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Paper No. 11
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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
Patent 6,895,280 B2

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

WIEKER, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

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

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition and the Preliminary Response shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see also* 37 C.F.R § 42.4(a) ("The Board institutes the trial on behalf of the Director."). Taking into account the arguments presented in the Preliminary Response, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail with respect to challenged claim 27, but not with respect to challenged claims 22–24, 26, or 28–30.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of the claim for which an *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

B. Related Proceedings

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

Petitioner also represents that the ’280 patent is the subject of IPR2017-01811, filed concurrently with the instant Petition. Pet. 72. IPR2017-01920, between the same parties, also involves challenges to certain claims of the ’280 patent.

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 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.

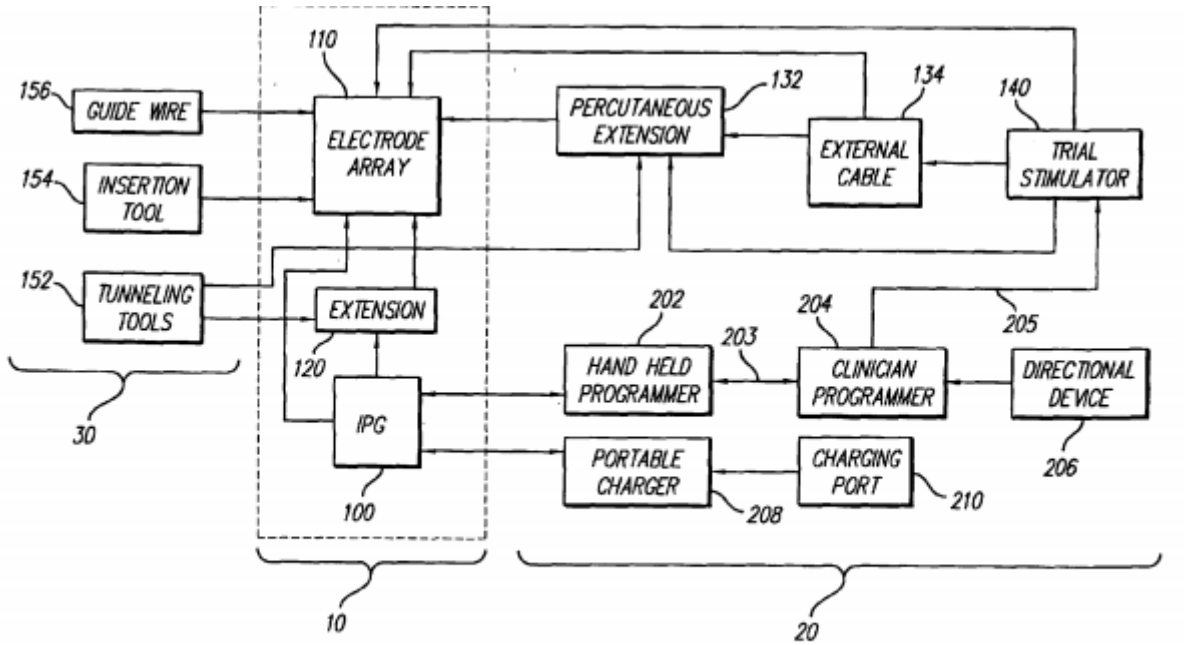

FIG. 1

Figure 1 depicts a block diagram of a spinal cord stimulation system, and identifies its implantable, external, and surgical components. *Id.* at 7:3–5, 8:33–35. Implantable components 10 of the system include implantable pulse generator

(IPG) 100, electrode array 110, and lead extension 120. *Id.* at 4:13–18, 8:38–41. These elements are implanted in the patient through use of surgical components 30. *Id.* at 35–38. External components 20 include, for example, various programmers 202, 204, external battery charger 208, and trial stimulator 140. *Id.* at Fig. 1, 4:18–21.

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 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 27:31–33; *see also id.* at 8:46–52 (electrode array 110 or lead extension 120 is "detachably secured, i.e., electrically connected," to IPG 100).

D. Illustrative Claims

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

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, 55:62–56:21, 57:13–58:20.

E. Applied References

Petitioner relies upon the following references, and the Declaration of Dr. Mark W. Kroll ("the Kroll Declaration," Ex. 1003). Pet. 8–9.

Reference	Patent No. or 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. 20, 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
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

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 22–24 and 26–30 of the '280 patent based on the following grounds. Pet. 8–9.

Reference(s)	Basis	Claim(s) Challenged
Barreras	§ 103	27
Barreras and Wang	§ 103	27
Barreras, with or without Wang, and Engebretson	§ 103	28–30
Holsheimer and Alo	§ 103	26
Holsheimer, Munshi, and Wang	§ 103	22–24

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (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).

Petitioner proposes, for construction, the claim phrases "multi-channel implantable pulse generator (IPG)" and "[sensing][1] the change in rectification in the IPG using circuitry means located in the external battery charger." Pet. 11–16. Patent Owner proposes for construction, *inter alia*, "external trial stimulator." Prelim. Resp. 23–24.

