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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00713
Patent 9,821,112 B2

Before WILLIAM V. SAINDON, JAMES A. TARTAL, and ALYSSA A. FINAMORE, *Administrative Patent Judges.*

FINAMORE, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314; 37 C.F.R. §42.4

I. INTRODUCTION

Axonics Modulation Technologies, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–22 of U.S. Patent No. 9,821,112 B2 ("the '112 patent") (Ex. 1001).[1] Paper 1 ("Pet."). Medtronic, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply addressing the issue of discretionary denial under 35 U.S.C. § 325(d) in view of *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte Advanced Bionics*, *GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential). Paper 8 ("Reply). Patent Owner filed a Sur-reply thereto. Paper 9 ("Sur-reply).

We have authority, acting under the designation of the Director, to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). We may not authorize an *inter partes* review to be instituted "unless . . . the information presented in the petition filed under section 311 and any response filed under section 313 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(a).

Upon consideration of the arguments and evidence presented by both parties, we determine Petitioner has demonstrated a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims

[1] On page 1 of the Petition, Petitioner refers to U.S. Patent No. 9,463,112 B2, instead of U.S. Patent No. 9,821,112 B2, which Petitioner submits as Exhibit 1001 and identifies as the patent at issue in the Exhibit List. We consider Petitioner's reference to U.S. Patent No. 9,463,112 B2 to be a typographical error.

challenged in the Petition. Accordingly, we institute an *inter partes* review of the challenged claims of the '112 patent.

II. BACKGROUND

A. Real Parties in Interest

Petitioner asserts that it is the real party in interest. Pet. 83. Patent Owner maintains it is the real party in interest. Paper 4, 1. Patent Owner further maintains that "Medtronic plc is the ultimate parent of Medtronic, Inc." (*id.*), and that "Medtronic, Inc. has granted certain rights with respect to the patent-at-issue to Medtronic Puerto Rico Operations Co., which in-turn has granted certain rights to Medtronic Logistics, LLC, which in-turn has granted certain rights to Medtronic USA, Inc." (*id.* at 1 n.1).

B. Related Matters

The parties identify as related matters *Medtronic, Inc. v. Axonics Modulation Technologies, Inc.*, No. 8:19-cv-02115 (C.D. Cal. filed Nov. 4, 2011) and *Axonics Modulation Technologies, Inc. v. Medtronic, Inc.*, IPR2020-00714 (PTAB filed Mar. 16, 2020) (challenging U.S. Patent No. 9,463,324 B2). Pet. 83; Paper 4, 1–2. Patent Owner further identifies U.S. Patent No. 10,369,275 B2 and U.S. Patent Application No. 16/450,399. Paper 4, 2.

C. The '112 Patent (Ex. 1001)

The invention "relates to implantable medical devices and, in particular, to energy transfer devices, systems, and methods for implantable medical devices." Ex. 1001, 1:31–33. An implantable medical device

requires an electrical power source to perform its therapeutic function, for instance, driving an electrical infusion pump, providing an electrical neurostimulation pulse, or providing an electrical cardiac stimulation pulse. *Id.* at 1:46–53. An internal power source, such as a battery, can be used to provide the electrical power. *Id.* at 2:7–10. When the battery has expended, or nearly expended, its capacity can be recharged transcutaneously via inductive coupling from an external power source temporarily positioned on the surface of the skin. *Id.* at 2:10–14.

According to the ’112 patent, “the efficiency at which energy is transcutaneously transferred is crucial.” *Id.* at 5:14–15. The higher the efficiency of energy transfer, the more energy can be transferred while limiting the heating of surrounding components and tissue, the faster the charging can be accomplished, and the larger the practical size of the internal power source can become. *Id.* at 5:15–47.

A transcutaneous inductive recharging arrangement is shown in Figure 3, reproduced below.

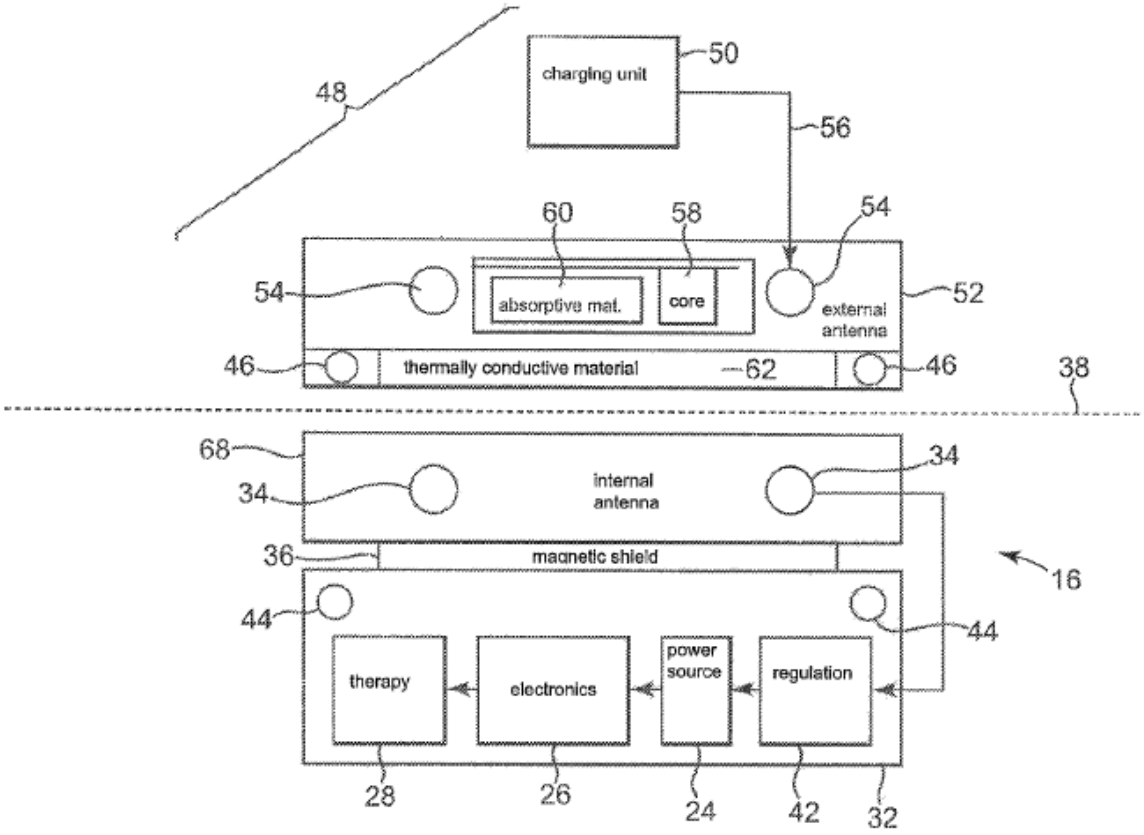


Fig. 3

Figure 3 is a block diagram of implantable medical device 16 implanted subcutaneously, i.e., below cutaneous boundary 38, and associated external charging device 48. *Id.* at 7:40–43, 9:22–25, 53–55. Implantable medical device 16 includes housing 32 enclosing rechargeable power source 24 such as a lithium ion battery, electronics 26, regulation module 42, therapy module 28 which is coupled to a patient, and internal telemetry coil 44 enabling programming and control of implantable medical device 16 and communication of information about implantable medical device 16. *Id.* at 8:64–9:4, 25–36, Fig. 3. Implantable medical device 16 further includes internal antenna 68 comprising secondary charging coil 34, which is

operatively coupled to rechargeable power source 24 via regulation module 42. *Id.* at 9:5–7, 10:16–25, Fig. 3.

External charging device 48 is used to charge rechargeable power source 24 while implantable medical device 16 is in place in a patient. *Id.* at 9:53–55. External charging device 48 comprises charging unit 50 and external antenna 52. *Id.* at 9:55–57. External antenna 52 includes primary coil 54 and external telemetry coil 46 enabling communication between external charging device 48 and implantable medical device 16. *Id.* at 9:64–10:1, Fig. 3. Cable 56 connects primary coil 54 to charging unit 50, which contains electronics to drive primary coil 54 with an oscillating current to induce a current in secondary coil 34 of implantable medical device 16 and charge rechargeable power source 24. *Id.* at 9:55–62.

As energy is transferred from primary coil 54 to secondary coil 34 of implantable medical device 16, heat may be generated in implantable medical device 16 and surrounding tissue, and such heat build-up is undesirable and should be limited to acceptable values. *Id.* at 15:57–63. Preferably, external charging device 48 includes temperature sensor 87 in external antenna 52 and control circuitry in charging unit 50. *Id.* at 20:6–11, Fig. 14. The control circuitry uses output from temperature sensor 87 to limit the energy transfer process and thereby limit the temperature external antenna 52 imparts to the patient. *Id.* at 20:26–29.

