been motivated to make this modification to improve the service life of the IPG, and reduce the number of surgical procedures required. *Id.* Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

We find that the cited portions of the prior art support Petitioner's contentions. Namely, Holsheimer teaches an implantable "multi-channel pulse generator," but does not teach that it is powered by a replenishable power source. Ex. 1004, Abstract, 1:8–13. Munshi teaches an implanted, "rechargeable battery-powered biomedical device" that is recharged through the patient's skin by electromagnetic induction between a pair of mutually coupled coils 72, 74. Ex. 1005, 1:8–9, 4:3–10, 10:27–36.

We determine that a POSITA would have found it obvious to include in Holsheimer's IPG a replenishable power source that can be recharged by induction through the patient's skin, as taught by Munshi, in order to improve the service life of the device and minimize the number of surgical procedures to which the patient is subjected. Pet. 52–55; Ex. 1003 ¶¶ 136 (explaining that non-rechargeable batteries had limited service life and required surgery to replace), 137–138, 144; Ex. 1005, 1:20–28, 4:3–4.

Thus, we determine that a POSITA would have found this limitation of claim 22 obvious over the combined teachings of Holsheimer and Munshi.

iii. "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

The Parties' Positions

In the Petition, Petitioner contends that Holsheimer discloses implanted lead 16 with an electrode array (at 18), which is connected to pulse generator 14. Pet. 56; Ex. 1004, 3:56–59, Fig. 1. Petitioner also contends that Holsheimer's Figure 1 depicts "a standard connector notch where the leads would connect to the IPG." Pet. 56; *see also* Ex. 1003 ¶¶ 115, 147 (asserting the same). According to Petitioner,

> a [POSITA] would have understood Holsheimer's leads, which carry the electrode arrays, would have been detachably connected to the IPG because—as the '280 admits—many different types of leads were known in the art and could be used with the same IPG. It was well-known at the time that leads can be attached and detached to IPGs, so medical professionals and patients could have the flexibility to select the type of lead that best suits the patient's particular stimulation needs and so malfunctioning leads could be replaced without having to replace the entire IPG.

Id. at 56–57 (citing Ex. 1001, 9:8–11, 10:19–24; Ex. 1003 ¶¶ 147–148; Ex. 1016, Abstract, 2:66–3:2).

In our Decision on Institution, we determined that the Petition failed to establish that Holsheimer's electrode array is detachably connected to the IPG. DI 24–26. We reiterated this determination in our Decision on Petitioner's Request for Rehearing. Dec. on Req. Reh'g 2–6. We

determined that Holsheimer did not describe a detachable connection and that Figures 19–20, depicting wires 80 connecting IPG 14 to electrodes 38, suggest that the connection may be permanent and unitary. DI 25. Moreover, we found that Petitioner and Dr. Kroll did not provide a sufficient evidentiary basis to support the conclusion that a POSITA would have understood the electrode array to be detachable. *Id.* at 25–26 (citing Ex. 1003 ¶¶ 147–148). For example, the cited prior art did not discuss a "standard connector notch" or explain that such connectors were detachable. *Id.* (citing Ex. 1016, Abstract, 2:66–3:2; Ex. 1008, 7:39–41); Dec. on Req. Reh'g 3–5. We determined that, at best, the cited evidence supported Petitioner's argument that "many different types of leads were known in the art and could be used" and that "leads can be attached and detached to IPGs," but did not establish that *Holsheimer's* lead was detachable. DI 26, 26 n.6 (noting Petitioner did not make an obviousness contention).

In its post-institution Response, Patent Owner argues that Petitioner has not met its burden to show that Holsheimer discloses detachable leads. PO Resp. 47–50 (citing Ex. 2033 ¶¶ 108–109). Patent Owner discusses Holsheimer's Figures 19–20, which show wires connecting the electrode array to the IPG. *Id.* at 48–49. Patent Owner also argues that Dr. Kroll failed to explain why Figure 1 depicts a standard connector notch, or how that is relevant to the claim limitation. *Id.* at 50.

In its Reply, Petitioner contends that a POSITA would have understood Holsheimer's connection to be detachable. Pet. Reply 2–3, 7–8 (citing, e.g., Ex. 1137 ¶¶ 37, 44–45). Petitioner makes two primary arguments: (1) all leads used for spinal cord stimulation (SCS)—the use for which Holsheimer's system was intended—were detachable, as required by

their implantation methods; and (2) Holsheimer discloses a Medtronic IPG—the "ITREL IIR"—that utilized detachable leads. *Id.* at 2–8.

In support of the first argument, Petitioner relies upon Dr. Lipson's testimony that, in his experience, all SCS systems used detachable leads. *Id.* at 3 (citing Ex. 1125, 29:19–30, 30:24–31:10, 34:22–35:6, 37:18–22; Ex. 2034 ¶¶ 3, 8). Petitioner also cites the deposition testimony of four inventors of the '280 patent, each of whom testified that all known SCS systems used detachable leads. *Id.* at 4 (citing Ex. 1128, 279:4–12; Ex. 1131, 110:21–111:10; Ex. 1132, 295:19–22; Ex. 1126, 198:3–22; Ex. 1137 ¶ 40). According to Petitioner, use of detachable leads was necessitated by the manner in which SCS systems were implanted. *Id.* at 4–6 (citing Ex. 1125, 27:18–28:22, 29:10–14, 29:19–25, 30:2–23, 31:11–33:9, 35:7–36:5, 37:25–39:10, 41:4–14, 45:15–50:17, 52:4–9; Ex. 1137 ¶¶ 41–43; Ex. 2034 ¶¶ 20–22, 24–25).

In support of the second argument, Petitioner contends that the evidence demonstrates that Holsheimer's disclosed IPG, the "ITREL II, like all SCS systems, used detachable leads." *Id.* at 6 (citing Ex. 1004, 3:60–65; Ex. 1122; Ex. 1124, 61:17–25, 68:21–69:13; Ex. 1125, 55:5–10; Ex. 1131, 109:4–22; Ex. 1139, 80:14–81:11, 141:19–143:12; Ex. 1137 ¶¶ 38–39); *see also* Pet. Opp. MTE 3–4 n.3 (citing Ex. 1139, 89:23–90:7).

In its Sur-Reply, Patent Owner argues that we should exclude much of the evidence provided with Petitioner's Reply. PO Sur-Reply 12–15; *see supra* Section III.B.2. With respect to the merits, Patent Owner argues that Dr. Kroll's testimony is not credible and is entitled to little weight. PO Sur-Reply 16–17. Patent Owner also disputes Petitioner's argument that detachable leads are necessary for implantation because (1) Holsheimer

discloses paddle leads, which are not implanted with a cannulated needle, and (2) Petitioner has not shown that Holsheimer's device was ever reduced to practice, or implanted, such that any conclusion as to how it might have been implanted is no more than unsupported speculation. *Id.* at 17–18. Patent Owner also disputes Petitioner's reliance on evidence directed to the ITREL II, because Holsheimer discloses an "ITREL IIR," and Petitioner has not shown these to be the same. *Id.* at 18–20.

Petitioner responds that Dr. Kroll's testimony is credible; that he opined that the "R" in "ITREL IIR" likely referenced a registered trademark; that he has seen the ITREL II, but not an ITREL IIR; and that Holsheimer is not limited to use of paddle leads. Pet. Sur-Sur-Reply 2–4.

Analysis

Although we maintain our conclusion that the Petition alone is insufficient to demonstrate that Holsheimer's leads are detachable, for the reasons noted above, that failure does not dictate resolution of the issue at this stage. As discussed above in Section III.B.2., we determine that the evidence submitted with Petitioner's Reply will not be excluded or stricken, but will be afforded appropriate weight. In light of the entire record before us, we find that Petitioner has carried its burden in demonstrating that a POSITA would have recognized Holsheimer's leads to be detachable.

1. Holsheimer

Holsheimer discloses a "spinal cord stimulator" system. Ex. 1004, [54]. The system includes implantable pulse generator 14 and lead 16, which is coupled to the patient's spinal cord by electrodes, at location 18 in Figure 1. *Id.* at 3:56–59, Fig. 1. Holsheimer explains that IPG 14

"preferably is an ITREL IIR implantable pulse generator available from Medtronic, Inc. with provisions for multiple pulse outputs." *Id.* at 3:60–62. Holsheimer does not specify whether lead 16 is detachable from IPG 14. With respect to Figure 19, Holsheimer discloses that the lead's "electrodes 38 [are] connected to these outputs [of IPG 14] with wire 80A connecting output 72 to electrode 38A, wire 80B connecting output 74 to electrode 38B," and so on. *Id.* at 7:19–32, 7:44–62 (similar description of Figure 20).

Petitioner's declarant, Dr. Kroll, testifies that a POSITA would have understood Holsheimer's lead to be detachable, in part because "all known SCS systems at the time of the '280 patent used detachable leads." Ex. 1137 ¶ 40. To support this opinion, Dr. Kroll cites the testimony of Dr. Lipson (Ex. 1125) and four inventors of the '280 patent—Mr. Joey Chen (Ex. 1126), Mr. Paul Meadows (Ex. 1128), Ms. Carla Mann Woods (Ex. 1131), and Mr. David Peterson (Ex. 1132). Dr. Kroll also discusses Dr. Lipson's testimony regarding the typical implantation process for SCS systems, which confirms his opinion that a POSITA would have understood Holsheimer's leads to be detachable. Ex. 1137 ¶¶ 41–43.

We credit Dr. Kroll's testimony and the underlying evidence cited in support thereof, which we discuss below.

2. SCS Systems

Holsheimer is an SCS system. Ex. 1004, [57], 1:7–8, 2:21–23, 3:55. Four inventors of the '280 patent testified that, prior to the critical date, all SCS systems known to them employed detachable leads. Ex. 1126, 198:3–22; Ex. 1128, 279:4–12; Ex. 1131, 110:14–111:10; Ex. 1132, 295:19–22. We recognize that these deponents did not testify regarding whether

Holsheimer's leads were detachable. PO MTE 9. This evidence, however, documents the knowledge that a POSITA would bring to bear in reading Holsheimer's disclosure of an SCS system. Ex. 1004, 3:55; *see, e.g.*, *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) ("Art can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art."). Therefore, this evidence supports Petitioner's contention that a POSITA would have understood Holsheimer's SCS leads to be detachable.

Additionally, Patent Owner's declarant, Dr. Lipson, testified that he is not aware of any SCS systems that do *not* utilize detachable leads, and that he has never implanted an SCS lead while it was attached to an IPG. Ex. 1125, 37:2–22; *see also id.* at 34:18–35:6, 36:6–25 (asserting the same). This testimony is consistent with that of the '280 patent inventors.[20]

3. SCS Implantation

The Lipson Declaration explains the process of implanting an SCS system. Ex. 2034 ¶¶ 20–27. According to Dr. Lipson, a lead is implanted, externalized through the skin, and connected to a trial stimulator for an initial testing period. *Id.* ¶¶ 20–22. If the trial succeeds, a permanent lead

[20] We note that Dr. Lipson did not begin practicing medicine until *after* the 1999 critical date of the '280 patent. Ex. 1125, 40:19–22 (graduating medical school in 2000, and beginning practice in 2001); Ex. 2034 ¶ 17. However, Dr. Lipson testified that "the general process of placing a lead, tunneling, and placing the pulse generator on the commercially available systems has been fairly consistent *from the 1990s to the present*." Ex. 1125, 44:2–10 (emphasis added). Thus, we afford some weight to Dr. Lipson's testimony as to the prevalent technology and procedures, at the critical date, even though he was not practicing at that time. Moreover, both parties rely on Dr. Lipson's testimony, and treat him as credible, in different contexts.

and IPG is implanted. *Id.* ¶¶ 23–24. Dr. Lipson testifies that, "[f]or percutaneous leads, a Tuohy needle is utilized to introduce the leads." *Id.* ¶ 25. Dr. Lipson explains that a Tuohy needle is a cannulated needle that is inserted into the epidural space, and through which a percutaneous electrode is passed. Ex. 1125, 27:15–28:22. Dr. Lipson testifies that, during this process, the lead is not attached to the IPG and, in fact, could not be so attached, because the lead's distal end must remain free so that the needle can be removed by sliding it back and over the free distal end of the lead. *Id.* at 29:19–30:23.

Dr. Lipson testifies that a Tuohy needle is not used to implant paddle electrodes. Ex. 1125, 28:23–29:5. Rather, that process requires an incision and a laminectomy (bone removal), in order to access the epidural space and pass the paddle electrode. *Id.* at 27:20–28:4, 29:5–9. Dr. Lipson states that although a paddle lead *could* be implanted while attached to an IPG, he has neither done so nor ever heard of this being done. *Id.* at 30:2–7, 30:24–31:10. Instead, to implant a permanent SCS system with paddle electrodes, Dr. Lipson testifies that two incisions are made, one for the paddle electrode and one for the IPG; the electrode is secured at its intended position; and the

free end of the electrode is then "tunneled" under the skin, to the location of the IPG, for connection thereto.[21] *Id.* at 32:3–33:9, 35:7–36:5.[22]

Dr. Lipson's testimony demonstrates that the process for implanting an SCS system requires that the electrode—whether percutaneous or paddle—be detachably connectable to the IPG. For percutaneous electrodes, the distal end of the electrode must be free, i.e., not connected to the IPG, such that the cannulated Tuohy needle may slide off the end. Ex. 1125, 29:19–30:23. For paddle electrodes, the distal end of the electrode must be free, i.e., not connected to the IPG, such that it can be "tunneled" under the patient's skin, from the location at which the electrode is implanted to the location at which the IPG is implanted, for connection to the IPG. *Id.* at 33:3–9, 35:9–36:5.

We have considered Patent Owner's arguments that Holsheimer discloses paddle leads, which are not implanted with a cannulated needle, and that Petitioner has not shown that Holsheimer's device actually was reduced to practice. PO Sur-Reply 17–18. However, as discussed above, Dr. Lipson's testimony shows that even paddle leads must be detachable in

[21] By contrast, if a paddle electrode were implanted without tunneling under the skin, i.e., with the electrode connected to the IPG, Dr. Lipson testified that "you'd have to make a big incision" so as to implant the connected structures at their different locations in the patient—an apparently undesirable outcome. *Id.* at 35:18–36:5. As noted above, Dr. Lipson testified that he is not aware of this ever being done, and is not aware of any non-detachable leads for SCS systems. Ex. 1125, 30:24–31:10, 37:2–22.

[22] Petitioner also offers a video depicting the process by which an SCS system is implanted. Ex. 1123. This video, however, is undated and, as such, is entitled to little to no weight as to a POSITA's understanding of the process at the critical date.

order to be tunneled under the skin for connection to the IPG. Patent Owner has not presented persuasive evidence disputing that testimony. Moreover, whether Holsheimer's system was reduced to practice and actually implanted does not alter our conclusion that a POSITA would have understood Holsheimer's leads to be detachable. Patent Owner has not presented persuasive argument or evidence to suggest that Holsheimer's SCS system was designed in a manner contrary to the documented prevailing practice.