We determine that these claim phrases do not require express construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Patent Owner also proposes, for construction, 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. Prelim. Resp. 21–23. According to Patent Owner, these phrases should be construed as "obtaining proper positioning between the primary and secondary coils such that reflected impedance is at a minimum." *Id.* at 22. Patent Owner asserts the '280 patent specification refers to "proper" alignment, which is

[1] 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.

described as occurring when reflected impedance is at a minimum. *Id.* at 22–23 (citing Ex. 1001, 41:14–17, 42:40–42, 44:18–24, 6:60–64). Petitioner does not offer an express construction for this language. *See generally* Pet.

We have reviewed the '280 patent specification, including those portions cited by Patent Owner. On this record, and at this stage of the proceeding, we determine that the broadest reasonable interpretation of this language does not require that reflected impedance be at a minimum, as Patent Owner proposes. Although the '280 patent indicates that "[r]eflected impedance is at a minimum when proper alignment has been obtained," we are not persuaded that this is a definition of "alignment" generally. *See id.* at 44:21–22. This disclosure simply indicates that minimized reflected impedance is one characteristic of "proper alignment." *Id.* Moreover, the '280 patent also explains that steady-state voltage is at a minimum, and coupling is at a maximum, when proper alignment is achieved. *Id.* at 44:21–26. We consider minimized steady-state voltage and maximized coupling also to be characteristics of "proper alignment," but not defining features of "alignment" generally.

At this stage of the proceeding, we determine that additional express construction of this language is not required. *Vivid Techs*, 200 F.3d at 803. The parties are encouraged to develop further the record regarding the proper construction and application of these limitations. *See, e.g.*, Section II.D.3.ii.

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).

"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).

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

C. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art "would have had at least (1) a bachelor's degree in electrical or biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices." Pet. 9 (citing Ex. 1003 ¶¶ 12–18). Patent Owner does not provide an assessment of the appropriate level of skill in the art. *See generally* Prelim. Resp.

At this stage of the proceeding, we are persuaded that the assessment proposed by Petitioner is correct. Further, in this case, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

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

Petitioner contends that claim 27 of the '280 patent is unpatentable as obvious over Barreras alone, or over the combined teachings of Barreras and Wang. Pet. 16–28. For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to the challenged claims, under both asserted grounds of unpatentability.

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.

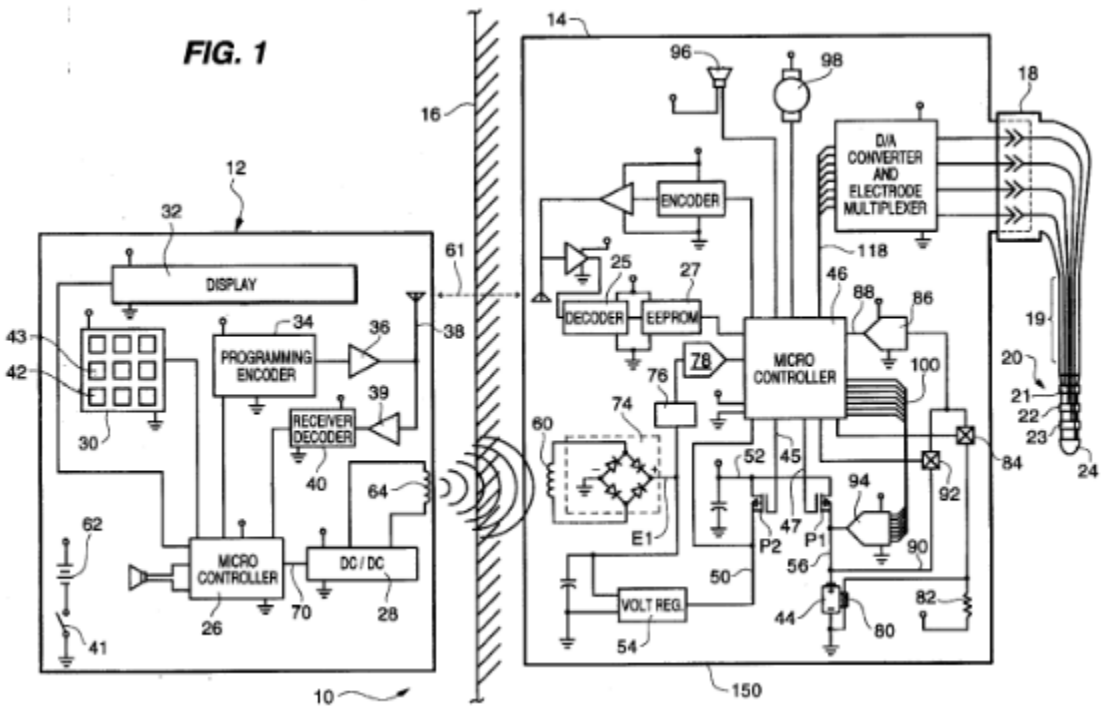

Figure 1 is a circuit diagram of the system, which includes transmitter 12 and implantable receiver 14. *Id.* at 7:6–9, 7:36–38. Receiver 14 is connected by