D. Challenged Claims

Petitioner challenges claims 1–22 of the ’112 patent. Pet. 1, 16. Claims 1, 8, 18, and 19 are independent. Ex. 1001, 21:63–22:7, 22:29–40, 23:22–24:17. Independent claims 1 and 8 are illustrative of the claimed

subject matter, and reproduced below with Petitioner's labels for the limitations.

> 1. [1.0] A medical system, comprising:
> an implantable medical device;
> an external charging device configured to transcutaneously transfer energy to the implantable medical device comprising;
> [1.1] a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device;
> [1.2] a control circuit configured to compare the measured temperature to a programmable limit and to control the transfer of energy based on the comparison; and
> [1.3] a memory configured to store the programmable limit.
>
> 8. [8.0] A method, comprising:
> transferring, via an external charging device, energy transcutaneously to an implantable medical device;
> [8.1] sensing, via a sensor, a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device;
> [8.2] obtaining a programmable limit from a memory;
> [8.3] comparing, via a control circuit, the temperature to the programmable limit; and
> [8.4] controlling the transfer of energy based on the comparison.

Id. at 21:63–22:7, 22:29–40.

Independent claim 18 recites a medical system similar to that of independent claim 1, and recites various means for performing functions similar to steps recited in independent claim 8. *Id.* at 23:22–24:5. Independent claim 19 recites a medical system similar to that of independent claim 1 but without an implantable medical device. *Id.* at 24:6–17.

Claims 2–7 and 22 depend from independent claim 1. *Id.* at 22:8–28, 24:26–27. Claims 9–17 depend from independent claim 8. *Id.*

at 22:41–23:21. Claims 20 and 21 depend from independent claim 19. *Id.* at 24:18–25.

E. Evidence

Petitioner relies on the following references in asserting that the challenged claims are unpatentable. Pet. 16.

Reference	**Exhibit No.**
Torgerson et al., WO 01/83029 A1, published Nov. 8, 2001 ("Torgerson")	1005
UL Standard for Safety for Medical and Dental Equipment, UL 544 (Underwriters Laboratories Inc. ("UL") 1998) ("UL 544")	1006
Barreras et al., WO 00/69012, published Nov. 16, 2000 ("Barreras")	1007
Wang et al., US 5,702,431, issued Dec. 30, 1997 ("Wang")	1008
Barreras, Sr. et al., US 5,733,313, issued Mar. 31, 1998 ("Barreras '313")	1010
Taylor et al., US 6,685,638 B1, issued Feb. 3, 2004 ("Taylor")	1011

Both parties present testimonial evidence at this stage of the proceeding. Petitioner relies on a Declaration of Dr. Michael Colvin (Ex. 1003), and Patent Owner relies on a Declaration of Dr. Ronald Berger (Ex. 2010).

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability. Pet. 18–19.

Challenged Claims	35 U.S.C. §	References
8, 12, 14–17, 19–21	103(a)	Torgerson, Barreras
9–11, 13	103(a)	Torgerson, Barreras, Wang
1–3, 7, 18, 22	103(a)	Torgerson, UL 544, Barreras
4–6	103(a)	Torgerson, UL 544, Barreras, Wang
8, 12, 14–17, 19–21	103(a)	Barreras ’313, Barreras
9–11, 13	103(a)	Barreras ’313, Barreras, Wang
1–3, 7, 18, 22	103(a)	Barreras ’313, Taylor, Barreras
4–6	103(a)	Barreras ’313, Taylor, Barreras, Wang

III. ANALYSIS

A. Discretionary Denial Under 35 U.S.C. § 325(d)

Pursuant to 35 U.S.C. § 325(d), “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.” In considering whether to exercise discretion to deny a petition under § 325(d), the Board uses a two-part framework, namely:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office

> erred in a manner material to the patentability of challenged claims.

Advanced Bionics, Paper 6 at 8. If a condition in the first part of the framework is satisfied, and absent a material error, the Director generally will exercise discretion not to institute *inter partes* review. *Id.* at 8–9.

Beginning with the first part of the *Advanced Bionics* framework, Torgerson, Barreras, Wang, and a reference having a disclosure similar to that of Barreras '313 were each listed on an Information Disclosure Statement (IDS) submitted during the prosecution of the '112 patent and initialed by the Examiner. Ex. 1002, 147, 154, 520; Pet. 17; Prelim. Resp. 45; Sur-reply 1. UL 544 and Taylor were not previously presented to the Office. Prelim. Resp. 46; Reply 2. Patent Owner argues UL 544 and Taylor are cumulative in view of Carbunaru[2] (Ex. 2008), which was before the Examiner during the prosecution of the '112 patent[3] and used by the Examiner to formulate a rejection during the prosecution of a related patent, U.S. Patent No. 8,554,322 B2 ("the '322 patent")[4] (Ex. 2007).[5] Prelim. Resp. 46–47; Sur-reply 2–3. According to Patent Owner, during prosecution of the '322 patent, the Examiner found Carbunaru teaches a temperature sensor on the external device, and Petitioner is relying on UL 544 and Taylor to teach a temperature sensor on the external device, making UL 544

[2] Carbunaru et al., US 2004/0098068, published May 20, 2004 ("Carbunaru").
[3] The prosecution history of the '112 patent is Exhibit 1002.
[4] The prosecution history of the '322 patent is Exhibit 2006.
[5] Like the '112 patent, the '322 patent claims priority as a continuation to U.S. Patent Application No. 11/687,061. Ex. 1001, code (60); Ex. 2007, code (63).

and Taylor cumulative of Carbunaru. Prelim. Resp. 46–47 (citing Ex. 2006, 124–25; Pet. 21–22, 61–62).

We disagree with Patent Owner that UL 544 and Taylor are cumulative of Carbunaru. Petitioner relies on UL 544 and Taylor for more than a temperature sensor on an external device; Petitioner relies on UL 544 and Taylor for teaching an external device having a temperature sensor and a control circuit for controlling the transfer of energy based on the measured temperature. Pet. 25, 63, 69. Accordingly, we are not persuaded that a single isolated cumulative teaching renders UL 544 and Taylor as cumulative references and the asserted grounds including UL 544 and Taylor substantially the same as the art previously before the Office, specifically when Petitioner relies on additional teachings from UL 544 and Taylor.

Even if UL 544 and Taylor were cumulative in view of Carbunaru such that substantially the same art was previously presented to the Office, Petitioner nonetheless has demonstrated that the Office erred in a manner material to the patentability of challenged claims pursuant to the second part of the *Advanced Bionics* framework. As Petitioner argues, during prosecution of the '112 patent, the Examiner rejected dependent claims reciting a "memory storing a programmable limit" only for non-statutory double patenting. Reply 1 (citing Ex. 1002, 139–42). Patent Owner filed terminal disclaimers and amended the independent claims to include "a memory configured to store the programmable limit," and the Examiner subsequently allowed the claims. *Id.* (citing Ex. 1002, 166–72, 508). As discussed in more detail below in sections III.E.3–4, III.I.2–3, and III.K.2–3, Petitioner, on the current record, has explained sufficiently how Barreras's

software-loaded variable teaches the recited "programmable limit." We, therefore, agree with Petitioner that the Examiner overlooked Barreras's teaching of the "programmable limit" recited in the independent claims challenged in the Petition.

For these reasons, even if the art asserted was previously before the Office, or cumulative to art previously before the Office, denial of institution is not warranted in this case. We decline to exercise discretion under 35 U.S.C. § 325(d).

B. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art would have had "a bachelor's degree in electrical or mechanical engineering and at least three years of experience in the industry working with rechargeable implantable medical devices; or a bachelor's of science with at least six years of experience designing, manufacturing, or overseeing rechargeable medical implantable systems." Pet. 6 (citing Ex. 1003 ¶ 52). Patent Owner "does not acquiesce" to Petitioner's proffered level of ordinary skill in the art, but does not provide its own explanation of the level of ordinary skill. Prelim. Resp. 9. Moreover, Patent Owner's declarant, Dr. Berger applies Petitioner's level of ordinary skill in the art. Ex. 2010 ¶ 13.