4. ITREL

Holsheimer states that its IPG "preferably is an ITREL IIR implantable pulse generator available from Medtronic, Inc. with provisions for multiple pulse outputs." Ex. 1004, 3:60–62. Petitioner presents, as Exhibit 1122, a photograph purporting to depict an ITREL II device. This photograph, however, is undated and, as such, does not speak to a POSITA's understanding of the components of such a device, at the critical date. Accordingly, we afford it, and the cited testimony concerning this exhibit, little to no weight. *See*, *e.g.*, Ex. 1124, 61:17–25 (discussing Ex. 1122), 68:21–69:13 (same); Ex. 1137 ¶ 38 (same).[23]

Petitioner presents additional evidence demonstrating that the ITREL II included detachable leads at the critical date. For example, Ms. Carla Mann Woods, an inventor on the '280 patent, testified that the ITREL system she utilized in 1997 included detachable leads. Ex. 1131,

[23] We afford little to no weight to the portion of Dr. Kroll's testimony that relies upon Exhibit 1122, but we credit those portions that rely upon other competent evidence, e.g., Exs. 1125, 1131, 1139, as discussed below.

109:4–22. Additionally, Dr. Lipson testified that, beginning in 2001, he implanted the ITREL I and ITREL II systems, which utilized detachable leads. Ex. 1125, 53:10–55–10. Finally, Petitioner provides the FRCP 30(b)(6) testimony of Mr. Johnathan C. Werder, a director at Medtronic, Inc. Ex. 1139, 9:3–6. Mr. Werder testified that the ITREL II includes detachable leads. *Id.* at 80:14–81:11, 141:19–143:12; *see also* Ex. 1137 ¶¶ 38–39 (asserting the same).

We recognize that this evidence is somewhat attenuated—only Ms. Mann's testimony concerns activity before the critical date, but she is non-specific as to the ITREL version. Ex. 1131, 109:4–22. On the other hand, Dr. Lipson is clear that he used the ITREL I and ITREL II, but that use occurred *after* the critical date. Ex. 1125, 53:10–55:10. Likewise, Mr. Werder clearly testifies regarding the ITREL II, but does not state whether those features were present at the critical date. Ex. 1139, 80:14–81:11, 141:19–143:12. Nonetheless, taken together, this testimony provides some support to Petitioner's contention that, as of the critical date, the ITREL II device included detachable leads. Namely, Ms. Mann's testimony establishes that an ITREL system included detachable connections before the critical date, and Dr. Lipson and Mr. Werder's testimony confirms that versions used later in time, i.e., the ITREL II, also included that feature.

The question remains, therefore, whether the ITREL II system discussed above is the same as the ITREL II<u>R</u> disclosed in Holsheimer, consistent with Petitioner's contention that Holsheimer's IPG included detachable leads. *See* PO Sur-Reply 18–20. Dr. Kroll testified that he believes that the "R" in "ITREL IIR" refers to a registered trademark, wherein his belief is based upon his experience developing the original

prototype that led to the ITREL, his familiarity with the ITREL II, and his lack of familiarity with an ITREL IIR. Ex. 2039, 109:6–111:13. Additionally, Medtronic's FRCP 30(b)(6) deponent, Mr. Werder, testified that he, a corporate representative of Medtronic speaking on its behalf, "do[es] not know of the ITREL IIR." Ex. 1139, 89:16–90:7. We credit the testimony of Medtronic's witness, a disinterested third party, and, based on this testimony, determine that the "ITREL IIR" referenced in Holsheimer does not appear to be an accurate recitation of a product name. As discussed above, record evidence indicates that the ITREL II included detachable leads. *See, e.g.*, Ex. 1125, 55:5–10; Ex. 1131, 109:4–122; Ex. 1139, 80:14–81:11, 141:19–143:12. We afford minimal weight to this evidence, however, because of the tenuous link to Holsheimer's disclosure of the IPG used in its system.

5. Summary

In light of the aforementioned evidence, we determine that a POSITA, reading Holsheimer's disclosure and its intended use as a spinal cord stimulation system, would have understood Holsheimer's connection to be detachable. Specifically, we rely upon:

(1) the deposition testimony of four named inventors of the '280 patent, stating that all known SCS systems at the critical date included detachable leads (Ex. 1126, 198:3–22; Ex. 1128, 279:4–12; Ex. 1131, 110:14–111:10; Ex. 1132, 295:19–22),

(2) Dr. Lipson's testimony that the process for implanting all known SCS systems at (or near) the critical date required detachable leads, regardless of whether those systems employed percutaneous or paddle leads (Ex. 1125, 29:19–30:23, 33:3–9, 35:9–36:5),

(3) the deposition testimony of Dr. Lipson, an inventor of the '280 patent, and Medtronic's corporate representative, that taken together, suggest the ITREL II included detachable leads (Ex. 1125, 53:10–55:4; Ex. 1131, 109:4–22; Ex. 1139, 80:14–81:11, 89:16–90:7, 141:19–143:12), in conjunction with the testimony of Medtronic's corporate representative that the ITREL IIR is unknown (Ex. 1139, 89:16–90:7), and

(4) Dr. Kroll's testimony that a POSITA would have understood Holsheimer's leads to be detachable, in light of this evidence (Ex. 1137 ¶¶ 37–45).[24]

Thus, we determine that Holsheimer teaches this limitation of claim 22.

iv. "a secondary, implanted coil coupled electrically to the replenishable power source"

Petitioner contends that Munshi teaches this limitation because Munshi teaches implanted coil 74. Pet. 52–54, 57–58. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

We find that Munshi discloses implanted coil 74, which is electrically coupled to rechargeable battery 92. Ex. 1005, 10:52–64, Fig. 2; Ex. 1003 ¶¶ 149–150; *see also* Section V.C.3.ii. (motivation to combine). Thus, we find that Munshi teaches this limitation of claim 22.

[24] We have considered Patent Owner's argument that Dr. Kroll's testimony is incredible and entitled to little weight. PO Sur-Reply 16–17. As discussed above, we are not persuaded by Dr. Kroll's original testimony, submitted with the Petition. However, Dr. Kroll's reply testimony is supported by independent evidence of record, discussed above. For that reason, we find it credible and persuasive.

v. "an external battery charger including: a primary coil; a rechargeable battery contained in the charger, electrically coupled to the primary coil; and a power amplifier for applying alternating current derived from the rechargeable battery in the charger to the primary coil"

Petitioner contends that Munshi teaches these limitations because Munshi teaches external charger 70, which Petitioner contends includes the recited components. Pet. 58–61. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

We find that Munshi discloses external charging unit 70 including, *inter alia*, external charging coil 72, a "rechargeable external battery pack," and power amplifier 78 for applying alternating current to coil 72. Ex. 1005, 10:20–51, 12:54–57, Fig. 2; Ex. 1003 ¶¶ 151–156; *see also* Section V.C.3.ii. (motivation to combine). Thus, we find that Munshi teaches these limitations of claim 22.

vi. "whereby the alternating current in the primary coil is transcutaneously transferred to the secondary implanted coil to the replenishable power source contained in the IPG"

Petitioner contends that Munshi teaches this limitation because Munshi's external charger 70 transfers alternating power from external coil 72 to implanted coil 74. Pet. 61–62. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

We find that Munshi discloses that "external charger 70 consists of an oscillator circuit 76 that drives the transmitting coil 72 with an alternating current." Ex. 1005, 10:38–40. Munshi explains that this current "is coupled through the patient's skin by magnetic induction between an external charging coil 72 and an input coil 74 . . . disposed just under the skin." *Id.* at

10:21–26, 10:52–64; Ex. 1003 ¶ 157; *see also* Section V.C.3.ii. (motivation to combine). Thus, we find that Munshi teaches this limitation of claim 22.

vii. "alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil as applied by the power amplifier"

Petitioner contends that the combined teachings of Holsheimer, Munshi, and Wang would have rendered obvious this limitation. Pet. 52–54, 62–66. Specifically, Petitioner acknowledges that Munshi does not disclose expressly "alignment circuitry," as claimed, but Petitioner relies on Wang's teaching of "an alignment circuit and indicator" that indicates when inductive coils are properly aligned. *Id.* at 62–63. Patent Owner does not dispute Petitioner's contentions in its Response, *see generally* PO Resp. 47–51, but presents arguments about Wang's pertinent teachings with respect to the asserted ground of unpatentability based on Schulman, Loeb, Munshi, and Wang, discussed below. *See infra* Section V.G.; PO Resp. 69–70; PO Sur-Reply 25–27. We treat those arguments here.[25]

We find that the cited portions of the prior art support Petitioner's contentions. Namely, Munshi teaches that external charging unit 70 is placed over the patient's skin, in proximity to the implanted rechargeable

[25] We recognize that Patent Owner did not make arguments regarding whether Wang satisfies this limitation with respect to this specific ground of unpatentability. Pet. Reply 21 n.8. However, in this ground, Petitioner utilizes Wang in the same manner as in the ground based on Schulman, Loeb, Munshi, and Wang, for which Patent Owner did present argument. *Compare* Pet. 53–54, 62–66, *with* –1920 Pet. 56–59, 68–74. Thus, we consider Patent Owner's arguments here, as well.

unit. Ex. 1005, 10:32–37, 10:52–61 (implanted circuitry includes watch dog circuit 86 that detects the presence of external charger), 12:54–62 (user places external charger in "close proximity to the implanted coil"). Munshi explains that the user adjusts the position of external charging coil 72 to "find the optimum position of maximum energy transfer [between the two coils] simply by noting the position at which the coil current is maximized." *Id.* at 13:1–5; *see also id.* at 12:66–13:1 (discussing coupling between the coils). Munshi, however, does not specify alignment circuitry as claimed.

We find that Wang discloses an implantable medical device that is recharged inductively through the skin. Ex. 1018, Abstract, 4:37–42. To permit recharging, Wang explains that the "coils of the external energy transmission device and the implanted medical device must be properly aligned for efficient energy transmission." *Id.* at 5:13–15. To achieve this, Wang provides "an alignment circuit and indicator . . . to indicate whether the coils are properly aligned." *Id.* at 5:15–17, 11:41–46; *see also* Ex. 1003 ¶ 160 (asserting the same).

We find that Wang's alignment circuitry includes a back telemetry receiver, as claimed, and as that phrase has been construed in Section II.A.2. Wang explains that the alignment circuitry monitors the magnitude of AC current at the primary coil, which correlates with AC voltage, and compares it to a reference peak value to determine whether proper alignment has been achieved. Ex. 1018, 12:1–29, 11:56–63, Fig. 5; Ex. 1003 ¶¶ 64–68, 160 (Dr. Kroll's unrebutted testimony that the monitored AC current is reflective of AC voltage). When proper alignment is reached, an indicator LED illuminates. *Id.* at 12:21–24. Thus, we find that Wang's circuitry monitors AC voltage, as claimed. *See, e.g.*, Ex. 1002 ¶¶ 64–68, 160; PO Sur-Reply 27

(acknowledging that "Wang's alignment circuitry . . . compares the current sensed voltage value to the scaled peak voltage value").

We do not agree with Patent Owner's arguments that Wang does not teach a back telemetry receiver, because Wang's alignment circuitry does not "receive information or data from the implanted device." PO Resp. 69–70; PO Sur-Reply 25–27. First, this is not required by the claim language, or by the broadest reasonable interpretation of "back telemetry receiver," for the reasons detailed in Section II.A.2. Second, even under Patent Owner's proposed construction, we do not agree that Wang's circuitry is not a "back telemetry receiver for monitoring the magnitude of the ac voltage," as claimed. Patent Owner argues that Wang simply takes a direct measurement of an electrical parameter (voltage), but does not receive "data or information." PO Resp. 69–70; PO Sur-Reply 25–27. However, Patent Owner has not explained persuasively why direct measurement of electrical parameters does not constitute receipt of data or information. Indeed, extrinsic evidence provided by Patent Owner confirms that "telemetry" describes "the ability of the pulse generator to provide *information such as pulse amplitude, pulse duration, lead impedance, battery impedance, lead current, charge, and energy*," i.e., to provide information regarding direct measurement of electrical parameters such as pulse amplitude or lead current. Ex. 2005, 1263 (emphasis added); Tr. 72:2– 76:19. Patent Owner's reliance on the Berger Declaration also does not demonstrate that monitoring and comparing voltage is not receiving data or information. Ex. 2033 ¶ 146 (providing near verbatim analysis as in the Patent Owner Response, e.g., acknowledging that Wang discloses a voltage comparison and concluding, without explanation, that "Wang is silent on whether or even how the

alignment circuit could be used to receive information or data from the implanted device"). Patent Owner's argument and evidence in this regard is conclusory. *Id.*; PO Resp. 69–70; PO Sur-Reply 25–27.

We determine that a POSITA 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.

Thus, we determine that a POSITA would have found this limitation of claim 22 obvious over the combined teachings of Holsheimer, Munshi, and Wang.

viii. "wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored"

Petitioner contends that Wang teaches this limitation because Wang monitors reflected impedance by monitoring current through the external coil. Pet. 67. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

We find that Wang teaches that the current through the primary, external coil "depends on the power draw of the load on the secondary [implanted] coil and the proximity and orientation" between the coils.

Ex. 1018, 11:24–27, 11:34–37, Fig. 5. We credit Dr. Kroll's unrebutted testimony that "by monitoring the current through the primary coil, which depends in part on the 'power draw of the load on the secondary coil,' Wang's alignment circuitry is monitoring the reflected impedance from the secondary coil due in part to the reflected impedance from the secondary coil." Ex.1003 ¶¶ 64, 163; *see supra* Section V.C.3.vii. (discussing Wang's monitoring of current through the primary coil; motivation to combine). Thus, we determine that Wang teaches this limitation of claim 22.

4. Analysis of Claim 23

Claim 23 further recites "an alarm generator that generates an audible alarm signal in response to changes sensed in the reflected impedance monitored by the back telemetry receiver." Ex. 1001, 56:22–36. Petitioner contends that Wang teaches this limitation. Pet. 58–61. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 47–51.

As discussed above in Sections V.C.3.vii.–viii., we find that because Wang's alignment circuitry monitors the current through the primary coil, which changes based on the "power draw from the secondary coil," Wang's alignment circuitry monitors AC voltage and reflected impedance from the secondary coil. Ex. 1018, 12:1–29, 11:56–63, Fig. 5; Ex. 1003 ¶¶ 64–68, 160, 163. Wang explains that when proper alignment is reached, an indicator is provided, which may be an LED or an "audible signal." Ex. 1018, 5:20–23, 11:28–31, 12:21–24; Ex. 1003 ¶¶ 164–165.