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, or over the combined teachings of Barreras and Wang. Pet. 16–28. Patent Owner disputes Petitioner's contentions regarding step (b) of claim 27, under both asserted grounds. Prelim. Resp. 27–37.

i. Steps (a) and (c)–(g)

Petitioner shows sufficiently, for purposes of institution, that Barreras teaches claimed steps (a) and (c)–(g) of claim 27. Pet. 17–25. At this stage of the proceeding, Patent Owner does not dispute Barreras's teachings regarding these limitations. Prelim. Resp. 27–37.

For example, with respect to the preamble of claim 27, the cited evidence shows that Barreras discloses "a method for non-invasively recharging the power source [44]" of implanted receiver 14 through induction from external transmitter 12. *See, e.g.*, Ex. 1008, 5:34–41 (cited Pet. 17–18). Barreras's method of induction utilizes output inductor 64 (a "primary" coil), in transmitter 12, and implanted inductor 60 (a "secondary" coil), in receiver 14. *Id.* at 8:38–43. This evidence is sufficient for purposes of institution.

With respect to claim step 27(a), Barreras discloses that external transmitter 12 includes rechargeable battery 62. *See, e.g.*, Ex. 1008, 4:18–20, Fig. 1 (cited Pet. 19). At this stage of the proceeding, we credit Dr. Kroll's testimony that this battery necessarily is charged from an external source prior to charging the

implanted medical device. Ex. 1003 ¶ 73 (cited Pet. 19). This evidence is sufficient for purposes of institution.

With respect to claim step 27(c), Barreras discloses transferring energy from output inductor 64 of external transmitter 12 to implanted receiver 14 through "an RF power link" between the two. *See, e.g.*, Ex. 1008, 5:34–41, 8:39–43 (cited Pet. 21–22). This evidence is sufficient for purposes of institution.

With respect to claim step 27(d), Barreras discloses that the RF energy output by inductor 64 is "coupled into the inductor 60 contained within the receiver 14." *See, e.g.*, Ex. 1008, 8:39–43 (cited Pet. 22). Petitioner also shows sufficiently that this received power produces an alternating current in the receiver. *See, e.g.*, *id.* at 4:62–67, 8:26–32; Ex. 1003 ¶¶ 80–83 (cited Pet. 22–23). This evidence is sufficient for purposes of institution.

With respect to claim step 27(e), Barreras discloses that the induced alternating current is rectified with rectifier 74. *See, e.g.*, Ex. 1008, 4:64–67, Fig. 1 (cited Pet. 22–23). This evidence is sufficient for purposes of institution.

With respect to claim step 27(f), Barreras discloses that while implanted power source 44 is being recharged, "micro controller 46 will monitor the voltage level of the power source 44" to avoid overcharging. *See, e.g.*, Ex. 1008, 9:7–17 (cited Pet. 24). This evidence is sufficient for purposes of institution.

With respect to claim step 27(g), Barreras discloses that receiver 14 sends a "'stop' recharging command" to transmitter 12 when a "fully charged state" is sensed. *See, e.g.*, Ex. 1009, 9:7–17 (cited Pet. 24–25). This evidence is sufficient for purposes of institution.

ii. Step (b)

With respect to claim step 27(b), Petitioner provides two alternative contentions in the two asserted grounds of unpatentability, which we address in turn.

First, Petitioner contends that Barreras discloses and/or renders obvious the claimed step of "aligning" the primary and secondary coils (inductors 64 and 60, respectively). Pet. 19–21. Petitioner contends that because Barreras discloses that the amount of RF energy output by inductor 64 varies depending on the distance between the inductors, "some form of alignment" is necessary to recharge implanted power source 44. *Id.* at 19–20. According to Petitioner, it would have at least been obvious to a person of ordinary skill in the art to align Barreras's inductors, "because better alignment between [them] . . . would conserve the transmitter's battery power by more efficiently recharging the implanted battery." Pet. 21 (citing, e.g., Ex.1003 ¶¶ 74–75).

Patent Owner argues that Petitioner's contentions in this regard rely upon an "overbroad construction of 'alignment,'" which would, in Patent Owner's view, "encompass any and all spatial relationship between the coils permitting energy transfer. Such an implied construction would make the 'alignment' claim element a nullity." Prelim. Resp. 27–28. According to Patent Owner, "no particular alignment between [Barreras's] coils is required," because Barreras discloses that the amount of energy transmitted is adjusted to account for the distance between the coils. *Id.* at 28–30.