Based on our review of the record at this stage of the proceeding, we find the evidence generally supports Petitioner's proposed level of ordinary skill in the art. The '112 patent is directed to a mechanism for transferring energy from an external power source to an implantable medical device to transcutaneously charge the battery of the implantable medical device. Ex. 1001, Title, Abstract, 1:31–33, 5:14–47, Fig. 3. Similarly, Torgerson

and Barreras '313 are each directed to rechargeable implantable medical devices. Ex. 1005, Title, 1:5–6, Figs. 3–5; Ex. 1010, Title, 1:8–11, Figs. 1, 3–6. Accordingly, for purposes of this decision on institution, we adopt Petitioner's explanation of the level of ordinary skill in the art.

C. Claim Construction and Requirement Therefor Under 37 C.F.R. § 42.104(b)(3)

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Furthermore, at this stage in the proceeding, we expressly construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner proposes constructions for the claim term "programmable limit" and each of the "means for" limitations in independent claim 18. Pet. 6–15. Patent Owner cursorily asserts that it "does not necessarily agree" with Petitioner's proposed constructions, but does not proffer any construction. Prelim. Resp. 10. On this record, we determine that no claim term requires an express construction for the purpose of determining whether to institute *inter partes* review.

With respect to Petitioner's constructions for the "means for" limitations, Patent Owner alleges that Petitioner has not performed the requisite analysis under 37 C.F.R. § 42.104(b)(3) because Petitioner has not identified the claimed function and the corresponding structure in the Specification for each of these limitations. Prelim. Resp. 10–11. We disagree. Petitioner relies on the function recited in the limitation itself and identifies the structure described in the Specification for performing that function. Pet. 10–15. For example, for the limitation of independent claim 18 reciting "means for transcutaneously transferring charging energy to the implantable medical device," Petitioner argues that the term should be construed as "a primary coil configured for transcutaneous energy transfer to the medical device by inductive coupling with the secondary coil" because the Specification describes paired coils for performing the recited function of transcutaneously transferring charging energy to the implantable medical device. Pet. 10–11 (citing Ex. 1001, 5:1–13, 9:22–52, Fig. 3). As Petitioner has identified the specific portion of the Specification that describes the structure corresponding to the recited function, the Petition is in compliance with 37 C.F.R. § 42.104(b)(4).

D. Application of Petitioner's Construction of "Programmable Limit"

Each of independent claims 1, 8, 18, and 19 recites a "programmable limit," and, for each asserted ground involving an independent claim, Petitioner relies on Barreras's software-loaded variable to teach the recited "programmable limit." Pet. 32–34, 50–51, 68–70, 77– 79. Patent Owner maintains that all of Petitioner's asserted grounds of unpatentability are deficient because Petitioner fails to explain how Barreras's software-loaded

variable is a "programmable limit" under Petitioner's construction of that claim term. Prelim. Resp. 43–44.

Petitioner construes the recited "programmable limit" as "a variable temperature limit stored on a memory that is able to be changed or modified by a user or software, excluding pre-determined, manufacturer presets." Pet. 7. As the name implies, a software-loaded variable is included with software, and, thus, is stored on a memory and able to be changed as the software is changed, in accordance with Petitioner's construction. On the current record, Petitioner has explained sufficiently how it contends Barreras's software-loaded variable teaches the "programmable limit" recited in the independent claims.

E. Obviousness Based on Torgerson and Barreras

Petitioner challenges claims 8, 12, 14, 15, and 19–21 under 35 U.S.C. § 103(a), contending the claimed subject matter is obvious over Torgerson and Barreras. Pet. 47–56. We begin our analysis of this asserted ground of unpatentability with an overview of the references, and then discuss the parties' contentions for each of the claims.

1. Torgerson (Ex. 1005)

Torgerson "relates generally to implantable medical devices, and more particularly to a battery recharge management system for implantable medical devices." Ex. 1005, 1:5–6. One type of implantable medical device is an implantable neuro stimulator (INS), and Figure 1, reproduced below, shows a neurostimulation system. *Id.* at 1:21.

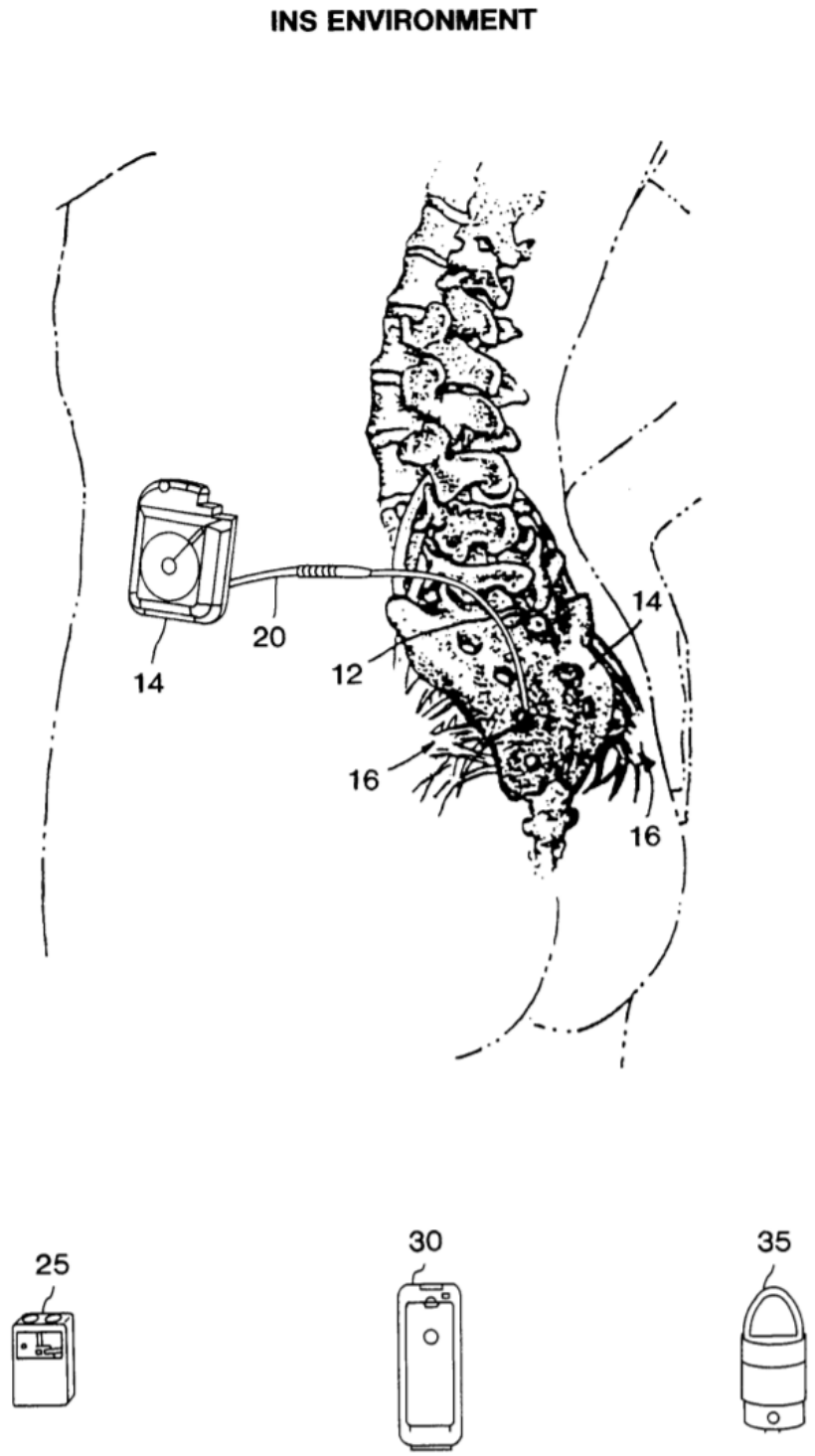


FIG. 1

As shown in Figure 1, the neurostimulation system includes INS 14 implanted in a human body, physician programmer 30, and patient programmer 35. *Id.* at 4:7–8, 5:1–4. INS 14 is programmed with a therapy and implanted in the body typically in a subcutaneous pocket at a site selected after considering physician and patient preferences. *Id.* at 6:29–7:2. The physician uses physician programmer 30 to communicate with INS 14 to manage the patient therapy and collect INS data. *Id.* at 7:12–13. The patient uses patient programmer 35 to communicate with INS 14 and make therapy adjustments, recharge the INS power source, and record diary entries about the effectiveness of the therapy. *Id.* at 7:13–16. The neurostimulation system may also include sensor 25 to provide closed-loop feedback control of INS 14. *Id.* at 7:19–20.

Figure 3, reproduced below, shows the components of INS 14.