We determine that a POSITA would have found it obvious to incorporate Wang's audible alignment indicator into the Holsheimer/Munshi combination, to inform the patient or a user when proper alignment has been realized, in order to maximize charging efficiency. Pet. 69; Ex. 1003 ¶ 166.

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. 69; Ex. 1003 ¶ 70.

5. Analysis of Claim 24

Claim 24 recites that "the alarm generator broadcasts a first audible tone when the primary coil is misaligned with the secondary coil, and the first audible tone stops the broadcast when the primary coil is properly aligned with the secondary coil." Ex. 1001, 56:27–31.

Petitioner contends that this claim would have been obvious over the combined teachings of Holsheimer, Munshi, and Wang. Pet. 69–70. Petitioner contends that Wang's alignment indicator 40, which may be a LED or an audible indication, indicates when proper alignment is reached. Pet. 70 (citing, e.g., Ex. 1018, 11:28–31 ("LED"), 14:21–24 ("audible indications"), 5:20–23 ("visual or audible signal")). Although Wang discloses providing an indication when *proper* alignment is reached, Petitioner contends that a POSITA would have considered it an obvious design choice to instead "use a first audible signal to indicate misalignment of the coils and a second, different audible signal to indicate their alignment . . . [or to] use an audible signal only to indicate that the coils are misaligned." *Id.* (citing Ex. 1003 ¶ 168).

Patent Owner argues that Wang's indicator only notifies when *proper* alignment is reached, not when the coils are *misaligned*, as claimed. PO

Resp. 50–51. Patent Owner also argues that Petitioner fails to support its contention that it would have been a matter of design choice to modify Wang as claimed. *Id.* at 51 (citing Ex. 2033 ¶¶ 112–113).

Petitioner replies that a POSITA would have recognized that "only three design options" existed: "(1) generate a tone only when the coils are properly aligned (e.g., Wang), (2) generate a tone only when the coils are misaligned (e.g., claim 24), and (3) generate a first tone when the coils are misaligned and a second, different tone when the coils are properly aligned." Pet. Reply 9 (citing Ex. 1124, 189:4–190:7; Ex. 1137 ¶¶ 46–47). According to Petitioner, "[w]hen the claimed option is one of only three predictable solutions, that in itself is a reason why a [POSITA] would have made the specific design choice." *KSR*, 550 U.S. at 421.[26]

In its Sur-Reply, Patent Owner contends that Petitioner's identification of only three design options "improperly restricts the many choices for audible tones alone (tempo, pitch, etc.)," and "ignores Dr. Berger's opinion that numerous options exist for signaling alignment or misalignment, including 'the presence or absence of lights, sounds, vibrations, text messages, or a timer, among other options,' and that 'furthermore, these indicators could be used in different ways.'" PO Sur-Reply 21 (citing Ex. 2033 ¶ 113).

[26] We do not consider the additional, improper, and new rationale provided in Petitioner's Reply, because this reasoning should have been presented in the Petition. Pet. Reply 9 (arguing that a POSITA "would have been motivated to generate a tone only when the coils are misaligned to encourage users to properly align the coils to turn off the tone") (citing Ex. 1137 ¶ 48); PO Sur-Reply 20–21.

We have considered the parties' arguments and evidence, and we determine that the prior art supports Petitioner's contentions. Wang clearly contemplates that "audible indications" may be employed to indicate proper alignment. Ex. 1018, 14:21–24 ("audible indications"). We credit Dr. Kroll's testimony that, within the universe of possible audible indications, only three options would have existed: (1) audibly alert when the coils are aligned; (2) audibly alert when the coils are misaligned; or (3) dual audible alerts to indicate both proper alignment and misalignment. Ex. 1003 ¶ 168. Dr. Kroll's testimony in this regard does not improperly "restrict[] the many choices for audible tones alone (tempo, pitch, etc.)," *see* PO Sur-Reply 21, because Dr. Kroll acknowledges that variations in tempo may be employed. *See* Ex. 1003 ¶ 168 (in option (3), opining that a first beeping tone could indicate misalignment, and a second constant tone could indicate proper alignment). Likewise, Dr. Berger's testimony regarding other non-audible forms of indicators, e.g., "lights, . . . vibrations, text messages, or a timer" does not demonstrate that more than three *audible* options would have existed, and is not responsive to the modification proposed in the Petition—modifying Wang's audible alignment tone to an audible misalignment tone. Ex. 2033 ¶ 113.

In this circumstance, where Petitioner (in the Petition) credibly presents evidence demonstrating that there would have been only three permissible options for an audible alignment indicator, we determine that a POSITA would have found it obvious to modify Wang's audible indicator of proper alignment to instead audibly indicate *misalignment*, as one of a finite number of identified, predictable solutions. *KSR*, 550 U.S. at 421 ("Where

there are a finite number of identified, predictable solutions, [POSITA] has good reason to pursue the known options.").

6. Secondary Considerations

As discussed in Section V.A.4. above, we determine that Patent Owner has not demonstrated a nexus to claims 22–24. Accordingly, we do not consider Patent Owner's evidence of secondary considerations, with respect to claims 22–24.

7. Conclusion

For the foregoing reasons, on this record, Petitioner has shown, by a preponderance of the evidence, that claims 22–24 would have been obvious in view of the combined teachings of Holsheimer, Munshi, and Wang.

D. Obviousness over the Combined Teachings of Holsheimer and Alo

Petitioner contends that claim 26 would have been obvious over the combined teachings of Holsheimer and Alo. Pet. 37–51. For reasons that follow, we determine Petitioner has not demonstrated that the challenged claim is unpatentable by a preponderance of the evidence.

1. Overview of Alo (Ex. 1009)

Alo is an article titled "Computer Assisted and Patient Interactive Programming of Dual Octrode Spinal Cord Stimulation in the Treatment of Chronic Pain," which evaluates the effectiveness of spinal cord stimulation with multiple independent programmable electrodes. Ex. 1009, 30.

According to Alo, two electrodes were placed in the epidural spaces of 80 patients. *Id.* at 33, 40. Electrode leads were externalized through a percutaneous extension and connected to a trial stimulator. *Id.* at 33–34.

The trial stimulator was programmed with various options, to be tested over a five to seven day trial period. *Id.* at 33–34. Specifically,

> The patient was sent home for the first 24 hours of the trial with a simple C-stim program. This allowed the patient to become familiar with the basic controls of amplitude and the sensation of paresthesia. The next day the patient was given up to 24 programs to choose from (PC-stim). . . . These 24 programs could be activated individually by the patient at home using the transmitter. The patient was instructed to try each program one at a time and to rate each of the programs. . . .
>
> Programs that did not provide effective paresthesias were deleted. Treatment evolved via this direct interactive approach to a set of optimal programs that were stored in the transmitter.

Id. at 34; *see also id.* at 36 (providing more detail about the programs). After the trial period, the leads were removed and "[s]ubsequent permanent implantation was performed 3 or 4 weeks later using the same epidural positioning technique." *Id.* at 33–35

2. Analysis of Claim 26

Petitioner contends that claim 26 would have been obvious over the combined teachings of Holsheimer and Alo. Pet. 37–51.

Patent Owner disputes Petitioner's contentions. PO Resp. 43–46. Patent Owner argues, *inter alia*, that Alo does not disclose or suggest the step of "waiting a specified period of time and re-programming the stimulation parameters to second optimal values." *Id.* at 43–44.

After considering the parties' arguments and evidence, we determine that Petitioner has not met its burden of demonstrating that the challenged claim is unpatentable, by a preponderance of the evidence.

Independent claim 26 recites, *inter alia*, "waiting a specified period of time and re-programming the stimulation parameters to second optimal

values." Ex. 1001, 57:27–28. Petitioner contends that Alo teaches this limitation. Pet. 46–47. According to Petitioner, Alo teaches connecting a lead to an external trial stimulator, and programming stimulation parameters at first optimal values, e.g., with C-stim and PC-stim programs. *Id.* at 45–46. Petitioner contends that Alo discloses a trial period of five to seven days. According to Petitioner, "after the patient evaluates the various programs in PC-stim mode, '[p]rograms that did not provide effective paresthesias were deleted' to establish 'a set of optimal programs' stored in the transmitter to be implemented in a so-called 'M-stim mode.'" *Id.* at 46 (quoting Ex. 1009, 34). Thus, Petitioner contends "Alo discloses 'waiting a specified period of time' (e.g., 5 to 7 days) and 'reprogramming the stimulation parameters to second optimal values' (e.g., selecting a set of optimal programs to run in 'M-stim mode' that each have their own specified electrodes, amplitude, frequency, pulse width)." *Id.* at 47.

Patent Owner argues that Alo does not suggest "waiting," as claimed, much less for a "specified period of time." PO Resp. 43. According to Patent Owner, Alo discloses that "[t]he patient was sent home for the first 24 hours of the trial with a simple C-stim program. This allowed the patient to become familiar with the basic controls of amplitude and the sensation of paresthesia." *Id.* (quoting Ex. 1009, 34). Thus, Patent Owner argues that Alo allows the patient to make changes to the stimulation parameters immediately after being sent home, rather than "waiting" as claimed. *Id.* at 43–44. Patent Owner also argues that the five to seven day trial period taught by Alo cannot be the claimed "specified period of time," because Alo teaches that the external trial stimulator can be reprogrammed "many times

during this period with no waiting period before any such reprogramming." *Id.* at 44.

Petitioner replies that "[c]laim 26 does not require waiting a specified period of time *before* any re-programming of stimulation parameters . . . . Rather, claim 26 recites waiting a specified period of time *and* re-programming parameters." Pet. Reply. 15. Petitioner argues that both Alo and the '280 patent permit patient reprogramming during the trial period. *Id.* at 15–16 (citing Ex. 1001, 29:41–49).

Patent Owner responds that "the context of the claim language and logic both require that the specified waiting period happen before re-programming," and that Petitioner's interpretation renders this limitation meaningless. PO Sur-Reply 11. Nonetheless, even under Petitioner's interpretation, Patent Owner argues that Alo fails to disclose waiting a *specified* period of time. *Id.* Patent Owner also contends that the portion of the '280 patent cited by Petitioner concerns one embodiment of the invention, but does not justify reading out this limitation from claim 26. *Id.*

We have considered the parties' arguments and cited evidence, and we agree with Patent Owner. "Unless the steps of a method [claim] actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001). However, a method claim may be construed to require that the steps be performed in a specific order where "the claim implicitly requires order, for example, if the language of a claimed step refers to the completed results of the prior step," or if "the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires" an order of steps. *See Kaneka*

Corp. v. Xiamen Kingdomway Grp. Co., 790 F.3d 1298, 1306 (Fed. Cir. 2015); *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 F. App'x 974, 978 (Fed. Cir. 2008).

Here, Patent Owner has not directed us to any portion of the specification that further explains the embodiment reflected in claim 26. Therefore, the specification does not clarify if an order of steps is required.[27]

Claim 26 itself, however, suggests that the steps must be performed in the articulated order. First, the use of ordered step headings in claim 26, i.e., "(a), (b), (c) . . . (i)," suggests that the recited steps must be performed in that order. Second, step (e) recites "programming," and step (f) recites "waiting . . . and re-programming." Ex. 1001, 57:27–28. Thus, the prefix "re-," in step (f) suggests that the recited "re-programming" is a new, second occurrence of programming that occurs *after* the first "programming" occurrence, recited in step (e). The "waiting," recited in step (f), occurs between the first "programming" step (e) and the second "re-programming" step (f).[28] Thus, we agree with Patent Owner that claim 26 requires sequential steps of "programming," then "waiting," and then "re-programming."

[27] The "waiting" limitation of claim 26 was present in the original claim set submitted during prosecution of the application that issued as the '280 patent. Ex. 1002, 90.

[28] Furthermore, the steps of "programming," "waiting," and "re-programming," as recited in steps (e–f), logically cannot be performed until the electrode array is implanted in the patient (step (a)), connected to the percutaneous extension (step (b)), externalized (step (c)), and connected to the external trial stimulator (step (d)).

We also agree with Patent Owner that Alo does not disclose steps of "waiting" and then "re-programming." PO Resp. 43. Alo explains that a trial period lasts for five to seven days. Ex. 1009, 34. For the first 24 hours, "[t]he patient was sent home . . . with a simple C-stim program," which "allowed the patient to become familiar with the basic controls of amplitude." *Id.* at 34, 36 (explaining that in C-stim mode "[p]atient control is limited to turning the single program on or off and control of amplitude and frequency"). Thus, during the first day of the trial period, while in C-stim mode, the patient *immediately* may re-program stimulation parameters, e.g., amplitude and frequency, to second optimal values, without waiting for any period of time before reprogramming.

Alo also explains that "[t]he next day the patient was given up to 24 programs to choose from (PC-stim)." *Id.* at 34. In PC-stim mode, "[t]hese 24 programs could be activated individually by the patient at home," so that the patient could rate the effectiveness of each program, and delete the programs deemed ineffective. *Id.* at 34–35. In this mode, "the patient is allowed to manually turn on or off predefined programs . . . [and] control the amplitude and frequency of the selected program." *Id.* at 36. Thus, during the remainder of the trial period, while in PC-stim mode, the patient *immediately* may re-program stimulation parameters, e.g., amplitude and frequency, to second optimal values, without waiting for any period of time before reprogramming.

Petitioner's interpretation that "[c]laim 26 does not require waiting a specified period of time *before* any re-programming" ignores the order required by claim 26, and renders meaningless the claimed step of "waiting." Pet. Reply 15. Petitioner has not explained persuasively how "waiting" is

satisfied by Alo's five-to-seven day trial period, during which frequent re-programming may occur. If anything, Alo appears to disclose the opposite of "waiting," by permitting an iterative process of immediately and continually re-programming stimulation parameters, to determine the parameters most effective for the patient. Ex. 1009, 34–36.

Accordingly, we determine that Petitioner has not met its burden of demonstrating the unpatentability of claim 26, by a preponderance of the evidence.

E. Obviousness over the Combined Teachings of Schulman and Loeb

Petitioner contends that claims 18 and 27 would have been obvious over the combined teachings of Schulman and Loeb. –1920 Pet. 20–25 (motivation to combine), 26–52 (grounds). For reasons that follow, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Schulman (Ex. 1012)

Schulman is a U.S. patent titled "Battery-Powered Patient Implantable Device," which performs, e.g., nerve or muscle stimulation. Ex. 1012, (54), (57). Schulman's Figure 2 is reproduced below.