We have considered Patent Owner's arguments, however, on this record, we are persuaded that Petitioner's cited evidence supports adequately its contentions regarding step (b). Barreras explains that the actual amount of RF energy transmitted to the receiver is adjusted as a function of the distance between

inductors 64 and 60, "to quickly recharge the rechargeable power source 44." *See, e.g.*, Ex. 1008, 8:26–32, 8:39–43, 8:49–55 (cited Pet. 20). Therefore, we are persuaded, at this stage, that inductors 64 and 60 are aligned sufficiently to permit the transfer and receipt of RF energy for "quick[] recharge [of the] power source." *See, e.g.*, Ex. 1003 ¶¶ 74–75 (cited Pet. 21). At this stage of the proceeding, we do not construe "alignment" to require a more specific relative positioning. *See* Section II.A. As such, Petitioner's evidence is sufficient for purposes of institution.

Second, Petitioner contends that it would have been obvious to a person of ordinary skill in the art to incorporate Wang's alignment circuitry into Barreras's recharging system to ensure charging efficiency is maximized. Pet. 26 (citing, e.g., Ex. 1003 ¶¶ 69–70) (also contending this modification would not require additional components and would work as expected).

Patent Owner argues that Wang does not disclose the "aligning" limitation because, "like Barreras, the Wang system adjusts the energy output of the primary coil to accommodate for any 'mis'-alignment."[2] Prelim. Resp. 33. Patent Owner also argues that a person of ordinary skill in the art would not have been motivated to combine Barreras and Wang, because Barreras solves any problem with misalignment by adjusting the level of energy output by the transmitting coil. *Id.* at 34–37.

We have considered Patent Owner's arguments, however, on this record, we are persuaded that Petitioner's cited evidence supports adequately its alternative

[2] We need not address Patent Owner's argument that Wang does not disclose minimizing reflected impedance because, as discussed in Section II.A, we determine this is not the broadest reasonable interpretation of the claim language. Prelim. Resp. 32–33.

contentions regarding step (b). Barreras acknowledges that when inductors 64 and 60 are in "close proximity," less RF energy is required to recharge the implanted power source over a fixed unit of time. *See, e.g.*, Ex. 1008, 8:49–55 (cited Pet. 26). In light of Barreras's explicit consideration of the impact of the relative positioning of inductors 64, 60 on the ability of those inductors to recharge quickly the implanted power source, we are persuaded that a person of ordinary skill in the art would have found it obvious to provide a mechanism to detect and identify proper alignment, for example, the alignment circuit and indicator taught by Wang. *See, e.g.*, Ex. 1003 ¶¶ 69–70 (cited Pet. 26). Indeed, Wang confirms that providing proper alignment between inductors permits efficient energy transmission. *See, e.g.*, Ex. 1018, 5:13–15 (cited Pet. 25). Furthermore, even if Wang and Barreras also teach that any mis-alignment may be mitigated by adjusting energy output, *see* Prelim. Resp. 33–37, we do not discern that this is in conflict with Wang's explicit teaching that energy transmission is more efficient when the coils are properly aligned; indeed, we discern the two are complementary. Accordingly, we are persuaded sufficiently that a person of ordinary skill in the art would have been motivated to modify Barreras in light of Wang's teachings to ensure effective energy transmission and charging. *See, e.g.*, Ex. 1003 ¶¶ 69–70; Ex. 1008, 8:49–55; Ex. 1018, 5:13–15. This evidence is sufficient for purposes of institution.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claim 27 on both asserted grounds, e.g., over Barreras and over the combined teachings of Barreras and Wang.

E. Obviousness over the Combined Teachings of Barreras, with or without Wang, and Engebretson

Petitioner contends that claims 28–30 of the '280 patent are unpatentable as obvious over Barreras, with or without Wang,[3] and Engebretson. Pet. 28–37. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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.