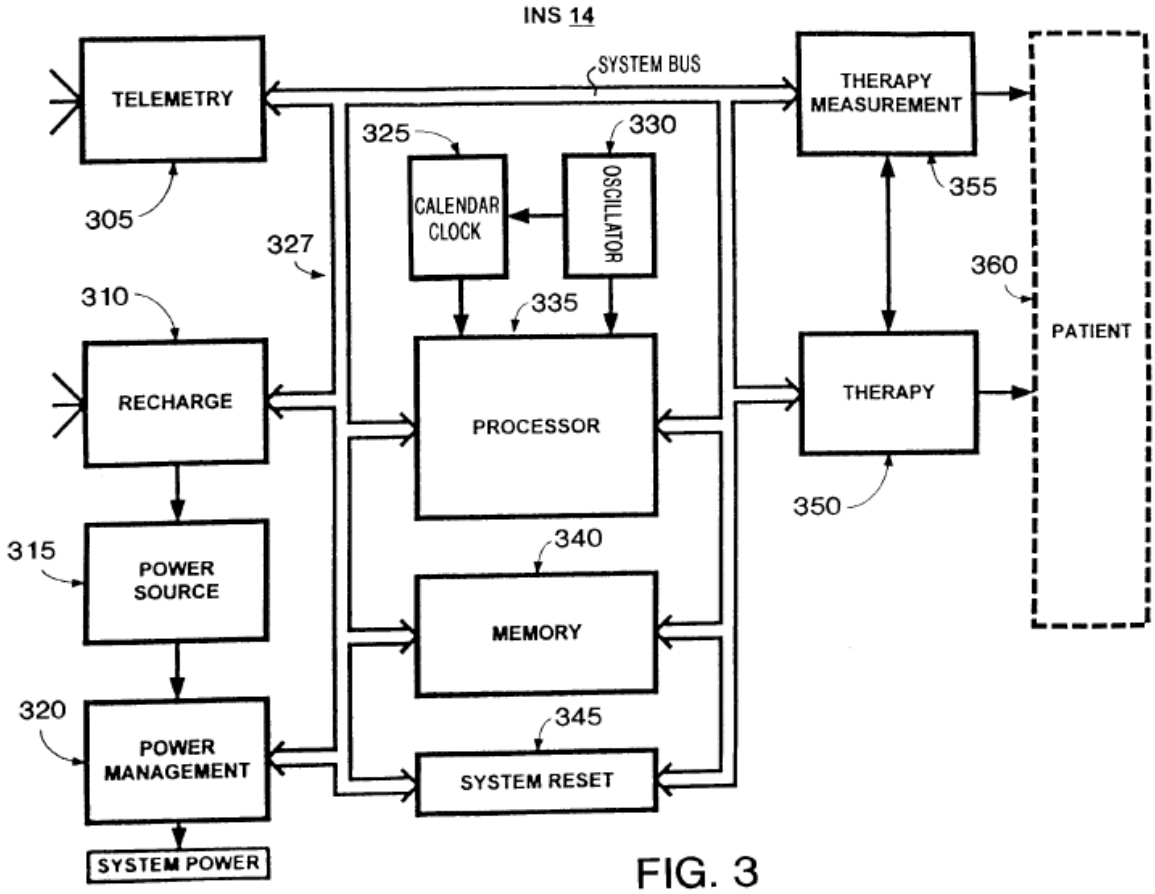


FIG. 3

Figure 3 is a schematic block diagram of INS 14 showing the components thereof. *Id.* at 4:11–12, 7:23–27. INS 14 includes processor 335 with memory 340, power source 315, recharge module 310, therapy module 350, therapy measurement module 355, and telemetry module 305 for bi-directional communication with external programmers 30, 35. *Id.* at 7:24–27, 8:19–20. Recharge module 310 regulates the charging rate of power source 315, and maintains the temperature of INS 14 within acceptable conditions to avoid an unsafe condition for the patient. *Id.* at 9:20–23.

Figure 5, reproduced below, shows recharge module 310 in detail. *Id.* at 4:15–16, 9:17–18.

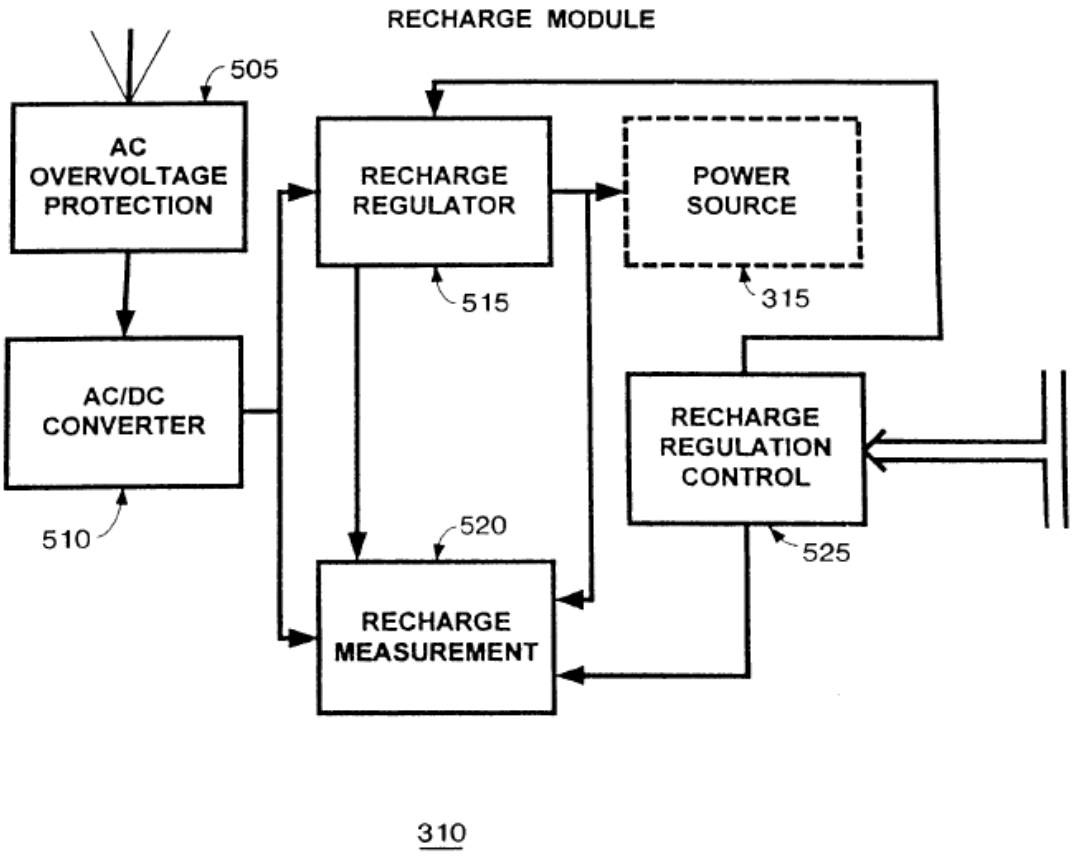


FIG. 5

Figure 5 is a schematic block diagram of recharge module 310. *Id.* Recharge module 310 comprises a recharge coil (not shown in Figure 5), recharge regulator 515, recharge measurement device 520, and recharge regulation control unit 525. *Id.* at 9:27–29. Recharge regulator 515 regulates the voltage to a level appropriate for charging power source 315. *Id.* at 10:10–11. Recharge regulator control unit 525 adjusts recharge regulator 515 in response to information from recharge measurement device 520 and a recharge program. *Id.* at 10:11–13. Recharge measurement device 520 measures various parameters of INS 14, including the temperature of INS 14. *Id.* at 10:15–20.

Recharge regulation control unit 525 also provides feedback regarding power source 315, such as whether the recharge energy being received is too high or too low, by communicating with the external component via telemetry module 305 or by modulating the load on the recharge coil, which is sensed in the circuitry driving the source coil of the external component. *Id.* at 12:23–25, 12:27–13:5. If components in INS 14 are heating up above safe limits, INS 14 will communicate to the charging device to lower the supplied energy. *Id.* at 13:10–12. Similarly, if the temperature is safe, and if the current and voltage levels are below the charge rate capacity of power source 315, INS 14 will communicate to the charging device that the energy can be increased. *Id.* at 13:12–14.

2. Barreras (Ex. 1007)

Barreras discloses power management system 1 including implantable medical device 4 with power source 10 and power management module 11 for safely managing the charge/discharge cycles of power source 10 and collecting performance data. Ex. 1007, 8:23–34, Fig. 1. Power management module 11 includes temperature sensor 98. *Id.* at 12:34–13:1, Fig. 4. When the temperature of power source 10 is nearing an unsafe value, which is a software loaded variable, microcontroller 100 will effectively disconnect power source 10 from circuitry 8 of implantable medical device 4. *Id.* at 13:1–5.