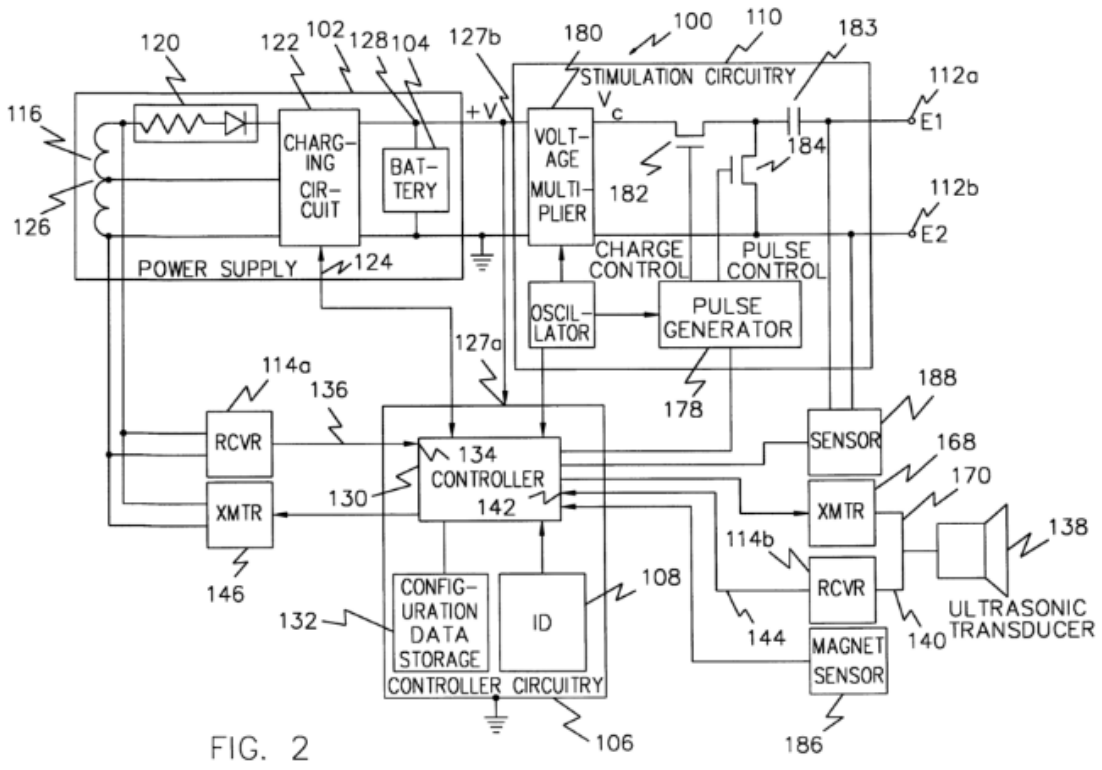

FIG. 2

Figure 2 depicts a block diagram of microstimulator 100, which includes rechargeable battery 104 and stimulation circuitry 110 for providing drive pulses to one or more electrodes 112. *Id.* at 2:37–40, 3:32–4:16. A plurality of devices 100 may be implanted under the skin of a patient. *Id.* at 4:40–42.

To charge rechargeable battery 104, Schulman explains that "coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118 . . . and responsively supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122," which monitors the voltage of battery 104. *Id.* at 4:27–35.

> [O]nce the charging circuit 122 determines that battery 104 has been sufficiently charged, the charging circuit preferably detunes coil . . . and thus minimizes any heat generation in the charging circuit 122 or in the battery 104 from overcharging. Thus, the external power source 118 can continue to provide charging power via an alternating magnetic field indefinitely. However in one preferred embodiment, the external power source

> periodically polls the implanted devices for status information and continues to provide charging power until it has received status information from each of the implanted devices 100 that its battery 104 is charged.

Id. at 4:43–56; *see also id.* at 6:2–16 (asserting the same).

2. Overview of Loeb (Ex. 1117)

Loeb is a U.S. Patent titled "Implantable Multichannel Stimulator." Ex. 1117, [54]. Loeb's Figure 2A is reproduced below.

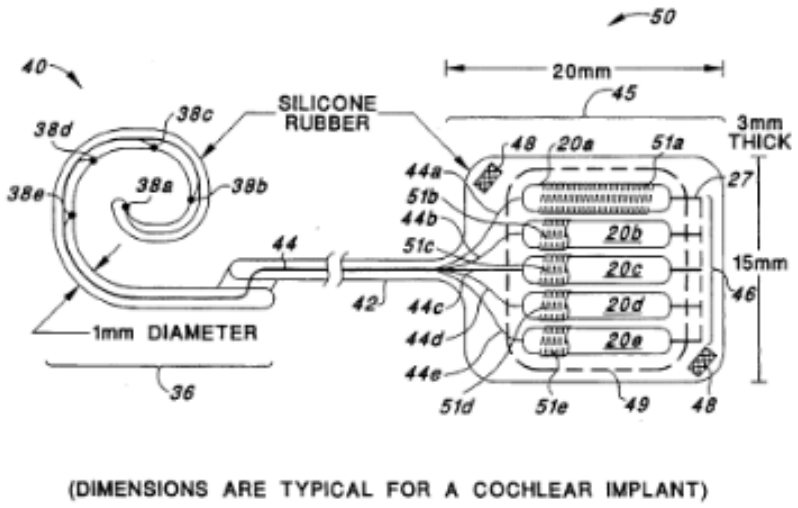

FIG. 2A

Figure 2A depicts an implantable multichannel stimulator that includes microstimulator array 45 (comprising a plurality of microstimulators 20a–e) and electrode array 36 (comprising a plurality of electrode contacts 38a–n). *Id.* at 6:24–28, 8:7–12, 8:17–20. Each electrode contact 38a–n of array 36 "is in electrical contact with one or more of the electrodes 26 or 27 that protrude out from the ends of each microstimulator 20 through respective conductive wires 44*a*, 44*b*, 44*c*, . . . 44*n*." *Id.* at 8:12–25.

Loeb describes that electrode array 36 and microstimulator array 45 are "sealed or molded in a body compatible material," for example, silicone

rubber, "to form an integral implantable multichannel stimulator unit 50." *Id.* at 8:66–9:5. According to Loeb, "conductive wires [44*a*–*n*] form a cable that is also encapsulated within the silicone rubber, which . . . adds physical strength to the wires and prevents the electrode array 36 from breaking or disconnecting itself from the microstimulator array 45." *Id.* at 9:11–16.

In Loeb's system, power is supplied to microstimulator array 45 through inductive coupling with an external power source. *Id.* at 9:33–58. Loeb explains that stimulator 50 includes "alignment means, such as a magnet or marker 48, that helps align the implanted microstimulator array 45, and more particularly the coils 30 . . . of the implanted microstimulator arrays, with an external coil . . . connected to an external source that generates the modulated power signal." *Id.* at 9:20–27. According to Loeb, "[o]ptimum inductive coupling occurs between the internal coils 30 and the external coil when good alignment is achieved. Hence, maintaining proper alignment allows the modulated power signal to be a relatively low power signal." *Id.* at 9:27–32.

3. Analysis of Claim 18

Petitioner contends that claim 18 would have been obvious over Schulman and Loeb. –1920 Pet. 20–25 (motivation to combine), 26–41.

Patent Owner disputes Petitioner's contentions. PO Resp. 51–56. Patent Owner argues that the prior art fails to teach an "electrode array detachably connected to the IPG." *Id.* at 51–55. Patent Owner also argues that a POSITA would not have been motivated to modify Schulman in view of Loeb, because Loeb does not disclose an SCS system. *Id.* at 56.

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 18 is unpatentable over Schulman and Loeb.

i. Preamble

The preamble of independent claim 18 recites "[a] spinal cord stimulation system." Ex. 1001, 54:55. Petitioner contends that this subject matter is rendered obvious by Schulman. –1920 Pet. 26–27.[29] Petitioner relies on Schulman's disclosure of a "system for stimulating tissue," including "nerve or muscle[] stimulation . . . to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain." *Id.* at 26 (quoting, e.g., Ex. 1012, claim 16, Abstract). Petitioner contends "it would have been obvious that Schulman's system could be used for SCS" based on these teachings. Ex. 1003 ¶ 73. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 51–56.

We find that Schulman teaches that its tissue stimulation system may be used for stimulating nerves and neural pathways to relieve pain. Ex. 1012, Abstract. We credit Dr. Kroll's unrebutted testimony that this is "a category in which SCS falls." Ex. 1103 ¶ 73; *see also id.* ¶ 22 ("SCS systems delivered these electrical pulses to the pain area to induce paresthesia to overlap and mask the pain."). We also credit Dr. Kroll's unrebutted testimony that "it would have been obvious to a POSA that Schulman's system could be used for SCS." *Id.* ¶ 73. Thus, we determine

[29] Petitioner contends that, alternatively, the preamble is not limiting. *Compare* –1920 Pet. 26 n.6, *with* PO Resp.25–26 (arguing that the preamble is limiting).

that a POSITA would have found the subject matter of the preamble of claim 18 obvious over Schulman's teachings.

ii. "a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry"

Petitioner contends that the combined teachings of Schulman and Loeb satisfy this limitation. –1920 Pet. 27–32, 20–25 (motivation to combine). Petitioner contends that Schulman's system includes a plurality of microstimulators 100, which can be controlled for separate or simultaneous operation. *Id.* at 27–28. Petitioner contends that each microstimulator 100 includes rechargeable battery 104 and stimulation circuitry 110. *Id.* at 31. Petitioner also contends that Loeb teaches a stimulation system that includes microstimulator array 45 and electrode array 36, enclosed within a housing. *Id.* at 30.

According to Petitioner, it would have been obvious to arrange Schulman's microstimulators 100 into an array configuration, as taught by Loeb, to prevent migration of the microstimulators and to improve charging efficiency. *Id.* at 22, 30; *see also id.* at 20–25 (asserting the same). As modified, Petitioner contends that Schulman's plurality of microstimulators 100, including replenishable power sources 104 and processing circuitry 110, arranged in an array configuration within a housing, as taught by Loeb, is a "multi-channel implantable pulse generator," as claimed. *Id.* at 32.

Patent Owner argues that a POSITA would not have been motivated to combine Schulman and Loeb, because Loeb discloses a cochlear stimulator, not an SCS system. PO Resp. 56 (citing Ex. 2033 ¶ 120).

We find that the cited prior art supports Petitioner's contentions. We find that Schulman discloses a plurality of microstimulators 100, each including rechargeable battery 104 and stimulation circuitry 110. Ex. 1012, 4:4–18, 4:40–42, 6:59–7:2, Fig. 2, Fig. 5A. We also find that Loeb discloses microstimulator array 45 and electrode array 36, which are "sealed or molded in a body compatible material . . . to form an integral implantable multichannel stimulator unit 50." *Id.* at 6:24–28, 8:7–20, 8:66–9:5.

Additionally, we determine that a POSITA would have found it obvious to arrange Schulman's microstimulators in an array configuration, as taught by Loeb. We credit Dr. Kroll's testimony in this regard. Ex. 1103 ¶¶ 66–71, 82. Dr. Kroll testifies that arranging Schulman's microstimulators in an array achieves two benefits: (1) the array is less likely to migrate from its implantation site, which provides better control in stimulating a targeted area, and (2) the array allows for better alignment of the charging coils of the implanted and external components of the system, thus allowing more efficient charging of the rechargeable power sources. *Id.* ¶ 67. Patent Owner does not dispute that these benefits would have been realized by the combination, or that such a combination would have been "straightforward" (*id.* ¶ 68). PO Resp. 56.

We do not agree with Patent Owner's argument that a POSITA would not have been motivated to combine the references as proposed, because Loeb discloses a cochlear stimulator, not an SCS system. PO Resp. 56; Ex. 2033 ¶ 120 (providing conclusory testimony). Both Schulman and Loeb are directed to tissue stimulation systems. Ex. 1012, Abstract ("tissue, e.g., nerve or muscle, stimulation"); Ex. 1117, Abstract ("[a] multichannel stimulation system"). Indeed, Schulman expressly incorporates Loeb by

reference, describing it as a known "[i]mplantable device for tissue stimulation." Ex. 1012, 1:15–19. Although Loeb discloses an "exemplary" cochlear electrode array (Ex. 1117, 8:1–6), Loeb explains that this is "one of many possible types of implantable electrode arrays that may be used with the invention" (*id.*). Thus, in light of the references' common focus on tissue stimulation generally, we determine that Loeb's teachings are not limited to cochlear stimulators, and a POSITA would have considered Loeb and Schulman as complementary. Ex. 1103 ¶¶ 65–66.

Accordingly, for the foregoing reasons, we determine that a POSITA would have found this limitation of claim 18 obvious over the combined teachings of Schulman and Loeb.

iii. "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

The Parties' Positions

As discussed regarding the previous limitation, Petitioner demonstrates that it would have been obvious to arrange Schulman's microstimulators in an array arrangement, as taught by Loeb. –1920 Pet. 33; *see supra* Section V.E.3.ii. According to Petitioner, although Loeb discloses that electrode array 36 is sealed with microstimulator array 45, "it would have been a matter of mere design choice to instead use a detachable version." Pet. 34. Petitioner contends that "many different types of leads were known in the art and could be used with the same IPG," and "it was well-known at the time that leads can be attached and detached to IPGs . . . [for] flexibility to select the type of lead that best suits the patient's

particular stimulation needs and so malfunctioning leads could be replaced without having to replace the entire IPG." *Id*.

In our Decision on Institution, we determined that the Petition failed to establish that it would have been obvious to modify the Schulman/Loeb electrode array to be detachable, in light of Loeb's express teaching that these components are "sealed or molded" together, to prevent disconnection. –1920 DI 14–15; *see also* Ex. 1117, 9:10–15 (asserting the same). At that time, we found that Petitioner and Dr. Kroll failed to provide a sufficient evidentiary basis to support their conclusion that a POSITA would have made such a modification. *Id.* at 15 (citing Ex. 1103 ¶¶ 85–87).

In its post-institution Response, Patent Owner argues that Loeb expressly teaches that the electrode array is not detachable. PO Resp. 51–52. Patent Owner argues that Petitioner fails to support its conclusory argument that the proposed modification would have been obvious. *Id.* at 53. According to Patent Owner, a POSITA would not have made this modification because the advantages of non-detachable leads, as described by Loeb, teach away from it. *Id*. at 54–55. Patent Owner also criticizes Petitioner's argument that detachability allows replacement of the lead, if it malfunctions, because the '280 patent discloses replacement of the *IPG*, not the lead. *Id.* at 55.

Petitioner replies that a POSITA would have "found it obvious (indeed, necessary) to modify the Schulman-Loeb combination to use a detachable lead for SCS." Pet. Reply 16 (citing Ex. 1137 ¶ 49 (incorporating *id.* ¶¶ 37–45)). According to Petitioner, "[t]he type of electrode array used depends on the intended application because different electrode arrays are used for different applications." *Id.* at 17 (citing

Ex. 1137 ¶ 50). And, "for SCS, a [POSITA] would have used a detachable lead," for the reasons identified by Petitioner in connection with the Holsheimer ground discussed above (*see supra* Section V.C.3.iii.)—namely, that *all* leads used for SCS were detachable, e.g., as required by their implantation methods. *Id.* Petitioner also reiterates its position that use of detachable leads allows a malfunctioning lead to be replaced. *Id.* at 17–18 (citing Ex. 1137 ¶¶ 51–53); *see also* –1920 Pet. 34 (asserting the same).