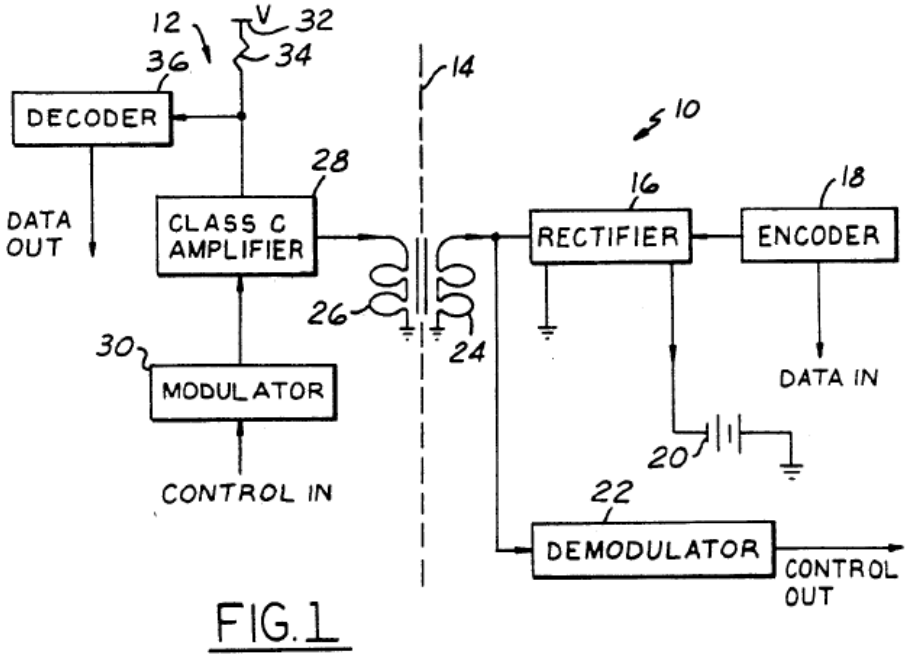

Figure 1 depicts a functional block diagram of the system, which includes implanted device 10 and external device 12. *Id.* at 2:9, 2:22–26. Implanted device 10 includes encoder circuit 18 and rectifier circuit 16, which provides an output

[3] Petitioner relies on Wang only to the extent discussed in Section II.D.3.

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 Claim 28

Petitioner contends that claims 28–30 would have been obvious based on of the combined teachings of Barreras, with or without Wang, and Engebretson. Pet. 28–37. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 38–41.

Dependent claim 28 recites "[sensing][4] 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.

[4] *See supra* n.1.

Petitioner contends that although Barreras's receiver 14 transmits a "'stop' recharging command" to transmitter 12, to indicate when the battery is fully charged, Barreras does not disclose sensing a change in rectification that indicates a fully charged state. Pet. 29–30. According to Petitioner, it would have been obvious to a person of ordinary skill in the art to have included such a feature, in light of Engebretson's teachings. *Id.* at 30–31. Petitioner contends that a person of ordinary skill in the art would have been motivated to modify Barreras to provide "a low-power, low-cost communication method" that is less susceptible to the electromagnetic interference acknowledged by Barreras. *Id.* at 29, 32–33 (citing, e.g., Ex. 1003 ¶¶ 91–92, 96–97).

Patent Owner argues, *inter alia*, that "Engebretson does not teach using changes in rectification as a way to indicate when the implanted rechargeable battery is fully charged, but rather discloses only coded binary communications about the parameters regarding the settings of the Engebretson implanted hearing aid." Prelim. Resp. 38–39.

We have considered the parties' arguments and cited evidence, and we determine that the Petition does not demonstrate sufficiently that the applied prior art would have rendered obvious 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]." The cited evidence supports Patent Owner's argument that the teachings of Engebretson do not render this limitation obvious. Specifically, Engebretson discloses that rectifier 16 of implanted device 10 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, for example, to convey the previous settings of the implanted device. *Id.*

at 3:37–40, 4:3–7. Moreover, although Engebretson discloses charging the 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, Petitioner's proposed modification of Barreras, in view of Engebretson, only appears to suggest use of Engebretson's disclosed rectification changes to convey information about sensed conditions beneath the skin, near Barreras's implanted receiver 14, and the Petition has not explained adequately how this information is related to Engebretson's battery status, as required to meet the aforementioned claim limitation.

Petitioner's citations to the 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 of about sensed subdermal conditions. Pet. 28–33 (citing Ex. 1003 ¶¶ 91–97). For example, paragraph 92 of the Kroll Declaration acknowledges that Engebretson only discloses using rectification changes to convey information about conditions sensed beneath the skin surface. Ex. 1003 ¶ 92. Although Dr. Kroll asserts that a person of ordinary skill in the art "would have recognized that Engebretson's communication method *could be used* to convey the 'stop' recharging command to the transmitter in Barreras' system," Dr. Kroll provides no persuasive underlying analysis or explanation as to how or why it *would have been obvious* to modify Engebretson's teachings to be used in this manner. *Id.* (emphasis added). Likewise, Dr. Kroll also fails to explain the basis for the conclusion that modifying Engebretson's teachings to sense battery status "would work as expected". *Id.* Merely touting the advantages associated with such a modified use is insufficient, without 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.").

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claim 28.

3. Analysis of Claims 29–30

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 in Petitioner's presentation for claim 28. Pet. 33–37.

Accordingly, for the same reasons discussed above in Section II.E.2, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 29 and 30.

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

Petitioner contends that claims 22–24 of the '280 patent are unpatentable as obvious over Holsheimer, Munshi, and Wang. Pet. 51–70. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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.

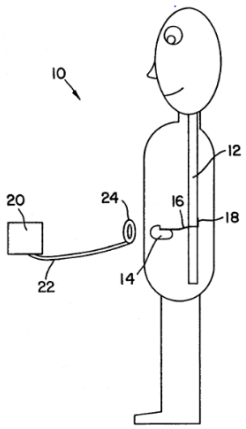

FIG. 1

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 claims 22–24 would have been obvious based on of the combined teachings of Holsheimer, Munshi, and Wang. Pet. 51–70. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 47–53.