3. Independent claim 8

a. Undisputed limitations (limitations 8.0–8.3)

Independent claim 8 begins "[a] method, comprising: transferring, via an external charging device, energy transcutaneously to an implantable medical device," i.e., limitation 8.0. Ex. 1001, 22:29–31. For this

limitation, Petitioner contends Torgerson discloses an external device, i.e., physician programmer 30 or patient programmer 35, having a primary coil coupled to a secondary coil of an implanted medical device, i.e., INS 14, to transcutaneously transfer energy to the implanted medical device. Pet. 27–28 (citing Ex. 1005, 11:12–23, Fig. 6; Ex. 1003 ¶ 122); *see also id.* at 49 (referring to arguments for limitation 1.0 with respect to the asserted ground based on Torgerson, UL 544, and Barreras).

Independent claim 8 also recites "sensing, via a sensor, a temperature indicative of heating resulting from the transcutaneous transfer of energy to the implantable medical device," i.e., limitation 8.1. Ex. 1001, 22:33–35. Petitioner argues Torgerson discloses a temperature sensor, i.e., recharge measurement 520, and control circuitry, i.e., recharge regulation control 525, adapted to control energy transfer to the implantable medical device based on temperature to limit temperature rise during recharge and prevent unsafe conditions for the patient. Pet. 49–50 (citing Ex. 1005, 9:21–23, 10:19–23, claim 36). Petitioner further argues Barreras also discloses this limitation because power management module controller 100 controls charging based on output from temperature sensor 98. *Id.* at 50 (citing Ex. 1007, 10:19–11:27, Fig. 4).

Independent claim 8 next recites "obtaining a programmable limit from a memory," i.e., limitation 8.2. Ex. 1001, 22:36. For this limitation, Petitioner contends Barreras teaches a temperature maximum that is a software-loaded variable by which charging is controlled to prevent overheating and control circuitry is revised. Pet. 50 (citing Ex. 1007, 3:2–7, 13:1–8, Fig. 4).

Independent claim 8 further recites "comparing, a via a control circuit, the temperature to the programmable limit," i.e., limitation 8.3. Ex. 1001, 22:37–38. For this limitation, Petitioner contends Barreras teaches comparing a sensed temperature to the programmable limit because Barreras teaches determining when the temperature of power source 10 nears a temperature maximum, which is a software-loaded variable. Pet. 32–33 (citing Ex. 1007, 12:34–13:8, Fig. 4; Ex. 1003 ¶¶ 124–125); *see also id.* at 51 (referring to arguments for limitation 1.2 with respect to the asserted ground based on Torgerson, UL 544, and Barreras). Petitioner also contends "utilizing the variable maximum temperature of Barreras in the recharge regulation control would necessarily include comparing the monitored temperature with the temperature maximum in order to control charging based on temperature and prevent charging when the temperature exceeds the maximum temperature, as described in Barreras." *Id.* at 51 (citing Ex. 1003 ¶ 164).

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions for claim limitations 8.0–8.3. On the current record, Petitioner's arguments and Dr. Colvin's testimony find support in the cited references. For instance, Torgerson discloses uses an external programmer, namely physician programmer 30 or patient programmer 35, to transcutaneously transfer energy to charge an implantable medical device, i.e., INS 14. Ex. 1005, 11:12–23. Torgerson also discloses that recharge measurement device 520 senses the temperature of INS 14, and that recharge regulation control 525 controls the transcutaneous transfer of energy based on the sensed temperature. *Id.* at 10:19–23. Barreras teaches determining when the temperature nears a temperature maximum, which is a

software-loaded variable. Ex. 1007, 13:1–3. Based on the record at this stage of the proceeding and for purposes of this Decision, Petitioner has sufficiently identified limitations 8.0–8.3 in the cited references.

b. Controlling the transfer of energy (limitation 8.4)

Independent claim 8 recites "controlling the transfer of energy based on the comparison," i.e., limitation 8.4. Ex. 1001, 22:39–40. According to Petitioner, Torgerson's recharge module 310 includes regulation control unit 525 that controls the transfer of energy based on the temperature sensed by recharge measurement device 520. Pet. 29–31 (citing Ex. 1005, 3:16–23, 9:17–26, 10:15–23, 13:6–14, claim 36, Fig. 5; Ex. 1003 ¶¶ 124–125); *see also id.* at 51 (referring to arguments for limitation 1.2 with respect to asserted ground based on Torgerson, UL 544, and Barreras). Petitioner also argues "incorporating the temperature maximum variable of Barreras within the temperature regulation of Torgerson necessitates control of energy transfer based on the comparison of monitored temperature and the programmable limit." *Id.* at 52.

Patent Owner maintains that this limitation of independent claim 8 requires controlling the transcutaneous transfer of energy, and that Torgerson discloses controlling only the transfer of energy within the implanted medical device, not the transcutaneous transfer of energy from the external charging device to the implanted medical device. Prelim. Resp. 26–29. We disagree with Patent Owner's characterization of Torgerson. Torgerson discloses that recharge regulation control unit 525 provides feedback regarding power source 315 of INS 14, such as whether the recharge energy being received is too high or too low, by communicating with the external component. Ex. 1005, 12:23–25. If components in INS 14

are heating up above safe limits, INS 14 will communicate to the external charging device to lower the supplied energy. *Id.* at 13:10–12. Similarly, if the temperature is safe, and if the current and voltage levels are below the charge rate capacity of power source 315, INS 14 will communicate to the external charging device that the energy can be increased. *Id.* at 13:12–14. As Torgerson discloses controlling energy supplied from the external charging device to the implantable medical device based on the temperature of the implanted medical device, Petitioner, on this record and for purposes of institution, has sufficiently identified limitation 8.4 in the cited references.

c. Rationale

Petitioner argues as follows:

> As Torgerson already teaches regulating charging based on temperature monitoring from a temperature sensor for safe charging, a [person of ordinary skill in the art] would have been motivated to utilize a software loaded variable stored on a memory of the control circuit as the temperature maximum in order to support the correct charge regimens and/or to allow software revisions with new improvements in limiting temperature rise and safe charging as taught in Barreras.

Pet. 48–49 (citing Ex. 1003 ¶ 160); *see also id.* at 50–51 (citing Ex. 1003 ¶ 165) (asserting a similar rationale for combining Torgerson and Barreras). At this stage of the proceeding, Patent Owner does not dispute Petitioner's rationale.

On the current record, Petitioner's arguments and Dr. Colvin's testimony find support in the cited references, as Barreras teaches selecting, via software, the correct regimen of current and voltage limits and downloading software revisions and improvements. Ex. 1007, 3:2–7. Accordingly, at this stage of the proceeding and for purposes of institution, Petitioner has provided sufficient reasoning why a person of ordinary skill

would have combined the teachings of Torgerson and Barreras in the manner set forth in the Petition.

d. Conclusion for independent claim 8

In view of the foregoing, Petitioner has shown sufficiently how it contends each limitation of independent claim 8 is found in Torgerson and Barreras. Petitioner also has articulated sufficient reasoning for why a person of ordinary skill would have combined the teachings of Torgerson and Barreras in the manner set forth in the Petition for purposes of this Decision. Based on this record, Petitioner has shown a reasonable likelihood that Petitioner would prevail in demonstrating independent claim 8 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Torgerson and Barreras.

4. Independent claim 19

Petitioner's arguments for independent claim 19 are similar to its arguments for independent claim 8. Pet. 54–55. Patent Owner relies on its arguments for independent claim 8 for independent claim 19. Prelim. Resp. 26–29. For the reasons discussed in section III.E.3, Petitioner has shown a reasonable likelihood that it would prevail in demonstrating independent claim 19 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Torgerson and Barreras.

5. Dependent claims 12, 14, 15, 20, and 21

Petitioner identifies the limitations of claims 12, 14, 15, 20, and 21 in the cited references. Pet. 52–56. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for independent claims 8 and 19. Prelim. Resp. 26–29. On the current record, Petitioner's arguments find support in the cited references.

F. Obviousness Based on Torgerson, Barreras, and Wang

Petitioner challenges claims 9–11 and 13 under 35 U.S.C. § 103(a) as unpatentable over Torgerson, Barreras, and Wang. Pet. 56–58. As we discuss Torgerson and Barreras in sections III.E.1–2, we begin our analysis of this asserted ground with an overview of Wang, and then turn to the parties' arguments.