In its Sur-Reply, Patent Owner argues that Loeb's "generalized statement . . . about other possible uses does not supply a motivation to modify," and that Dr. Kroll's analysis involves hindsight reasoning, seeking to create an SCS system. PO Sur-Reply 22 (citing Ex. 2039, 26:9–35:22); *but see* Pet. Sur-Sur-Reply 4. Patent Owner also argues that "Dr. Kroll admitted that a POSA would not take a cochlear implant and introduce it into the body cavity as Schulman discloses for its BION device. Conversely, a POSA would not use Schulman's BION as a cochlear implant." *Id.* (citations omitted).

Analysis

Although we maintain our conclusion that the Petition alone is insufficient to demonstrate that a POSITA would have found it obvious to modify the Schulman/Loeb device to include detachable leads, for the reasons noted above, that failure does not dictate resolution of the issue at this stage. In light of the entire record before us, we determine that a POSITA would have found it obvious to utilize detachable leads in the Schulman/Loeb combination proposed by Petitioner, i.e., in an SCS system.

As discussed in Section V.E.3.i., we determine that a POSITA would have found it obvious to utilize Schulman's system for SCS, given its

disclosure of stimulating nerves and neural pathways to relieve pain. Ex. 1012, Abstract. And as discussed in Section V.E.3.ii., we determine that a POSITA would have found it obvious to configure Schulman into an array arrangement, as taught by Loeb, to prevent migration of microstimulators and to improve charging efficiency. Ex. 1103 ¶¶ 66–71, 82. Thus, we consider Petitioner's contention that when modified in this manner, i.e., an array configuration used for SCS, the electrode array *must* be detachable. Pet. Reply 16–17.

Much of the evidence considered in Section V.C.3.iii., above, is relevant here. For example, four inventors of the '280 patent testified that, prior to the critical date, *all* SCS systems known to them employed detachable leads. Ex. 1126, 198:3–22; Ex. 1128, 279:4–12; Ex. 1131, 110:14–111:10; Ex. 1132, 295:19–22. This evidence documents the knowledge a POSITA would bring to bear in evaluating the appropriate lead arrangement for an SCS system, e.g., that rendered obvious by Schulman. Additionally, Patent Owner's declarant, Dr. Lipson, testified that he is not aware of any SCS systems that do not utilize detachable leads, and that he has never implanted an SCS lead while it was attached to an IPG. Ex. 1125, 37:2–22; *see also id.* at 34:18–35:6, 36:6–25 (asserting the same). Additionally, Dr. Lipson explained that the process by which an SCS system is implanted requires a detachable connection to the IPG. *See* Ex. 1125, 29:19–30:23, 33:3–9, 35:9–36:5; Ex. 2034 ¶¶ 20–27.

Taken together, this evidence persuades us that a POSITA would have found it an obvious and necessary design choice to utilize detachable leads when the Schulman/Loeb array is used as a SCS system, as Petitioner contends. Specifically, we rely upon:

(1) the deposition testimony of four named inventors of the '280 patent, stating that all known SCS systems at the critical date included detachable leads (Ex. 1126, 198:3–22; Ex. 1128, 279:4–12; Ex. 1131, 110:14–111:10; Ex. 1132, 295:19–22),

(2) Dr. Lipson's testimony that the process for implanting all known SCS systems at (or near) the critical date required detachable leads (Ex. 1125, 29:19–30:23, 33:3–9, 35:9–36:5), and

(3) Dr. Kroll's testimony that a POSITA would have found it obvious to use detachable leads, in light of this evidence (Ex. 1137 ¶¶ 37–45, 49–53).

We do not agree with Patent Owner that Loeb's teaching of non-detachable leads is dispositive. PO Resp. 52. We recognize that Loeb teaches that the electrode and microstimulator arrays are "encapsulated . . . [to] prevent[] the electrode array 36 from breaking *or disconnecting itself from the microstimulator array 45*." Ex. 1117, 9:10–15 (emphasis added). However, the test for obviousness is what the combined teachings of the references as a whole would have suggested to a POSITA, not merely what Loeb disclosed. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Here, Petitioner has demonstrated sufficiently that in the proposed combination, i.e., an array configuration used for SCS, a POSITA would have found it obvious to provide a detachable electrode array, because this was the universal practice at the critical date, and was necessary for

implantation of the SCS system. Ex. 1125, 29:19–30:23, 33:3–9, 35:9–36:5; Ex. 1126, 198:3–22; Ex. 1128, 279:4–12; Ex. 1131, 110:14–111:10; Ex. 1132, 295:19–22; Ex. 1137 ¶¶ 37–45, 49–53. Thus, even if Loeb alone discourages detachment (Ex. 1117, 9:10–15), we disagree with Patent Owner's argument that, in the proposed combination, a detachable connection would not have been obvious.

We also do not agree with Patent Owner's argument that Dr. Kroll's analysis involves hindsight reasoning, seeking to create an SCS system. PO Sur-Reply 22. As discussed above, record evidence demonstrates that a POSITA would have found it obvious to utilize Schulman's system for SCS. Patent Owner does not dispute that conclusion. Record evidence also demonstrates that, in an SCS system, detachability is required and expected by those skilled in the art. Thus, we determine that Dr. Kroll's testimony is based adequately in record evidence, and is not based in improper hindsight.[30]

Thus, we determine that a POSITA would have found this limitation of claim 18 obvious over the combined teachings of Schulman and Loeb.

[30] We also disagree with Patent Owner's argument that "Dr. Kroll admitted that a POSA would not take a cochlear implant and introduce it into the body cavity as Schulman discloses for its BION device. Conversely, a POSA would not use Schulman's BION as a cochlear implant." PO Sur-Reply 22. This is not the modification proposed by Petitioner.

iv. *"a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is independently programmable with different stimulation parameters, wherein m is equal to or less than n, and m is 2 or greater"*

Petitioner contends that the combined teachings of Schulman and Loeb teach a plurality of microstimulators with stimulation channels that can be programmed independently with different stimulation parameters. –1920 Pet. 35–38; *see supra* Section V.E.3.ii. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 51–56.

We find that Schulman discloses that each of the plurality ("m") of microstimulators 100 "can be actuated (enabled/disabled) or have its characteristics altered via communications with one or more devices external to itself." Ex. 1012, 4:40–5:28, Fig. 3A (depicting a multiplicity of microstimulators, i.e., a multiplicity of "m" stimulation channels wherein is greater than two). Exemplary stimulation parameters are shown in Table 1. *Id.* at 6:53–7:30 (e.g., charging current values, pulse frequency and width). Each microstimulator 100 includes "one or more ['n'] electrodes 112," thus, "m" is equal to or less than "n," the number of electrodes. *Id.* at 4:4–16.

Additionally, we find that Loeb discloses a microstimulator array arrangement with five ("m") microstimulators 20a–20e and five ("n") electrodes, i.e., "m" is equal to "n." Ex. 1017, Figs. 2A, 5.

Thus, we determine that a POSITA would have found this limitation of claim 18 obvious over the combined teachings of Schulman and Loeb.

v. *"wherein the IPG contains a soft ramping circuit that ramps up the stimulation pulse magnitude at the beginning of a burst of stimulation pulses in at least one channel"*

Petitioner contends that Schulman discloses this limitation through its discussion of a "Ramp On Time" parameter of stimulation circuitry 110.

–1920 Pet. 39–41. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 51–56.

We find that Schulman discloses that microstimulators 100 are programmed with pulse parameters, e.g., a "Ramp On Time" parameter. Ex. 1012, Table 1, 4:64–5:4, 6:59–7:2. We credit Dr. Kroll's testimony that this "Ramp On Time" parameter controls the duration of time during which electrical stimulus gradually will be increased before applying stimulation at the full operating amplitude, i.e., that ramps up the pulse magnitude. Ex. 1003 ¶¶ 94–95; *see also id.* ¶¶ 96–97 (asserting the same). Thus, we find that Schulman teaches this limitation of claim 18.

4. Analysis of Claim 27

Petitioner contends that claim 27 would have been obvious over Schulman and Loeb. –1920 Pet. 20–25 (motivation to combine), 41–51.

Patent Owner disputes Petitioner's contentions. PO Resp. 56–66. Patent Owner argues that the prior art fails to teach the steps of "aligning the primary antenna coil with the implanted secondary coil," and "stopping the charging at the battery charger." *Id.* at 56–61. Patent Owner also argues that a POSITA would not have been motivated to combine Schulman and Loeb as proposed. *Id.* at 61–66.

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 27 is unpatentable over Schulman and Loeb.

vi. Preamble

The preamble of independent claim 27 recites "[a] method of charging a rechargeable battery contained within an implantable pulse generator (IPG), which IPG is connected to an implanted, secondary coil antenna, the

method employing an external battery charger, which charger contains a rechargeable battery electrically connected to an external, primary antenna coil, the method comprising . . . ." Ex. 1001, 57:37–43. Petitioner contends that the combined teachings of Schulman and Loeb satisfy the preamble. –1920 Pet. 41–45. Specifically, Petitioner contends that Schulman discloses a process for recharging batteries 104 in implanted microstimulators 100 with external charger 118. *Id.* at 41. Petitioner contends that this recharging process occurs when the implanted microstimulators' coil 116 receives energy from the transmitting coil of external charger 118. *Id.* at 41–43. Although Schulman does not specify that external charger 118 includes a rechargeable battery, Petitioner contends that it would have been obvious to include one, in light of Loeb's disclosure of a rechargeable battery in its external charging device, which "render[s] the [external] processor 60 portable." *Id.* at 43–44 (quoting Ex. 1017, 11:9–12, 11:40–43).

Patent Owner does not dispute Petitioner's contentions regarding the preamble. *See* PO Resp. 56–66; *but see id.* at 61–66 (disputing combination regarding the "aligning" step).

We find that the cited prior art supports Petitioner's contentions. Schulman explains that coils 116 of implanted microstimulators 100 receive recharging power from external power source 118, which, as shown in Figure 3A, includes an external coil. Ex. 1012, 4:26–56, Fig. 3A. Moreover, Loeb discloses external processor 60, which provides power to capacitors within implanted microstimulators, wherein external processor 60 includes rechargeable battery 68, such that the processor is portable. Ex. 1117, 11:9–12, 11:40–43. In light of these teachings, we determine that

a POSITA would have been motivated to include a rechargeable battery in Schulman's external power source 118, to allow portability. Ex. 1103 ¶ 100.

Thus, we determine that a POSITA would have found the preamble of claim 27 obvious over the combined teachings of Schulman and Loeb.

vii. "(a) charging the rechargeable battery in the external battery charger using an external power source"

Petitioner contends that Loeb teaches this limitation because, as discussed regarding the preamble, Loeb's external processor 60 includes a rechargeable battery that must be charged before it can operate to transfer power. –1920 Pet. 45. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 56–66.

We find that Loeb's external processor includes a rechargeable battery. Ex. 1117, 11:9–12. We credit Dr. Kroll's testimony that this rechargeable battery necessarily must be charged from an external power source in order for it to operate. Ex. 1003 ¶ 101. Thus, we find that Loeb teaches this limitation of claim 27.

viii. "(b) aligning the primary antenna coil with the implanted secondary coil"

Petitioner contends that the combined teachings of Schulman and Loeb satisfy this limitation. –1920 Pet. 20–25 (motivation to combine), 46–48. Petitioner contends that it would have been obvious to arrange Schulman's microstimulators in an array configuration, as taught by Loeb, to prevent migration of the microstimulators and to improve charging efficiency. *Id.* at 46, 20–25; *see supra* Section III.E.3.ii.

Additionally, according to Petitioner, Schulman discloses using external charger 118 to inductively charge implanted microstimulators 100,

and explains that this process "requires that the user remain in close proximity to the drive coil" of the external charger. *Id.* at 46 (citing Ex. 1012, 1:26–34) (emphasis omitted).

Petitioner also contends that Loeb teaches that, when inductively powering its implanted microstimulators, "[o]ptimum inductive coupling occurs between the internal coils 30 and the external coil when good alignment is achieved. Hence, maintaining proper alignment allows the modulated power signal to be a relatively low power signal." *Id.* at 46 (citing Ex. 1017, 9:28–32). Thus, Petitioner contends that Loeb teaches "alignment means" to align the implanted and external coils. *Id.* at 46–47. In light of Loeb's teachings, Petitioner contends that a POSITA would have found it obvious to align the coil of Schulman's external charger with the coils of the implanted microstimulators (configured in an array arrangement, as taught by Loeb), to optimize inductive coupling and preserve the external charger's battery. *Id.* at 47–48.

Patent Owner argues that neither Schulman nor Loeb "align[]" the coils under Patent Owner's proposed construction. PO Resp. 56–58. Patent Owner argues that Schulman teaches only a "general spatial arrangement" of the coils, and Loeb teaches only "mechanical means of alignment such as a 'magnet or marker'" and a focusing coil. *Id.* at 57–58. According to Patent Owner, neither Schulman nor Loeb measures an electrical parameter, as required by Patent Owner's construction. *Id.* at 56–58; *see also* PO Sur-Reply 28 (asserting the same).

Patent Owner also argues that a POSITA would not have been motivated to combine Schulman and Loeb as proposed by Petitioner. PO Resp. 61–66. Patent Owner argues that Schulman and Loeb address

different problems—rechargeable power supplies for implanted microstimulators, and auditory nerve stimulators, respectively. *Id.* at 61–62. According to Patent Owner, each reference provides adequate power mechanisms for their respective uses and Petitioner has not identified a non-hindsight based reason to modify them. *Id.* at 62. Patent Owner also argues that a POSITA would not have been motivated to align Schulman's coils based on Loeb's disclosure of "good alignment," because Loeb does not explain what this is or how to achieve it. *Id.* at 63. In fact, Patent Owner argues that Loeb "teaches away from achieving any particular alignment position," because it uses a focusing coil. *Id.* Additionally, Patent Owner argues that because Loeb lacks implanted batteries, a POSITA would not be motivated by Loeb's discussion of alignment. *Id.* at 64–65. Finally, Patent Owner argues that "although the Petition purports to use Schulman as the primary reference, and Loeb as the secondary reference, Petitioner inverts the arrangement in its motivation-to-combine analysis to argue that a POSA would have been motivated to alter Loeb to incorporate Schulman's stimulation configuration." *Id.* at 65–66.