Independent claim 22 recites, *inter alia*, "an implantable electrode array detachably connected to the IPG." Ex. 1001, 55:65–66. Petitioner contends that Holsheimer discloses an implanted lead with an electrode array, which is connected to a pulse generator. Pet. 56; Ex. 1004, 3:56–59 (pulse generator 14,

lead 16, electrodes at 18), 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. According to Petitioner,

> a [person of ordinary skill in the art] 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). Petitioner does not rely on Munshi or Wang with respect to this limitation. *Id.* at 51–54, 56–57.

Patent Owner argues that Holsheimer's electrode array is not detachable from pulse generator 14. Prelim. Resp. 48–50. According to Patent Owner, wires connect the outputs of Holsheimer's pulse generator to the electrodes of the array. *Id.* at 48–49 (citing Ex. 1004, 7:22–27, 7:47–58, Figs. 19–20). Thus, Patent Owner asserts that "Petitioner's conclusory assertion that Holsheimer utilized detachable leads is not only unsupported by the reference itself, but refuted by it." *Id.*

We have considered the parties' arguments and cited evidence, and we determine that the Petition does not demonstrate sufficiently that Holsheimer's electrode array is detachably connected to pulse generator 14. The cited evidence supports Patent Owner's argument that these elements are connected by wires 80. Holsheimer's Figure 19 is reproduced below.

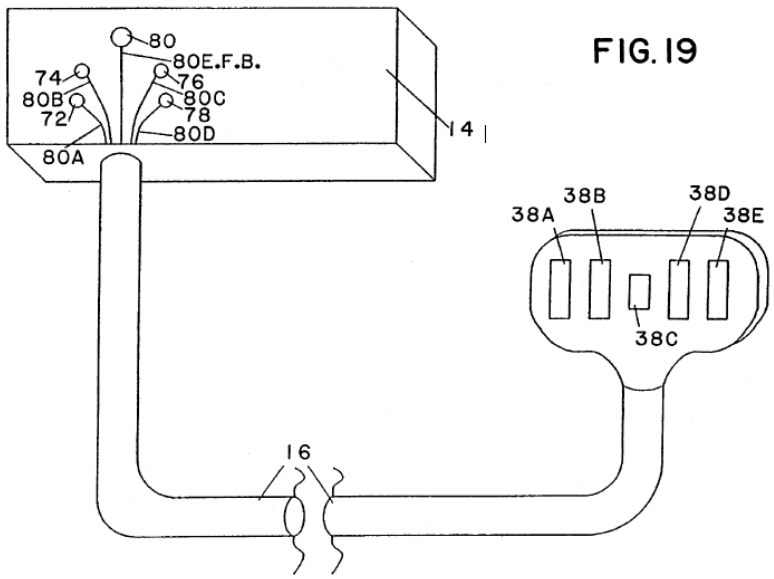

FIG. 19

Figure 19 depicts a first embodiment of Holsheimer's pulse generator and lead, and a second embodiment is depicted in Figure 20. *Id.* at 3:44–47. As shown, pulse generator 14 includes outputs 72, 74, 76, 78. *Id.* at 7:17–20. "Line 16[5] has electrodes 38 connected to these outputs with *wire 80A connecting output 72 to electrode 38A*, wire 80B connecting output 74 to electrode 38B," and so on. *Id.* at 7:22–28 (emphasis added); *see also id.* at 7:47–57 (describing a similar arrangement in Figure 20). The Petition does not explain how the electrode array and pulse generator 14 are considered to be "detachably connected," when Figures 19 and 20, and their corresponding description, appear to disclose an apparently permanent, unitary connection with wires 80A–F. While the Petition does assert that "a [person of ordinary skill in the art] would have understood Holsheimer's leads, which carry the electrode arrays, would have been detachably connected to the IPG . . . ," the Petition does not provide any supporting evidentiary basis for this otherwise conclusory assertion that wires 80 are detachable from either electrode array 38 or from pulse generator 14. As such, we are unpersuaded that

[5] Elsewhere termed "lead 16." *See* Ex. 1004, 3:58, 4:7.

Petitioner demonstrates sufficiently that Figures 19–20 of Holsheimer disclose the recited detachable connection. Pet. 56.

Petitioner's contention that Figure 1 depicts "a standard notch connector" is likewise unpersuasive to show that the electrode array is detachably connected to the pulse generator. Pet. 56–57. Figure 1 itself does not depict any details of the connection. Ex. 1004, Fig. 1. Similarly, Holsheimer's disclosure regarding Figure 1 does not discuss "notch connectors" or any other detachable connector that would allow wires 80 to detach from the pulse generator or electrode array. *Id.* at 2:46–48, 3:53–4:5.