1. Wang (Ex. 1008)

Wang relates to "an external energy transmission device for recharging batteries inside an implantable medical device." Ex. 1008, 1:18–21. Wang discloses two different charging protocols that deliver the same amount of energy in the same amount of time as prior art recharging systems, but with less peak temperature rise than the prior art systems. *Id.* at 4:42–44, 7:42–45, 48–53. Wang's charging protocols, as well as the charging protocol of a typical prior art system, are graphically represented on current-versus-time plots in Figures 4A–4C, reproduced below. *Id.* at 5:41–46.

FIG. 4A
(Prior Art)

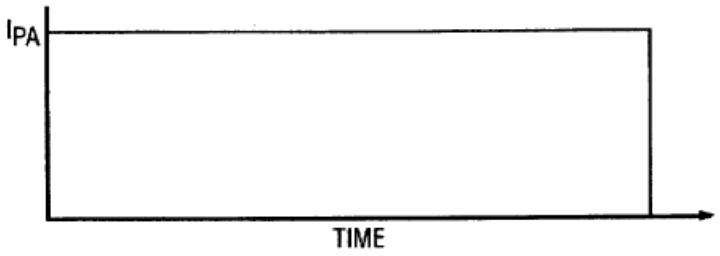


FIG. 4B

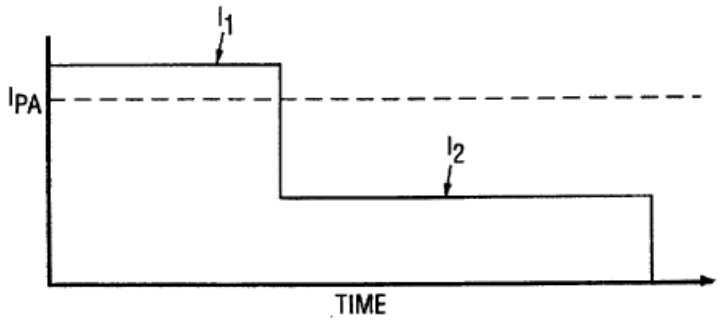
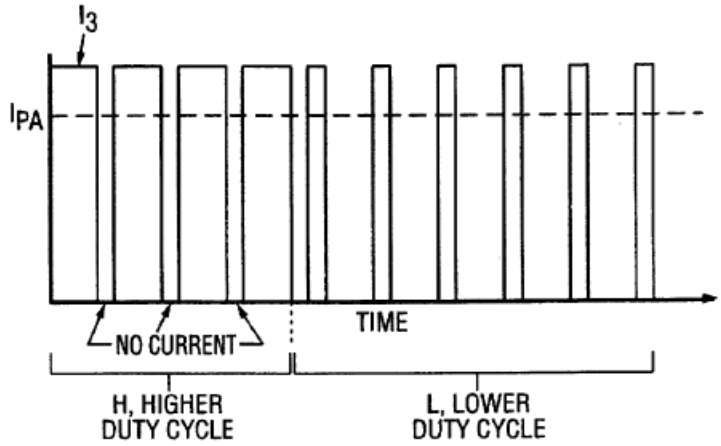


FIG. 4C



As shown in Figure 4A, the prior art recharging system charges the battery by delivering prior art constant current I_{PA} for the entire charging period. *Id.* at 7:58–61. Wang's first charging protocol, which is shown in Figure 4B, delivers charging current I_1, which is higher than prior art constant current I_{PA}, for a first predetermined period of time and then delivers lower current

I_2, which is lower than prior art constant current I_{PA}, for the remainder of the charge cycle. *Id.* at 4:45–53; 7:61–67. Wang's second charging protocol, which is depicted in Figure 4C, delivers charging current I_3, which is higher than prior art constant current I_{PA}, with intermittent periods of no charging current. *Id.* at 4:66–5:12, 8:9–12.

2. Dependent claims 9–11 and 13

Petitioner identifies the limitations of claims 9–11 and 13 in Wang. Pet. 43–47; *see also id.* at 57 (referring to the arguments regarding Wang in the asserted ground based on Torgerson, UL 544, Barreras, and Wang). Petitioner also provides a rationale for combining the teachings of Torgerson, Barreras, and Wang. *Id.* at 57. At this stage of the proceeding, Patent Owner does not raise arguments for claims 9–11 and 13 apart from its arguments for independent claim 8. Prelim. Resp. 29. On the current record, Petitioner's arguments find support in Wang.

G. Obviousness Based on Torgerson, UL 544, and Barreras

Petitioner challenges claims 1–3, 7, 16–18, and 22 under 35 U.S.C. § 103(a), contending the claimed subject matter is obvious over Torgerson, UL 544, and Barreras. Pet. 19–41. Notably, independent claim 1 is similar to independent claim 8, and more specifically recites that the temperature sensor and control circuit are part of the external charging device such that the control circuit is configured to control the transfer of energy based on the temperature measured at the external charging device. Ex. 1001, 21:63–22:7. As we discuss Torgerson and Barreras in sections III.E.1–2, we begin our analysis of this asserted ground with an overview of UL 544, and then turn to the parties' arguments.

1. UL 544 (Ex. 1006)

UL 544 is directed to a UL standard for safety for medical and dental equipment. Ex. 1006, tr1. According to the standard, "[d]uring the temperature test, the temperature on a part that is necessary to be applied to the patient so as to perform its intended function, but not intended to supply heat to [the] patient, shall not exceed 41°C (106°F)." *Id.* § 36.2. The standard also provides that, if thermocouples are used to measure temperature during the test, "[a] thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured." *Id.* § 45.1.9.

2. Independent claim 1

Independent claim 1 recites an external charging device comprising "a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device," i.e., limitation 1.1, and "a control circuit configured to compare the measured temperature to a programmable limit and to control the transfer of energy based on the comparison," i.e., limitation 1.2. Ex. 1001, 21:65–22:6. Independent claim 1 thus requires an external charging device having a temperature sensor to measure a temperature indicative of the transcutaneous transfer of energy, as well as a control circuit configured to control the transfer of energy based on the measured temperature of the external charging device.

Petitioner relies on Torgerson's external programmer, i.e., physician programmer 30 or patient programmer 35, for disclosing an external charging device. Pet. 28 (citing Ex. 1005, 11:12–23, Fig. 6; Ex. 1003

¶ 122). Petitioner argues Torgerson's external device includes control circuitry for controlling the transfer of energy based on temperature measured by a sensor on the implantable medical device. *Id.* at 31 (citing Ex. 1005, 9:17–26, 10:19–24, 13:6–14, Fig. 5; Ex. 1003 ¶¶ 124–125). Petitioner acknowledges Torgerson does not explicitly disclose a temperature sensor on the external device, and argues it would have been obvious in view of UL 544 to add a temperature sensor to Torgerson's external device. *Id.* at 28–29, 31. According to Petitioner, UL 544 teaches using a thermocouple to determine the temperature of an external device, as well as safety standard prescribing a temperature limit of 41°C for devices applied to a patient, such as Torgerson's external device. *Id.* at 28–29 (citing Ex. 1005, §§ 36.2, 45.1.9; Ex. 1003 ¶ 123). Petitioner maintains "it would have been obvious to include a temperature sensor on the external device of Torgerson to measure a temperature of the device applied to the patient during charging to ensure compliance with mandatory safety requirements." *Id.* at 29 (citing Ex. 1003 ¶ 123). Petitioner also maintains "[i]t would have been within the skill of a [person of ordinary skill in the art] to modify the control circuitry of Torgerson to control energy transfer based on this external temperature parameter of the combination." *Id.* at 31–32 (citing Ex. 1003 ¶¶ 124–125).

Patent Owner argues the combined teachings of the references do not render obvious the recited temperature sensor or the recited control circuit. Prelim. Resp. 12–25. In particular, Patent Owner argues Petitioner's proposed combination of the references to yield an external charging device having the recited temperature sensor and control circuit is based on impermissible hindsight. *Id.* at 18–19. Patent Owner also argues the

thermocouple in UL 544 is not part of a medical device used in its normal operation, but, instead, is used as a part of a laboratory test to ensure compliance with the standard. *Id.* at 20.

Indeed, the temperature sensor, i.e., thermocouple, disclosed in UL 544 is used in conjunction with a one-off temperature test for a safety standard certification. Ex. 1006 § 45.1.9. Using a temperature sensor to measure the temperature of an external device during a test does not disclose an external device having a temperature sensor. Moreover, UL 544 does not specify a temperature sensor or any other means for complying with the temperature limit of 41°C for a device applied to a patient. *Id.* § 36.2. Compliance with the temperature limit of UL 544 does not bridge the gap between a temperature sensor used for a one-off test and an external charging device having a sensor for measuring temperature and a control circuit for controlling the transfer of energy based on the measured temperature. On the present record, Patent Owner's argument that Petitioner has not explained sufficiently how the combined teachings of the references render obvious an external charging device having a temperature sensor and control circuit, as recited in independent claim 1, appears to have merit.