We have considered the parties' arguments and cited evidence, and determine that the cited evidence supports Petitioner's contentions. As an initial matter, we determine that a POSITA would have been motivated to modify Schulman in light of Loeb's teachings, as proposed by Petitioner.[31]

[31] We do not agree with Patent Owner's arguments regarding Petitioner's purported use of Schulman and Loeb as "primary" or "secondary" references. PO Resp. 65–66; *see In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012); *In re Bush*, 296 F.2d 491, 496 (CCPA 1961); *In re Cowles*, 156 F.2d 551, 554 (CCPA 1946)). The Petition proposes modifying Schulman to include an array arrangement and improved alignment features, as taught by

As discussed above regarding claim 18, we do not agree with Patent Owner's characterization of Schulman and Loeb. *See* Section V.E.3.ii. Both references are directed to tissue stimulation systems, and Schulman expressly incorporates Loeb by reference, describing it as a known "[i]mplantable device for tissue stimulation." Ex. 1012, Abstract, 1:15–19; Ex. 1117, Abstract. Thus, we agree with Dr. Kroll that, in light of the references' common focus on tissue stimulation generally, a POSITA would have considered Loeb and Schulman as complementary, and would have found it obvious to modify Schulman to include an array configuration, as taught by Loeb, to prevent migration from the implantation site and to allow for better alignment of the charging coils. *Id.* ¶¶ 65–67, 104–105.

This conclusion is supported by Loeb's disclosure. As shown in Figure 4A, Loeb's coils are "aligned," under the proper construction of this phrase, *see* Section II.A.1, because they are in relative position to permit energy transfer. Loeb explains that "[o]ptimum inductive coupling occurs between the internal coils 30 and the external coils when good alignment is achieved." Ex. 1117, 9:27–29. Loeb also explains that good alignment is achieved through "alignment means, such as a magnet or marker 48, that help[] align" the coils, as well as focusing coil 49, which captures and redirects the transmitted power. *Id.* at 9:20–45. Thus, we do not agree with Patent Owner that Loeb "teaches away" from aligning the coils. That Loeb discloses mechanical alignment means and a focusing coil to improve alignment does not conflict with Loeb's explicit teaching that energy transmission is more efficient when the coils are properly aligned; indeed,

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Loeb. *See, e.g.*, –1920 Pet. 20–25 (modifying Schulman to include an array arrangement), 46 (same), 47–48 (modifying Schulman to align its coils).

we discern the two are complementary. Loeb's disclosure of these techniques serves to emphasize the importance of alignment in optimizing energy transfer, and further supports Dr. Kroll's testimony that a POSITA would have been motivated to modify Schulman in light of Loeb to allow for better alignment of the charging coils. *Id.* ¶¶ 65–67, 104–105.[32]

We have considered Patent Owner's arguments, but do not agree that Loeb's purported failure to teach the measurement of electrical parameters is dispositive. Under the broadest reasonable interpretation of "aligning," discussed above, the claim does not require a specific relative position, or the measurement of electrical parameters. *See supra* Section II.A.1. Thus, we determine that a person of ordinary skill in the art would have been motivated to modify Schulman in light of Loeb's teachings to optimize inductive coupling and preserve the charger's battery. *See, e.g.*, Ex. 1103 ¶¶ 104–105; Ex. 1117, 9:20–32.

Accordingly, we determine that a POSITA would have found this limitation of claim 27 obvious over the combined teachings of Schulman and Loeb.

[32] That Loeb does not include implanted batteries is immaterial. PO Resp. 62, 64. Both Schulman and Loeb rely on inductive coupling to power the implanted components. Ex. 1012, 4:4–16, Ex. 1117, 7:40–60. We discern no importance in Schulman's choice to store the transferred energy in batteries before operating the implanted components, over Loeb's choice to utilize directly the transferred energy to operate the implanted components, without storing it in batteries.

ix. "(c) broadcasting electromagnetic energy through the primary antenna coil"

Petitioner contends that Schulman discloses this limitation because external charger 118 broadcasts an alternating magnetic field through its coil. –1920 Pet. 48. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 56–66.

We find that Schulman discloses that implanted "coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118." Ex. 1012, 4:27–32, Fig. 3A (coil); Ex. 1103 ¶ 106. Thus, we find that Schulman teaches this limitation of claim 27.

x. "(d) receiving the broadcast electromagnetic energy through the secondary antenna coil, whereby an alternating current is produced in the secondary coil"

Petitioner contends that Schulman discloses this limitation because implanted coils 116 receive power in the form of an alternating magnetic field broadcasted by external charger 118. –1920 Pet. 49–50. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 56–66.

We find that Schulman explains that "coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118 . . . and responsively supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122." Ex. 1012, 4:27–31; Ex. 1103 ¶ 107. Thus, we find that Schulman teaches this limitation of claim 27.

xi. "(e) rectifying the induced, alternating current received by the secondary coil"

Petitioner contends that Schulman discloses this limitation because the current received by coils 116 is rectified. –1920 Pet. 50. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 56–66.

We find that Schulman explains that "coil 116 receives power in the form of an alternating magnetic field generated from an external power source 118 . . . and responsively supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122." Ex. 1012, 4:27–31; Ex. 1103 ¶¶ 108–109. Thus, we find that Schulman teaches this limitation of claim 27.

xii. "(f) charging the rechargeable battery carried within the IPG, while monitoring the charging current or voltage across the battery as the battery is being charged to prevent overcharging"

Petitioner contends that Schulman discloses this limitation because charging circuit 122 monitors the voltage level of battery 104, while it is being recharged, to avoid overcharging. –1920 Pet. 51. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 56–66.

We find that Schulman explains that charging circuit 122 "monitors the voltage V on battery 104 and charges it according to its preferred charging characteristics (current and voltage)," to avoid overcharging. Ex. 1012, 4:31–34, 10:60–64; Ex. 1103 ¶ 110. Thus, we find that Schulman teaches this limitation of claim 27.

xiii. "(g) stopping the charging at the battery charger when the current or voltage at the battery in the IPG reaches a prescribed level"

Petitioner contends that Schulman discloses this limitation because once Schulman's implanted batteries are recharged, charging circuit 122 can "detune receiving coil 116 to stop receiving charging power," "and/or 'external power source . . . continues to provide charging power until it has received status information from each of the implanted devices 100 that its battery 104 is charged.'" –1920 Pet. 51–52 (citing Ex. 1012, 4:32–35, 4:44–56, 5:55–66, 6:14–17).

Patent Owner argues that Schulman does not disclose that the *battery charger* stops the charging of the implanted battery. PO Resp. 58. According to Patent Owner, Schulman discloses two variations for stopping the charging. *Id.* at 59. In the "typical" application, charging circuit 112 detunes implanted coil 116 when the battery is sufficiently charged. *Id.* (citing Ex. 1012, 4:39–51, 3:62–64). Thus, Patent Owner argues that this stops charging *within* the implanted device, i.e., by detuning the implanted coil, and not *at the battery charger*, as claimed. *Id.* Patent Owner argues that the second variation is the same as the first, except that external charger 118 also periodically polls the implanted batteries' power status, and stops transmitting power when the implanted batteries are fully charged. *Id.* at 60 (citing Ex. 1012, 4:52–56). Patent Owner contends that even in this arrangement, however, charging is still stopped *within* the implanted device by detuning the coils before the charger stops transmitting power. *Id.*

Petitioner replies that detuning coils 116 is merely one preferred embodiment. Pet. Reply. 24 (citing Ex. 1012, 4:39–51). Petitioner contends that in another preferred embodiment, the external charger stops the

charging once it receives acceptable status information. *Id.* (citing Ex. 1012, 4:52–56, 5:55–6:17; Ex. 1137 ¶¶ 56–57).

Patent Owner responds that the difference between Schulman's first and second embodiments is that the second embodiments adds polling, but that it "says nothing to derogate from the disclosure that, upon achieving a full charge, each device's charging circuit detunes its coil to prevent overcharging the battery." PO Sur-Reply 29 (citing Ex. 1012, 4:49–51). Patent Owner argues that detuning the coils is necessary to minimize heat generation and avoid overcharging. *Id.*

We have considered the parties' arguments and evidence, and determine that the cited evidence supports Petitioner's contention. Schulman discloses a first "typical application" in which charging circuit 122 "preferably detunes coil 116 . . . and thus minimizes any heat generation in the charging circuit 122 or in the battery 104 from overcharging." Ex. 1012, 4:40–51. In this embodiment, "external power source can continue to provide charging power via an alternating magnetic field indefinitely." *Id.* at 4:49–51. We agree with Patent Owner that in this embodiment, charging is not stopped at the external charger but, rather, may continue indefinitely.

In connection with this embodiment, Schulman discloses a further variation in which "the external power source periodically polls the implanted devices for status information and continues to provide charging power until it has received status information from each of the implanted devices 100 that its battery 104 is charged." Ex. 1012, 4:52–56. By disclosing this polling in conjunction with the disclosure of detuning

coils 116, we tend to agree with Patent Owner that this embodiment may not teach "stopping the charging at the battery charger," as claimed.[33]

However, Petitioner identifies additional portions of Schulman's disclosure, which Patent Owner does not address. –1920 Pet. 52 (citing Ex. 1012, 5:55–66, 6:14–17); Pet. Reply 24 (citing Ex. 1012, 5:55–6:17). Schulman explains another "preferred embodiment" that includes "means for transmitting status and data to external devices." Ex. 1012, 5:55–6:17. Specifically, Schulman discloses "an exemplary charging mode" in which "each device 100 can individually communicate with charger 118 so that charger 118 can determine when all of the implanted devices 100 have been fully charged." *Id.* at 5:57–59. In this mode, Schulman explains that "charger 118 emits an alternating magnetic field for a first time period 148," modulates the alternating magnetic field "with a series of bits corresponding to polling data corresponding to a selected microstimulator 100 (i.e., including an address for one implanted device)," and "then goes into a receive mode for a second time period 150 during which time the selected

[33] In the Decision on Institution, we determined that Schulman's disclosure that charger 118 "provid[es] charging power *until* it has received status information from each of the implanted devices 100 that its battery 104 is charged" was sufficient to satisfy the claim language, at that preliminary stage of the proceeding, because it conveys that charging is stopped at charger 118 *when* a subsequent poll reports that all batteries are completely charged, even if not *immediately when* charging is complete. –1920 DI 20 (quoting Ex. 1012, 4:52–56). We determined that Patent Owner had not shown that the passage of some period of time between battery re-charge and termination of power at the charger does not meet the plain language of the claim. *Id.* In other words, Patent Owner had not shown that "when" should be construed as, e.g., "immediately when." *Id.* However, we need not resolve this question, in light of additional disclosure of Schulman that satisfies both constructions.

device 100 emits a magnetic signal modulated with a series of bits corresponding to its battery status." *Id.* at 5:60–6:12. Schulman discloses that:

> This *charging/polling cycle preferably repeats* for all of the implanted devices within the operational range of the charger 118. *Once the charger 118 determines that all of the devices 100 have been charged, the cycle is terminated* and the patient or clinician is preferably notified, e.g., using a visual or audio annunciator 152.

Id. at 6:12–17 (emphasis added).

Thus, in this embodiment, Schulman explains that charger 118 alternates between charging and polling phases, wherein those phases repeat until all microstimulators are sufficiently charged. *Id.* When the polling so indicates, the "charging/polling cycle" is terminated, i.e., all future polling and all future charging from the external charger is stopped. Schulman does not describe this as happening within the implanted device, e.g., by detuning coils 116. *Id.* Rather, Schulman explains that this process occurs at the charger. *See, e.g., id.* at 6:3, 6:8–9. Patent Owner does not address these disclosures in the Response or Sur-Reply, nor does Dr. Berger address them in his declaration. PO Resp. 58–61; PO Sur-Reply 28–30; Ex. 2033 ¶¶ 124–129. Accordingly, we find that Schulman teaches this limitation of claim 27.

5. Secondary Considerations

As discussed in Section V.A.4. above, we determine that Patent Owner has not demonstrated a nexus to claim 18, but has demonstrated a nexus to claim 27. Accordingly, we do not consider Patent Owner's evidence of secondary considerations, with respect to claim 18.

For claim 27, for the reasons discussed in Section V.A.4., we find that Patent Owner has presented moderate evidence of industry recognition and commercial success, and some, but almost non-existent, evidence of long-felt need. We weigh this evidence in conjunction with the other factors relevant to an obviousness analysis. As discussed in Section V.E.4., we find that Petitioner has demonstrated that these claims would have been obvious to a POSITA, especially in light of Loeb's explicit recognition of the importance of aligning coils for inductive power transfer. Overall, upon weighing the factors, we determine that the moderate evidence of industry recognition and commercial success, and some, but almost non-existent, evidence of long-felt need is insufficient to outweigh our determination that Schulman and Loeb account for every limitation of claim 27.

6. Conclusion

For the foregoing reasons, on this record, Petitioner has shown, by a preponderance of the evidence, that claims 18 and 27 would have been obvious in view of the combined teachings of Schulman and Loeb.

F. Obviousness over the Combined Teachings of Schulman, Loeb, and Rutecki

Petitioner contends that claim 8 would have been obvious over the combined teachings of Schulman, Loeb, and Rutecki. –1920 Pet. 52–56. For reasons that follow, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Overview of Rutecki (Ex. 1007)

Rutecki is a U.S. patent titled "Treatment of Pain by Vagal Afferent Stimulation," which discloses applying programmable pulse waveform

stimulation to an implanted lead to treat a patient's pain. Ex. 1007, [54], [57]. Rutecki explains that the lead may be "implanted on the patient's cervical vagus nerve or other site preferably above the location of the pain to stimulate afferent fibers for activating a descending anti-nociceptive pathway and thereby blocking incoming pain signals." *Id.* at [57].

Prior to permanent implantation, Rutecki states that tests should be conducted to determine whether the patient responds appropriately to stimulation. *Id.* at 14:3–7. Rutecki explains that

> an external stimulus generator may be employed with leads extending percutaneously to the implanted nerve electrode assembly. The most serious problem encountered with such a temporary arrangement is the potential for infection, but that risk can be suitably minimized to justify the relatively short term tests required to determine whether the pain suffered by the patient under observation is sufficiently relieved to characterize the neurostimulation of the present invention as successful treatment. If it is, a permanent implant may be performed.

Id. at 14:8–18.

2. Analysis of Claim 8

Petitioner contends that claim 8 would have been obvious over Schulman, Loeb, and Rutecki. –1920 Pet. 52–56.

Patent Owner disputes Petitioner's contentions. PO Resp. 66–69. Patent Owner argues that Rutecki fails to teach an "external trial stimulator" under Patent Owner's construction of the phrase. *Id.* at 67. Patent Owner also argues that a POSITA would not have been motivated to combine Schulman, Loeb, and Rutecki as proposed. *Id.* at 67–69.