Petitioner's citation to other prior art references, *see* Pet. 56–57 (citing Ex. 1016, Abstract, 2:66–3:2; citing Ex. 1003 ¶¶ 147–148 (citing Ex. 1008, 7:39–41)), also fails to shed light on the type of connection between Holsheimer's components. At best, this evidence aligns with Petitioner's argument that "many different types of leads were known in the art and *could* be used with the same IPG" and that "leads *can be* attached and detached to IPGs." Pet. 56–57 (emphasis added). Again, however, these arguments do not establish that *this particular* arrangement disclosed by Holsheimer is detachable.[6]

The cited portions of the Kroll Declaration do not remedy the Petition's failure. Pet. 57 (citing Ex. 1003 ¶¶ 147–148). Like the Petition, Dr. Kroll's testimony that detachable connections *could be* used does not establish that Holsheimer's connection is detachable.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claim 22.

[6] We note that Petitioner did not contend that it would have been obvious to have modified Holsheimer to include a detachable connection. *Id.* at 56–57; *see also* Prelim. Resp. 50.

4. Analysis of Claims 23 and 24

Dependent claims 23 and 24 depend, directly or indirectly, from claim 22. Ex. 1001, 56:22–31. Petitioner's contentions with respect to these claims do not remedy the deficiency in Petitioner's presentation for claim 22. Pet. 68–70.

Accordingly, for the same reasons discussed above in Section II.F.3, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 23 and 24.

G. Obviousness over the Combined Teachings of Holsheimer and Alo

Petitioner contends that claim 26 of the '280 patent is unpatentable as obvious over Holsheimer and Alo. Pet. 37–51. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

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," and 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 space of the 80 patients enrolled in the study. *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 33–34; *see also id.* at 34–35.

2. Analysis of Claim 26

Petitioner contends that claim 26 would have been obvious based on of the combined teachings of Holsheimer and Alo. Pet. 37–51. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 41–47.

Unlike claim 22, discussed in Section II.F.3 above, independent claim 26 does not recite expressly that a lead with its electrode array is "detachably connected" to any other component. *Compare* Ex. 1001, 55:65–66, *with id.* at 57:13–36. However, claim 26 recites steps (a), (b), (g), and (h), which taken together, implicitly require that the implanted electrode array be detachably connectable to other components, through a lead connector, to permit the recited steps of connecting and disconnecting. Specifically, as recited in step 26(a), the claim requires implanting a lead that includes, at its distal end, an electrode array, and at its proximal end, a "lead connector." *Id.* at 57:16–18. In step 26(b), the lead connector must be *connected* to a percutaneous extension. *Id.* at 57:19–20; *see also id.* at 57:24–25 (then connecting that percutaneous extension to an external trial stimulator (ETS)). Then, as recited in step 26(g), that percutaneous extension must be *disconnected* from the lead connector. *Id.* at 57:30–31. Finally, as recited in step 26(h), the lead connector then must be *connected* to a multi-

channel implantable pulse generator. *Id.* at 57:34–36. These steps of connection, disconnection, and connection to another component implicitly require that the lead connector have the capability to detachably connect.

Petitioner contends that Holsheimer discloses claimed step (a) of implanting a nerve stimulation lead with a distally located, multi-electrode array, wherein the lead has a lead connector on the proximal end. Pet. 42–43. Petitioner relies on Holsheimer's Figure 1 to support the contention that Holsheimer discloses a "standard connector notch commonly used to depict lead connectors." *Id.* at 42. Petitioner also contends that a person of ordinary skill in the art "would have understood Holsheimer's leads detachably connect to the IPG and have lead connectors on their proximal ends because—as the '280 admits—it was well-known [that] lead connectors are necessary to establish an electrical connection between the electrodes on the leads and the IPG." *Id.* at 43.

As we discussed with respect to Petitioner's asserted ground of unpatentability based on Holsheimer, Munshi, and Wang, the cited evidence does not support sufficiently Petitioner's contention that Holsheimer's lead and its electrode array are detachably connected to pulse generator 14. *See supra* Section II.F.3. For the same reasons articulated in that regard, Petitioner's citation to Holsheimer's Figure 1, additional prior art references, and Declarant testimony is insufficient to establish that the connection is detachable, in light of Holsheimer's express disclosure that wires connect the lead and its electrode array to pulse generator 14. *Compare* Ex. 1004, Fig. 1; Ex. 1008, 7:38–41; Ex. 1003 ¶¶ 114–116, *with* Ex. 1004, 7:15–62.[7]

[7] Again, we note that Petitioner did not contend that it would have been obvious to modify Holsheimer's lead to be detachable. Pet. 42–43.

With respect to claimed steps (b) and (g), Petitioner relies on Alo's disclosure of connecting and disconnecting a percutaneous extension and a lead. Pet. 43–44, 47. However, Petitioner's reliance on Alo does not cure the Petition's failure to show sufficiently that Holsheimer's lead is capable of connection or disconnection with another component, e.g., Alo's percutaneous extension. Although the Petition explains why use of a percutaneous extension may have been beneficial, e.g., to test stimulation therapy prior to permanent implantation of an IPG, this does not show sufficiently that Holsheimer's lead was capable of being connected to, or disconnected from, such a percutaneous extension to achieve that benefit, or that it would have been obvious to modify Holsheimer to make possible the recited connection and disconnection. *See id*.; Ex. 1004, 7:15–62.