3. Claims 2, 3, 7, 16–18, and 22

For independent claim 18, as well as for dependent claims 2, 3, 7, 16, 17, and 22, Petitioner relies on its arguments with respect to Taylor in regard to independent claim 1. Pet. 34–40. Patent Owner makes the same arguments in opposition as raised in regard to independent claim 1 (Prelim. Resp. 11–26), which appear to have merit for the reasons discussed in section III.G.2.

H. Obviousness Based on Torgerson, UL 544, Barreras, and Wang

Patent Owner's opposition to the asserted obviousness of the subject matter of claims 4–6 in view of Torgerson, UL 544, Barreras, and Wang is the same as its opposition to the asserted obviousness of the subject matter of independent claim 1 in view of Torgerson, UL 544, and Barreras. Prelim. Resp. 26. As discussed in section III.G.2, Patent Owner's opposition appears to have merit.

I. Obviousness Based on Barreras '313 and Barreras

Petitioner challenges claims 8, 12, 14, 15, and 19–21 under 35 U.S.C. § 103(a), contending the claimed subject matter is obvious over Barreras '313 and Barreras. Pet. 75–81. Barreras is discussed in section III.E.2, and we summarize Barreras '313 before turning to the parties' contentions for each of the claims.

1. Barreras '313 (Ex. 1010)

Barreras '313 relates to "an implantable medical device including a rechargeable back-up power source and a charging unit for recharging the back-up power source via RF coupling." Ex. 1010, 1:8–11. As shown in Figure 1, reproduced below, a system, such as implantable, rechargeable tissue stimulator system 10, comprises transmitter 12 and receiver 14 surgically implanted beneath patient's skin 16. *Id.* at 7:33–38.

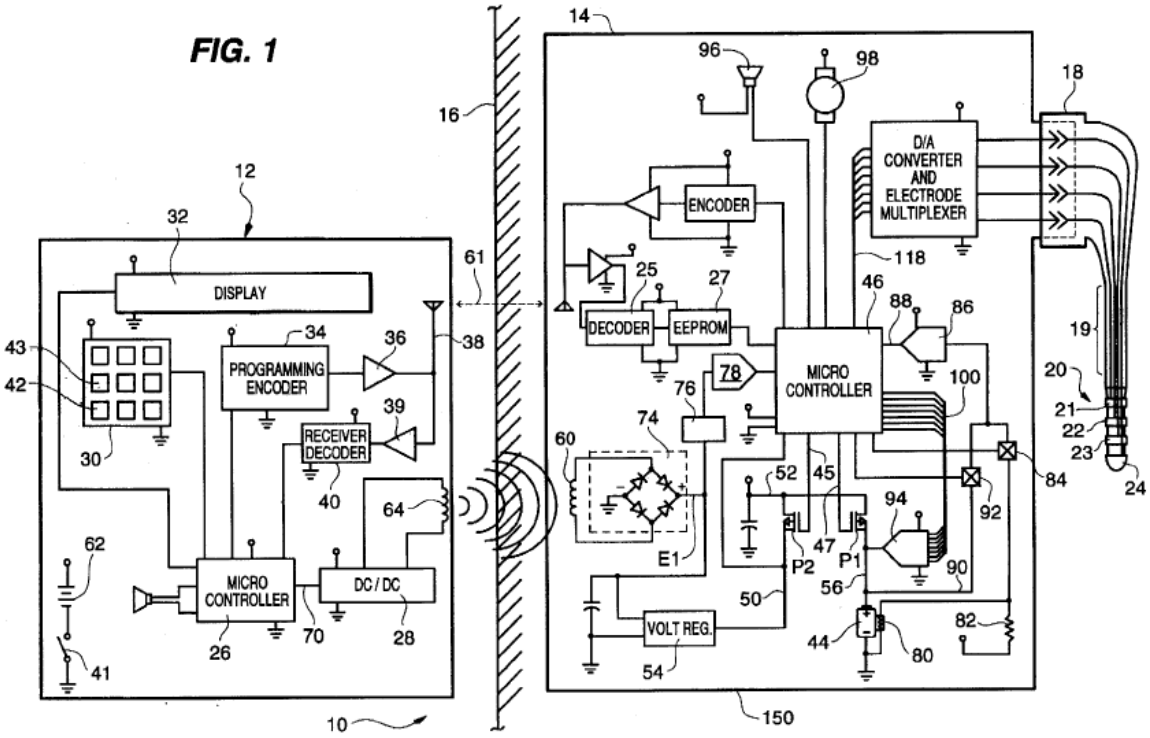


Figure 1 is a block electrical schematic circuit diagram of the overall system. *Id.* at 7:6–9. Transmitter 12 includes micro controller 26 that is used to regulate the amount of energy to be coupled to receiver 14, transmit therapy parameter values to receiver 14, and receive commands and a patient's diagnostic data from receiver 14. *Id.* at 7:48–59. Receiver 14 includes back-up rechargeable power supply 44 that receives energy from transmitter 12 to recharge back-up rechargeable power supply 44. *Id.* at 8:1–7, 35–43. Receiver 14 also includes thermistor 80 connected to micro controller 46. *Id.* at 8:61–64. During the recharging operation, micro controller 46 regulates the current level used to recharge back-up rechargeable power source 44 as a function of temperature to restrict the temperature rise of the back-up rechargeable power source 44. *Id.* at 8:56–60, 8:67–9:5.

2. Independent claim 8

a. Undisputed limitations (limitations 8.0–8.3)

For limitation 8.0, which recites transferring energy transcutaneously via an external charging device to an implanted medical device, Petitioner argues Barreras '313 discloses an implantable, rechargeable stimulator system 10 comprising external transmitter 12 that transcutaneously transfers energy from output inductor 64 to receiving inductor 60 of implanted receiver 14. Pet. 76–677 (citing Ex. 1010, 8:39–60, 12:6–9, Fig. 6). For the step of sensing temperature recited in limitation 8.1, Petitioner argues Barreras '313 discloses using thermistor 80 in implanted receiver 14 to regulate the charging of rechargeable power source 44 to restrict temperature rise. *Id.* at 77 (citing Ex. 1010, 8:56–9:5).

For limitation 8.2, which recites obtaining a programmable limit from memory, Petitioner argues Barreras teaches a control circuit having a microcontroller that compares the monitored temperature to a maximum temperature, which is a software-loaded variable. *Id.* at 78 (citing Ex. 1007, 13:1–5). For the step of comparing the temperature to the programmable limit set forth in limitation 8.3, Petitioner argues that, because Barreras teaches comparing the monitored temperature with the maximum temperature variable loaded by software, using Barreras's software-loaded temperature maximum in the controlled charging scheme of Barreras '313 would necessarily include comparing the monitored temperature with the maximum temperature variable to control charging based on temperature and prevent charging when the temperature exceeds the maximum. *Id.* at 78–79 (citing Ex. 1003 ¶¶ 223–224).

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions for these limitations. On the current record, Petitioner's arguments and Dr. Colvin's testimony find support in the cited references. In particular, Barreras '313 discloses transcutaneously transferring energy from external transmitter 12 to implanted receiver 14, and using thermistor 80 to sense the temperature in implanted receiver 14. Ex. 1010, 8:35–43, 8:56–9:5, Figs. 1, 6. Moreover, as set forth in section III.E.3.a, Barreras teaches determining when the temperature nears a temperature maximum, which is a software-loaded variable. Ex. 1007, 13:1–3. For purposes of this Decision, Petitioner sufficiently identified limitations 8.0–8.3 in the cited references.

b. Controlling the transfer of energy (limitation 8.4)

For this limitation, Petitioner contends Barreras '313 discloses "regulating the rate of recharging the back-up power source contained within the implanted receiver as a function of temperature." Pet. 79 (emphasis omitted) (quoting Ex. 1010, 5:42–50). Petitioner further contends that "[b]ecause Barreras '313 already teaches a control circuit that regulates charging based on temperature, incorporating the maximum temperature variable from Barreras would necessarily control the transfer of energy based on the comparison with the programmable limit." *Id.* at 79–80 (citing Ex. 1003 ¶¶ 223–224).