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 8 is unpatentable over Schulman, Loeb, and Rutecki.

i. Preamble

With respect to the preamble of claim 8, reciting "[a] spinal cord stimulation system," Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 54. For the reasons discussed regarding claim 18, we find that a POSITA would have found this limitation obvious over Schulman's teachings. *See also* Ex. 1103 ¶ 117 (asserting the same).

ii. "a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry"

With respect to this limitation of claim 8, Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 54. For the reasons discussed regarding claim 18, we determine that a POSITA would have found this limitation to have been obvious over the combined teachings of Schulman and Loeb. *See also* Ex. 1103 ¶ 118 (asserting the same).

iii. "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

With respect to this limitation of claim 8, Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 54. For the reasons discussed regarding claim 18, we determine that a POSITA would have found this limitation to have been obvious over the combined teachings of Schulman and Loeb. *See also* Ex. 1103 ¶ 119 (asserting the same).

iv. "a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is independently programmable with different stimulation parameters, wherein m is equal to or less than n, and m is 2 or greater"

With respect to this limitation of claim 8, Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 54–55. For the reasons discussed regarding claim 18, we determine that a POSITA would have found this limitation to have been obvious over the combined teachings of Schulman and Loeb. *See also* Ex. 1103 ¶¶ 120–121 (asserting the same).

v. "an external trial stimulator (ETS)"

Petitioner contends that Rutecki teaches an external trial stimulator, and that it would have been obvious to include an ETS as taught by Rutecki in Schulman's modified system. –1920 Pet. 55–56, 53–54 (motivation to combine). Specifically, Petitioner contends that Rutecki discloses using an "external stimulus generator," consistent with well-known industry practice. *Id.* at 55 (citing Ex. 1007, 14:8–10; Ex. 1103 ¶¶ 122–123). Petitioner contends that it would have been obvious for a POSITA to use Rutecki's external stimulus generator, in Schulman's modified system, to determine whether the patient responds appropriately to stimulation therapy before permanent implantation of an IPG. *Id.* (citing Ex. 1007, 14:3–8; Ex. 1103 ¶ 124). Petitioner contends that this is important because "[i]f the patient does not respond to the stimulation therapy, the patient can avoid the unnecessary trauma and expense of receiving a fully implanted system." *Id.* at 53–54 (citing Ex. 1007, 14:3–18; Ex. 1103 ¶ 116).

Patent Owner contends that Rutecki does not disclose an "external trial stimulator" under Patent Owner's construction of the phrase, i.e., "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," because Rutecki's external stimulus generator: (1) is not used during a trial period because it is used with leads extending percutaneously to the implanted electrode assembly; and (2) is not used outside of the operating room because Rutecki teaches that the patient is "under observation." PO Resp. 67 (citing Ex. 2033 ¶ 141). In connection with the second argument, in its Sur-Reply, Patent Owner also argues that Rutecki's lead "is implanted on the patient's cervical vagus nerve," or "wrapped around the cervical vagus nerve," such that it would be dangerous for the patient to exit the operating room. PO Sur-Reply 23–24 (citing, e.g., Ex. 1124, 206:1–19).

Petitioner replies that even under Patent Owner's proposed construction, Rutecki teaches this limitation because Rutecki discloses using the external stimulus generator for "short term tests . . . to determine whether" the patient responds to therapy, which Petitioner contends is a trial period "used temporarily for evaluation purposes before implantation of the IPG." Pet. Reply 19–20 (citing Ex. 1007, 14:10–17; Ex. 1137 ¶¶ 67–68). Petitioner also contends that Rutecki's use while "under observation" does not preclude use outside of the operating room, as Dr. Berger admitted and as Dr. Lipson testified was expected for ETS used for SCS systems. *Id.* at 20 (citing Ex. 1124, 202:3–203:7; Ex. 1125, 58:16–25, 59:2–7). Petitioner also contends that it would have been obvious to a POSITA to use an ETS outside of the operating room. *Id.* (citing Ex. 1137 ¶¶ 69–70).

We have considered the parties' arguments and evidence, and we determine that Rutecki teaches an ETS even under Patent Owner's construction of this phrase. Rutecki discloses that its "external stimulus

generator" is "employed with leads extending percutaneously to the implanted nerve electrode assembly." Ex. 1007, 14:8–18. Thus, Rutecki's external stimulus generator is a "pulse generator externally-worn by a patient," pursuant to Patent Owner's construction, because its leads extend through the patient's skin, i.e., external to the patient. That Rutecki's external stimulus generator includes percutaneous leads is not determinative, *see* PO Resp. 67, because a percutaneous extension is required by the claim. *See infra* Section III.F.2.vi.

Rutecki also discloses that the external stimulus generator is used in a "temporary arrangement," i.e., in a "relatively short term test[] required to determine whether the pain suffered by the patient under observation is sufficiently relieved." *Id.* at 14:8–18. Thus, it is "used temporarily for evaluation purposes before implantation of the IPG," pursuant to Patent Owner's construction.

We do not agree with Patent Owner's argument that Rutecki's external stimulus generator it is not capable of use outside of the operating room. PO Resp. 67; PO Sur-Reply 23–24. Rutecki discloses that when using the external stimulus generator, the patient is "under observation." Ex. 1007, 14:8–18. As Dr. Berger testifies, a patient may be under observation outside of the operating room, depending on the condition for which they are being observed. Ex. 1124, 202:3–203:7. And as both Dr. Lipson and Dr. Kroll testify, in a SCS system, such as that rendered obvious by Schulman (*see supra* Section V.F.2.i.), external trial stimulators were designed to be worn outside of the operating room. Ex. 1125, 58:2–25, 59:2–7; Ex. 1137 ¶¶ 69–70; *see also* Ex. 1009, 34 (patient sent home during SCS trial period).

Moreover, Patent Owner does not identify any structural feature of Rutecki's external stimulus generator that would preclude it from being "*capable of* being used outside of the operating room," as required by Patent Owner's construction. We disagree with Patent Owner's argument that the placement of Rutecki's lead "*on* the patient's cervical vagus nerve," or "*wrapped around* the cervical vagus nerve" precludes the safe use of Rutecki's system outside of the operating room. PO Sur-Reply 23–24 (emphasis added; citing Ex. 1007, Abstract). The portion of Rutecki's disclosure cited by Patent Owner does not support its argument that the lead must be placed "on," or "wrapped around," the cervical vagus nerve. Ex. 1007, Abstract. Rather, Rutecki explains that the lead may be "implanted on the patient's cervical vagus nerve *or other site preferably above the location of the pain* to stimulate afferent fibers for activating a descending anti-nociceptive pathway and thereby blocking incoming pain signals." Ex. 1007, Abstract. Patent Owner does not demonstrate that placement of the lead "above" the patient's cervical vagus nerve or at "[an]other site" precludes Rutecki's external stimulus generator from being "capable of being used outside of the operating room." Nor does Dr. Berger support sufficiently his deposition testimony that the "electrode is wrapped around the vagus nerve." Ex. 1124, 206:9–19 (testifying, without sufficient explanation and contrary to the portion of Rutecki cited above, that "[t]his isn't just implanted alongside the vagus nerve. This is wrapped around the vagus nerve"). Thus, we determine that Rutecki's external stimulus generator is "capable of being used outside of the operating room," pursuant to Patent Owner's construction.

For the foregoing reasons, we find that Rutecki teaches an "external trial stimulator," as claimed.

We also determine that a POSITA would have found it obvious to employ Rutecki's external trial stimulator in Schulman's modified system. Dr. Kroll testifies that a POSITA would have been motivated to use Rutecki's external stimulus generator in Schulman's system, because it was well known to be advantageous to test the efficacy of stimulation therapy before permanent implantation of an IPG. Ex. 1103 ¶¶ 116, 124. According to Dr. Kroll, "[i]f the therapy does not prove to be effective during the test period, the permanent system is not implanted and the trauma and medical expenses associated with a fully implanted system are avoided." *Id.* ¶ 116. Dr. Kroll explains that "[u]sing Rutecki's external trial stimulator in Schulman's system would merely require substituting Rutecki's external trial stimulator with an external trial stimulator that has the characteristics and features of Schulman's microstimulator array," and that such a modification "could be implemented in Schulman's system with a high degree of predictability and the combination yielding the claimed structure would work as expected." *Id.* ¶ 124. The evidence cited by Dr. Kroll supports this testimony. *Id.* ¶¶ 116, 124 (citing, e.g., Ex. 1007, 14:10–18; Ex. 1009, 33).

We do not agree with Patent Owner's argument that Dr. Kroll fails to explain how Rutecki would have been modified to work with Schulman, or why a POSITA would have made such a modification. PO Resp. 68. It is not necessary that Rutecki's external stimulus generator be bodily incorporated into Schulman's system, as Patent Owner's argument presumes. Rather, "the test is what the combined teachings of those

references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d at 425; *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.").

Dr. Kroll testifies that a POSITA would have found it obvious to include an ETS, as taught by Rutecki, into Schulman's modified stimulation system, wherein that ETS would have been appropriate for use with the array configuration of Schuman's modified system, and that such a modification would work as expected. Ex. 1103 ¶ 116; Ex. 1137 ¶ 72; Reply 28. Patent Owner relies on Dr. Berger's testimony that a POSITA would not have understood how Rutecki's external stimulus generator "could be connected to electrodes that would be placed at the sites of the BIONs in Schulman," because "[e]lectrodes used for this would be inconsistent with the structure of the implantable BIONs." Ex. 2033 ¶ 143. Patent Owner and Dr. Berger, however, fail to recognize that Petitioner proposes employing an ETS for the *modified* system of Schulman and Loeb. –1920 Pet. 53–54, 55–56; Ex. 1103 ¶ 124. As proposed, Schulman's system is modified to employ an electrode array, instead of separate BION devices, as Dr. Berger's argument presumes. Because these arguments do not concern the modifications proposed by Petitioner, we do not agree with Patent Owner.

Moreover, Dr. Kroll clearly specifies why such a modification would have been made—to allow testing of stimulation therapy prior to undertaking the costs and trauma associated with permanent implantation. Ex. 1103 ¶ 116. That Schulman allows post-implantation modification of stimulation parameters (*see* PO Resp. 68–69) does not nullify this benefit

because, as Dr. Kroll testifies, if stimulation therapy is not effective, e.g., because the leads are implanted in the wrong area, adjustment of stimulation parameters after permanent implantation would not solve this problem. Ex. 1137 ¶ 73; Pet. Reply 28.

Thus, we determine that a POSITA would have found this limitation of claim 8 obvious over the combined teachings of Schulman, Loeb, and Rutecki.

vi. "a percutaneous extension which temporarily couples the ETS with the implantable electrode array"

Petitioner contends that Rutecki teaches this limitation because the external stimulus generator has "'leads extending percutaneously to the implanted nerve electrode assembly.'" –1920 Pet. 56 (quoting Ex. 1007, 14:8–10). Patent Owner does not dispute this contention. *See* PO Resp. 66–69.

We find that Rutecki discloses that leads extend percutaneously to couple the external stimulus generator to the implanted electrodes. Ex. 1007, 14:8–10. In the combination proposed by Petitioner, the leads would have been coupled to the electrode array of the Schulman and Loeb combination. Ex. 1003 ¶¶ 125–126. Thus, we determine that a POSITA would have found this limitation of claim 8 obvious over the combined teachings of Schulman, Loeb, and Rutecki.

3. Secondary Considerations

As discussed in Section V.A.4. above, we determine that Patent Owner has not demonstrated a nexus to claim 8. Accordingly, we do not consider Patent Owner's evidence of secondary considerations, with respect to claim 8.

4. Conclusion

For the foregoing reasons, on this record, Petitioner has shown, by a preponderance of the evidence, that claim 8 would have been obvious in view of the combined teachings of Schulman, Loeb, and Rutecki.

G. Obviousness over the Combined Teachings of Schulman, Loeb, Munshi, and Wang

Petitioner contends that claims 22–24 would have been obvious over the combined teachings of Schulman, Loeb, Munshi, and Wang. –1920 Pet. 56–72. For reasons that follow, we determine Petitioner has demonstrated that the challenged claims are unpatentable by a preponderance of the evidence.

1. Analysis of Claim 22

Petitioner contends that claim 22 would have been obvious over Schulman, Loeb, Munshi, and Wang. –1920 Pet. 56–75.

Patent Owner disputes Petitioner's contentions. PO Resp. 69–72. Patent Owner incorporates arguments made with respect to Petitioner's contentions regarding Schulman and Loeb, which we addressed above in Section V.E. *Id.* at 69. Patent Owner also argues that Wang does not disclose the claimed "alignment circuitry" including a "back telemetry receiver"—an argument we addressed in connection with the asserted ground of unpatentability over Holsheimer, Munshi, and Wang. *Id.* at 69–70; *see supra* Section V.C.3.vii., *id.* at n.15. Additionally, Patent Owner argues that a POSITA would not have been motivated to combine these references as proposed. PO Resp. 71–72.

After considering the parties' arguments and evidence, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claim 22 is unpatentable over Schulman, Loeb, Munshi, and Wang.

i. Preamble

The preamble of independent claim 22 recites "[a] spinal cord stimulation system . . . ." Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 59. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 69–72.

For the reasons discussed regarding claim 18, we find that a POSITA would have found this limitation obvious over Schulman's teachings. *See supra* Section V.E.3.i.; *see also* Ex. 1103 ¶ 143 (asserting the same).

ii. "an implantable, multi-channel implantable pulse generator (IPG) having a replenishable power source"

With respect to this limitation of claim 22, Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 59–60. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 69–72.

For the reasons discussed regarding claim 18, we determine that a POSITA would have found this limitation obvious over the combined teachings of Schulman and Loeb. *See supra* Section V.E.3.ii.; *see also* Ex. 1103 ¶ 144 (asserting the same).

iii. "an implantable electrode array detachably connected to the IPG, the electrode array having a multiplicity of n electrodes (En) thereon"

With respect to this limitation of claim 22, Petitioner relies on its contentions made with respect to claim 18. –1920 Pet. 60. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 69–72.

For the reasons discussed regarding claim 18, we determine that a POSITA would have found this limitation obvious over the combined teachings of Schulman and Loeb. *See supra* Section V.E.3.iii.; *see also* Ex. 1103 ¶ 145 (asserting the same).

iv. "a secondary, implanted coil coupled electrically to the replenishable power source"

Petitioner contends that Schulman teaches this limitation because Schulman discloses implanted coils 116. –1920 Pet. 60–61. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 69–72.

We find that Schulman discloses implanted coils 116, which receive power to charge implanted rechargeable batteries 104. Ex. 1012, 4:17–35, Fig. 2; Ex. 1103 ¶ 146. Thus, we find that Schulman teaches this limitation of claim 22.

v. "an external battery charger including: a primary coil"

Petitioner contends that Schulman teaches these limitations because Schulman discloses external charger 118. –1920 Pet. 61–63. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 69–72.