With respect to claimed step (h), Petitioner relies on Holsheimer's disclosure of IPG 14, as well as Alo's disclosure of connecting an implantable permanent receiver to the lead. Pet. 47, 50. According to Petitioner, a person of ordinary skill in the art "would have found it obvious to substitute Holsheimer's implantable IPG in the place of Alo's implantable receiver so that Holsheimer's IPG is connected to the leads." *Id.* at 50. We acknowledge that Holsheimer discloses pulse generator 14 connected to lead 16 and electrode array 38. *See, e.g.*, Ex. 1004, Figs. 19–20. Again, however, Petitioner's contentions in this regard do not cure the Petition's failure to show sufficiently that Holsheimer's lead is capable of being connected to pulse generator 14, after being disconnected from a percutaneous extension, or that it would have been obvious to modify Holsheimer to make possible the recited connection. *See id*.; Ex. 1004, 7:15–62.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claim 26.

H. Redundancy

Patent Owner argues that Petitioner advances several redundant grounds across this Petition and that presented in Case IPR2017-01920. Prelim. Resp. 24–27 (citing *Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.*, Case CBM2013-00003, at *1 (PTAB Oct. 25, 2012)). Because we determine that Petitioner has not demonstrated a reasonable likelihood it would prevail with respect to claims 22–24, 26, and 28–30, on the merits of each asserted ground, *see supra* Sections II.E–G, we need not address Patent Owner's argument regarding those claims. We address Patent Owner's arguments with respect to claim 27, for which we determine Petitioner has met its burden for institution.

Patent Owner contends that Petitioner presents horizontally redundant grounds against claim 27 based on (1) Barreras, (2) Barreras and Wang, and (3) Schulman and Loeb (as presented in IPR2017-01920). Prelim. Resp. 26. According to Patent Owner, "Petitioner nowhere explains why it offers multiple references or grounds," and instead "shifts the burden to the Board and Patent Owner to decipher their litany of grounds, references, and conclusory explanations for why the challenged claims are invalid." *Id.* at 25. Patent Owner also contends that this Petition presents vertically redundant grounds against claim 27 based on (1) Barreras, and (2) Barreras and Wang, without providing a bidirectional explanation for the vertical redundancies. *Id.* at 26–27. Thus, according to Patent Owner, trial should not be instituted on these asserted grounds.

We have considered Patent Owner's argument, but decline to exercise our discretion to deny institution of the grounds presented in this Petition. In determining whether to institute an *inter partes* review, the Board may "deny some or all grounds for unpatentability for some or all of the challenged claims." *See* 37 C.F.R. § 42.108(b); *see also* 35 U.S.C. § 314(a) (authorizing, but not mandating,

institution). Our discretionary determination of whether to institute review is guided in part by 35 U.S.C. § 325(d), which states that, "[i]n determining whether to institute or order a proceeding . . . the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." The statutory language gives the Director the authority not to institute review on the basis that the same or substantially the same prior art or arguments were presented previously to the Office, but does not require that result.

Here, we do not exercise our discretion to deny the Petition under, *inter alia*, 37 C.F.R. § 42.108(b) or 35 U.S.C. § 325(d). As discussed above, Petitioner has shown a reasonable likelihood that it will prevail in showing unpatentability of claim 27 based on Barreras and/or Barreras and Wang. *Harmonic,* 815 F.3d at 1363. Barreras and Wang were not considered during prosecution of the '280 patent. *See* Ex. 1001, (56). Additionally, neither reference is at issue with respect to claim 27 in IPR2017-01920. Thus, we are not persuaded that the analysis in the Petition is substantially the same as that presented previously to the Office, either during prosecution or in IPR2017-01920. Furthermore, we are unpersuaded that consideration of both grounds including Barreras places an undue burden on either the parties or the Board. Although we are mindful of the burden on Patent Owner and the Office in hearing two challenges to the '280 patent, based on the particular facts of these proceedings, we determine that conducting trial in this case and in IPR2017-01920 would not implicate the policy considerations reflected in 35 U.S.C. § 325(d), and does not persuade us to exercise discretion to deny institution in this proceeding. Furthermore, the Board retains discretion to coordinate multiple proceedings, if it deems it appropriate. *See* 35 U.S.C. § 315(d).

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claim 27 of the ’280 patent, and we institute an *inter partes* review of that claim. We determine also that Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claims 22–24, 26, or 28–30.

At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim or as to the construction of any claim term.

IV. ORDER

For the reasons given, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claim 27 of the ’280 patent on the following asserted grounds:

Claim 27 under 35 U.S.C. § 103(a) as unpatentable over Barreras; and

Claim 27 under 35 U.S.C. § 103(a) as unpatentable over Barreras and Wang.

FURTHER ORDERED that the trial is limited to the grounds identified above, and no other grounds are authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this Decision.

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