We find that Schulman discloses external power source 118 including externally mounted coil 18, used for charging implanted batteries 104. Ex. 1012, 3:40–45, 4:27–44, Figs. 1, 3A; Ex. 1103 ¶¶ 147–149. Thus, we find that Schulman teaches this limitation of claim 22.

vi. "[the external battery charger further including:] . . . a rechargeable battery contained in the charger, electrically coupled to the primary coil"

Petitioner contends that the combined teachings of Schulman and Loeb satisfy this limitation. –1920 Pet. 63–64. Specifically, Petitioner contends that although Schulman does not specify that external charger 118 contains a rechargeable battery, Petitioner contends that it would have been obvious to include one, in light of Loeb's disclosure of including a rechargeable battery in its external device, "to render the [external] processor 60 portable," for charging the implanted microstimulators. *Id.* at 63–64 (quoting Ex. 1017, 11:9–12, 11:40–43; citing Ex. 1017, Fig. 4B (battery 68)). Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 69–72.

We find that the cited prior art supports Petitioner's contention. Namely, Loeb explains that external processor 60 provides power to capacitors within implanted microstimulators through the skin, wherein external processor 60 includes rechargeable battery 68, such that the processor can be portable. Ex. 1117, 11:9–12, 11:40–43. In light of these teachings, we determine that a POSITA would have been motivated to include an external rechargeable battery in Schulman's external power source 118, to allow portability. Ex. 1103 ¶ 151.

Thus, we determine that a POSITA would have found this limitation of claim 22 obvious over the combined teachings of Schulman and Loeb.

vii. "[the external battery charger further including:] . . . a power amplifier for applying alternating current derived from the rechargeable battery in the charger to the primary coil"

Petitioner contends that the combined teachings of Schulman, Loeb, and Munshi satisfy this limitation. –1920 Pet. 64–66. Specifically, Petitioner contends that although Schulman does not specify that external charger 118 contains a power amplifier, Petitioner contends that it would have been obvious to include one when Schulman's charger is modified to include a rechargeable battery, as discussed above. *Id.* at 64–65; *see supra* Section V.G.1.vi. Petitioner contends that "[b]ecause batteries are direct current ('DC') sources, the DC power from the external charger's battery must be converted to AC for Schulman's external power source to transmit an 'alternating magnetic field' through its transmitting coil." *Id.* at 65. Thus, Petitioner contends that a POSITA would have found it obvious to include a known power amplifier, such as Loeb's circuitry for performing power conversion, or Munshi's power amplifier 78. *Id.* (citing, e.g., Ex. 1017, 12:11–13, 12:16–25, Fig. 6; Ex. 1005, 10:38–47, Fig. 2); *see also id.* at 57–59 (asserting the same). Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 69–72.

We find that the cited prior art supports Petitioner's contention. Namely, Loeb teaches circuitry and Munshi teaches a power amplifier for converting power before passing it to an external coil. Ex. 1017, 12:11–25, Fig. 6; Ex. 1005, 10:38–47, Fig. 2. In light of these teachings, we determine that a POSITA would have been motivated to include a power amplifier in Schulman's external power source 118, to perform the required power conversion before supplying power to the coil. Ex. 1103 ¶¶ 141–142, 153–158.

Thus, we determine that a POSITA would have found this limitation of claim 22 obvious over the combined teachings of Schulman, Loeb, and Munshi.

viii. "whereby the alternating current in the primary coil is transcutaneously transferred to the secondary implanted coil to the replenishable power source contained in the IPG"

Petitioner contends that Schulman teaches this limitation because Schulman's external charger transfers alternating current to implanted coils 116. –1920 Pet. 67–68. Patent Owner does not dispute Petitioner's contentions. *See generally* PO Resp. 69–72.

We find that Schulman discloses that implanted "coil 116 receives power in the form of an alternating magnetic field generated from external power source 118 . . . and responsively supplies an AC current to a rectifier 120 which is passed as a rectified DC current to a charging circuit 122. The charging circuit 122 then monitors the voltage V on battery 104 and charges it according to its preferred charging characteristics (current and voltage)." Ex. 1012, 4:27–35; *see also id.* at 1:66–2:9, 4:40–44 (asserting the same). As shown in Figure 3A, this transfer occurs through the patient's skin (transcutaneously). Thus, we find that Schulman teaches this limitation of claim 22.

ix. "alignment circuitry for detecting alignment between the primary and secondary coils, the alignment circuitry including a back telemetry receiver for monitoring the magnitude of the ac voltage at the primary coil as applied by the power amplifier"

Petitioner contends that the combined teachings of Schulman, Loeb, Munshi, and Wang would have rendered obvious this limitation. –1920 Pet. 68–74. Petitioner contends that although neither Schulman nor Loeb

expressly teach this limitation, Loeb recognizes that "optimum inductive coupling occurs . . . when good alignment is achieved." *Id.* at 69 (quoting Ex. 1017, 9:28–32). Petitioner contends that Wang also teaches that efficient energy transmission occurs when the coils are properly aligned, and provides an "alignment circuit and indicator" to detect proper alignment. *Id.* (citing Ex. 1018, 5:13–17, 11:41–46, Figs. 1, 5). Petitioner also contends that Wang's alignment circuit and indicator is a "back telemetry receiver," as claimed. *Id.* at 69–72. Petitioner contends that a POSITA would have found it obvious to use Wang's alignment circuitry in the modified system to determine when the coils are properly aligned, to optimize inductive coupling, preserve battery life, and maximize charging efficiency. *Id.* at 72–74; *see also id.* at 57–59; Ex. 1103 ¶¶ 138–142, 160–166 (asserting the same).

Patent Owner disputes Petitioner's contentions. PO Resp. 69–71; *see also* PO Sur-Reply 25–27 (asserting the same). Specifically, Patent Owner argues that Wang does not teach a "back telemetry receiver," under Patent Owner's proposed construction of that phrase. PO Resp. 69–70. Patent Owner also argues that a POSITA would not have been motivated to combine Schulman, Loeb, and Wang, because Loeb teaches aligning coils through use of mechanical means and a focusing coil. *Id.* at 71–72.

We find that the cited portions of the prior art support Petitioner's contentions. For the reasons discussed in Section V.C.3.vii, we find that Wang discloses "an alignment circuit and indicator . . . to indicate whether the coils are properly aligned." *Id.* at 4:37–42, 5:13–17, 11:41–46; *see also* Ex. 1103 ¶¶ 129, 162 (asserting the same). For the same reasons discussed above, we find that Wang's alignment circuitry includes a back telemetry

receiver, as construed in Section V.A.2, because Wang monitors voltage and compares it to a reference value, to illuminate an indicator LED when proper alignment is reached. Ex. 1018, 12:1–29, 11:56–63, Fig. 5; Ex. 1103 ¶¶ 129–133, 162–163; PO Sur-Reply 27 (acknowledging that "Wang's alignment circuitry . . . compares the current sensed voltage value to the scaled peak voltage value"). As discussed above, we do not agree with Patent Owner's argument that a back telemetry receiver must "receive information or data from the implanted device," or that Wang fails to do so. PO Resp. 69–70; PO Sur-Reply 25–27.

We determine that a POSITA would have found it obvious to use Wang's alignment circuitry in the external charger of the modified Schulman system, to indicate proper alignment of the inductive coils and to preserve battery life. –1920 Pet. 57–59, 72–74; Ex. 1103 ¶¶ 164–165. We also determine that such a combination would have been expected to be successful, due to the similarities of the systems, and because Schulman and Wang are directed to solving the same problem of noninvasively recharging an implanted battery. Ex. 1103 ¶ 166.

We do not agree with Patent Owner's argument that a POSITA would not have been motivated to combine Wang with Schulman and Loeb, because Loeb aligns the coils with mechanical means. PO Resp. 71–72. Loeb explains that "[o]ptimum inductive coupling occurs between the internal coils 30 and the external coils when good alignment is achieved." Ex. 1117, 9:27–29. Loeb also explains that this is achieved through "alignment means, such as a magnet or marker 48, that help[] align" the coils, as well as focusing coil 49, which captures and redirects the transmitted power. *Id.* at 9:20–45. That Loeb discloses mechanical

alignment means and a focusing coil to achieve proper alignment does not conflict with Wang's teaching that energy transmission is more efficient when the coils are properly aligned (Ex. 1018, 5:13–15); indeed, we discern the two are complementary. Loeb's disclosure of these techniques serves to emphasize the importance of achieving proper alignment to optimize energy transfer, and further supports Petitioner's contention that a POSITA would have been motivated to achieve proper alignment, including through application of Wang's teachings.

Thus, we determine that a POSITA would have found this limitation of claim 22 to be obvious over the combined teachings of Schulman, Loeb, Munshi, and Wang.

x. "wherein reflected impedance associated with energy magnetically coupled through the primary coil is monitored"

Petitioner contends that Wang teaches this limitation. –1920 Pet. 74–75. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 69–72.

We find that Wang teaches that the current through the primary, external coil "depends on the power draw of the load on the secondary [implanted] coil and the proximity and orientation" between the coils. Ex. 1018, 11:24–27, 11:34–37, Fig. 5. We credit Dr. Kroll's unrebutted testimony that "by monitoring the current through the primary coil, which depends in part on the 'power draw of the load on the secondary coil,' Wang's alignment circuitry is monitoring the reflected impedance from the secondary coil." Ex. 1103 ¶¶ 129–133, 162–163, 167; *see* Section V.G.1.ix. (discussing monitoring current through the primary coil; motivation to

combine). Thus, we determine that Wang teaches this limitation of claim 22.

2. Analysis of Claim 23

Claim 23 further recites "an alarm generator that generates an audible alarm signal in response to changes sensed in the reflected impedance monitored by the back telemetry receiver." Ex. 1001, 56:22–36. Petitioner contends that Wang teaches this limitation, because Wang discloses an alignment indicator that activates an LED or audible signal. –1920 Pet. 75–77. Patent Owner does not dispute Petitioner's contention. *See generally* PO Resp. 69–72.

As discussed above in Sections IV.G.1.ix.–x., we find that because Wang's alignment circuitry monitors the current through the primary coil, which changes based on the "power draw from the secondary coil," Wang's alignment circuitry effectively monitors AC voltage and reflected impedance from the secondary coil. *See* Ex. 1018, 12:1–29, 11:56–63, Fig. 5; Ex. 1103 ¶¶ 129–133, 162–163, 167. Wang explains that when proper alignment is reached, an indicator is provided, which may be an LED or an "audible signal." Ex. 1018, 5:20–23, 11:28–31, 12:21–24; Ex. 1103 ¶ 169.

We determine that a POSITA would have found it obvious to incorporate Wang's audible alignment indicator into the modified Schulman system, to inform a patient or user when proper alignment has been reached, in order to maximize charging efficiency and preserve battery supply. Ex. 1103 ¶ 170. This is supported by Schulman's express disclosure of a visual or audio indicator to notify the patient or user that the microstimulators are fully charged. Ex. 1012, 6:14–17. We also determine that such a combination would have been expected to be successful, due to

the similarities of the systems, and because Schulman and Wang are directed to solving the same problem of noninvasively recharging an implanted battery. Ex. 1103 ¶ 137.

3. Analysis of Claim 24

Claim 24 recites that "the alarm generator broadcasts a first audible tone when the primary coil is misaligned with the secondary coil, and the first audible tone stops the broadcast when the primary coil is properly aligned with the secondary coil." Ex. 1001, 56:27–31.

Petitioner contends that this claim would have been obvious over the combined teachings of Schulman, Loeb, Munshi, and Wang. –1920 Pet. 77–78. Petitioner contends that Wang's alignment indicator 40, which may be a LED or an audible indication, indicates when proper alignment is realized. *Id.* at 77 (citing, e.g., Ex. 1018, 11:28–31 ("LED"), 14:21–24 ("audible indications"), 5:20–23 ("visual or audible signal")). Although Wang discloses providing an indication when *proper* alignment is reached, Petitioner contends that a POSITA would have considered it an obvious design choice to instead "use a first audible signal to indicate misalignment of the coils and a second, different audible signal to indicate their alignment . . . [or to] use an audible signal only to indicate that the coils are misaligned." *Id.* (citing Ex. 1103 ¶ 172).

As discussed above in Section V.C.5., Patent Owner argues that Wang's indicator only notifies when *proper* alignment is reached, not when the coils are *misaligned*, as claimed. PO Resp. 70 (incorporating *id.* at 50–51). Patent Owner also argues that Petitioner fails to support its contention that it would have been a matter of design choice to modify Wang as

claimed. *Id.* at 51 (citing Ex. 2033 ¶¶ 112–113); *see also* Pet. Reply 9; PO Sur-Reply 21 (asserting the same).

We have considered the parties' arguments and evidence, and we determine that the prior art supports Petitioner's contentions. For the reasons detailed in Section V.C.5., we find that Wang clearly contemplates "audible indications," and that Petitioner (in the Petition) credibly presented evidence demonstrating that there would have been only three permissible options for an audible alignment indicator in this context. *See supra* Section V.C.5.; Ex. 1018, 14:21–24; Ex. 1103 ¶ 172. Thus, we determine that a POSITA would have found it obvious to modify Wang's audible indicator of proper alignment to instead audibly indicate *misalignment*, as one of a finite number of identified, predictable solutions. *KSR*, 550 U.S. at 421.

4. Secondary Considerations

As discussed in Section V.A.4. above, we determine that Patent Owner has not demonstrated a nexus to claims 22–24. Accordingly, we do not consider Patent Owner's evidence of secondary considerations, with respect to claims 22–24.

5. Conclusion

For the foregoing reasons, on this record, Petitioner has shown, by a preponderance of the evidence, that claim 22–24 would have been obvious in view of the combined teachings of Schulman, Loeb, Munshi, and Wang.

VI. CONCLUSION

For the foregoing reasons, we determine Petitioner ***has*** demonstrated that the following claims are unpatentable, by a preponderance of the evidence:

challenged claim 8 is unpatentable over Schulman, Loeb, and Rutecki;

challenged claim 18 is unpatentable over Schulman and Loeb;

challenged claims 22–24 are unpatentable over Holsheimer, Munshi, and Wang;

challenged claims 22–24 are unpatentable over Schulman, Loeb, Munshi, and Wang;

challenged claim 27 is unpatentable over Barreras; and

challenged claim 27 is unpatentable over Schulman and Loeb.

Furthermore, for the foregoing reasons, we determine Petitioner ***has not*** demonstrated that challenged claims 26 and 28–30 are unpatentable by a preponderance of the evidence.

VII. ORDER

Upon consideration of the record before us, it is:

ORDERED that challenged claims 8, 18, 22–24, and 27 have been shown to be unpatentable;

FURTHER ORDERED that challenged claims 26 and 28–30 have not been shown to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 56) is *denied*;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 60) is *dismissed-in-part* and *denied-in-part*; and

FURTHER ORDERED that the parties' Joint Objections to Demonstratives (Paper 75) is *dismissed as moot*.

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