Patent Owner maintains that Barreras '313 does not disclose controlling the transcutaneous transfer of energy based on temperature, as limitation 8.4 requires. Prelim. Resp. 36–42. According to Patent Owner, micro controller 26 does not receive the temperature measurement from thermistor 80, but instead receives a voltage measurement indicative of the

distance between inductors 64 and 60. *Id.* at 39–41 (citing Ex. 1010, 8:39–55, Fig. 1; Ex. 2010 ¶ 57). We agree with Patent Owner that micro controller 26 receives a voltage measurement to regulate the transfer of energy as a function of the distance between the inductors. Ex. 1010, 8:43–55. Nonetheless, as Petitioner argues, Barreras '313 expressly discloses "regulating the rate of recharging the back-up power source contained within the implanted receiver as a function of temperature." Pet. 79 (emphasis omitted) (quoting Ex. 1010, 5:42–50). Petitioner also argues, claim 4, which depends from independent claim 1, discloses an implantable medical system comprising a transmitting unit having a first control means for controlling the amount of energy transmitted to a receiving unit having a rechargeable battery, and further comprising a temperature sensor on rechargeable battery and in communication with the first control means to save energy. Pet. 68; *see also id.* at 79 (referring to the arguments for limitation 1.2). That notwithstanding, as Patent Owner acknowledges, Barreras '313 teaches that micro controller 46 regulates the current level used to recharge rechargeable power source 44 as a function of the temperature measured by thermistor 80. Prelim. Resp. 41; Ex. 1010, 8:56–9:5. As transmitter 12 transcutaneously transfers energy to induce the current that recharges rechargeable power source 44 (Ex. 1010, 8:35–43), regulating the current level as a function of temperature in turn regulates the transcutaneous transfer of energy. For these reasons, Petitioner, on this record and for purposes of institution, has sufficiently identified limitation 8.4 in the cited references.

c. Rationale

Petitioner's rationale for combining the teachings of Barreras '313 and Barreras is similar to that for combining Torgerson with Barreras. *Compare* Pet. 75–76, *with id.* at 48–49. At this stage of the proceeding, Patent Owner does not oppose Petitioner's rationale, which, as discussed in section III.E.3.c., finds support in Barreras. Accordingly, for purposes of institution, Petitioner has provided sufficient reasoning why a person of ordinary skill would have combined the teachings of Barreras '313 and Barreras.

d. Conclusion for independent claim 8

Petitioner has shown sufficiently how it contends each limitation of independent claim 8 is found in Barreras '313 and Barreras. Petitioner also has articulated sufficient reasoning for why a person of ordinary skill would have combined the teachings of Barreras '313 and Barreras in the manner set forth in the Petition for purposes of this Decision. Based on this record, Petitioner has shown a reasonable likelihood that Petitioner would prevail in demonstrating independent claim 8 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Barreras '313 and Barreras.

3. Independent claim 19

Petitioner's arguments for independent claim 19 are similar to its arguments for independent claim 8. Pet. 81. Patent Owner relies on its arguments for independent claim 8 for independent claim 19. Prelim. Resp. 36–42. For the reasons discussed in section III.I.2, Petitioner has shown a reasonable likelihood that it would prevail in demonstrating independent claim 19 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Barreras '313 and Barreras.

4. Dependent claims 12, 14, 15, 20, and 21

Petitioner identifies the limitations of claims 12, 14, 15, 20, and 21 in the cited references. Pet. 80–81. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for independent claims 8 and 19. Prelim. Resp. 36–42. On the current record, Petitioner's arguments find support in the cited references.

J. Obviousness Based on Barreras '313, Barreras, and Wang

Petitioner identifies the limitations of claims 9–11 and 13 in Wang. Pet. 43–47; *see also id.* at 82 (referring to the arguments regarding Wang in the asserted ground based on Torgerson, UL 544, Barreras, and Wang). Petitioner also provides a rationale for combining the teachings of Torgerson, Barreras, and Wang. *Id.* at 82. At this stage of the proceeding, Patent Owner does not raise arguments for claims 9–11 and 13 apart from its arguments for independent claim 8. Prelim. Resp. 42–43. On the current record, Petitioner's arguments find support in Wang.

K. Obviousness Based on Barreras '313, Taylor, and Barreras

Petitioner challenges claims 1–3, 7, 16–18, and 22 under 35 U.S.C. § 103(a), contending the claimed subject matter is obvious over Barreras '313, Taylor, and Barreras. Pet. 58–73. As Barreras '313 and Barreras are discussed in sections III.I.1 and III.E.2, respectively, we begin our analysis of this asserted ground with a summary of Taylor and then turn to the parties' contentions for each of the claims.

1. Taylor (Ex. 1011)

Taylor relates to "a method for detecting the activity of an implanted adjustable shunt valve using an acoustic monitoring device and system." Ex. 1011, 1:18–20. Acoustic monitoring system 100 includes first and second transmitters 120 and 130, respectively. *Id.* at 6:36–42, Fig. 2A. Each transmitter 120, 130 includes coils that create magnetic fields to energize a valve stepper motor and adjust the implanted shunt valve, and second transmitter 130 further includes acoustic sensor 140 to pick up acoustic signals generated from the implanted shunt valve during the adjustment cycle. *Id.* at 6:51–54, 6:65–7:2. Each transmitter can also include a temperature sensor to ensure that the coils do not generate too much heat and endanger a patient's comfort and safety. *Id.* at 6:57–59.

Figure 2B, reproduced below, shows second transmitter 130.

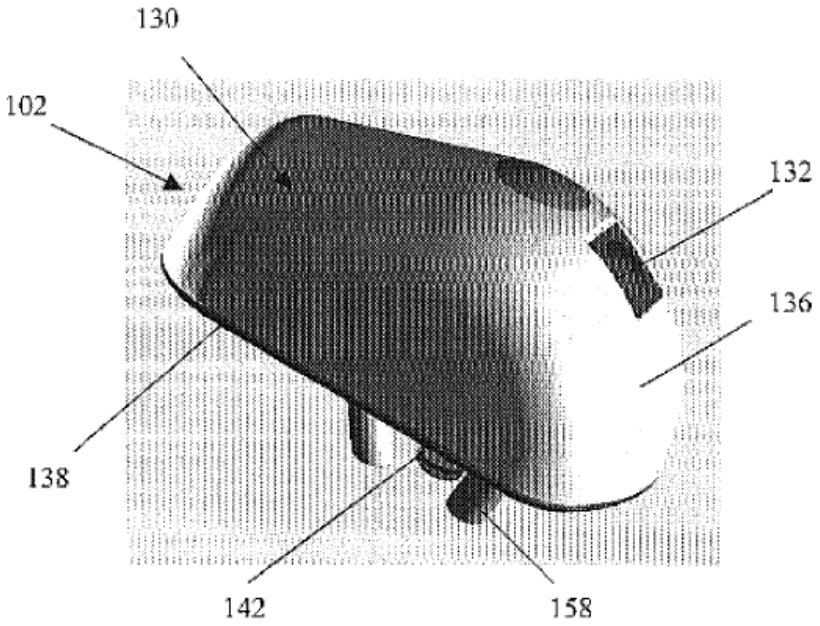


FIG. 2B

Figure 2B is an enlarged view of the second transmitter. *Id.* at 4:52–53. Second transmitter 130 comprises housing 136 enclosing transmitter

assembly 134. *Id.* at 7:60–62. Housing base 138 includes a plurality of feet 158 for resting and balancing housing 136 against the patient and over the implanted valve. *Id.* at 8:1–4. A thermistor can be incorporated into second transmitter 130 to assure that the temperature of legs 158 stays within acceptable limits, such as those for brief patient contact defined in the EN60601 safety standard. *Id.* at 9:17–21, 16:23–26.

2. *Independent claim 1*

a. Undisputed limitations (limitations 1.0, 1.1, and 1.3)

For limitation 1.0, which recites "[a] medical system, comprising: an implantable medical device; [and] an external charging device configured to transcutaneously transfer energy to the implantable medical" (Ex. 1001, 21:63–67), Petitioner contends Barreras '313 discloses an implantable, rechargeable stimulator system 10 comprising external transmitter 12 that transcutaneously transfers energy from output inductor 64 to receiving inductor 60 of implanted receiver 14. Pet. 64–65 (citing Ex. 1010, 8:39–60, 12:6–9, Fig. 6).

For the temperature sensor recited in limitation 1.1, Petitioner argues Barreras '313 discloses thermistor 80 in implanted receiver 14. *Id.* at 65 (citing Ex. 1010, 8:58–60). Petitioner also argues Barreras '313 discloses regulating the charging of rechargeable power source 44 of receiver 14 based on a temperature reading of thermistor 80 to restrict temperature rise. *Id.* (citing Ex. 1010, 8:56–9:5). Petitioner acknowledges Barreras '313 does not disclose explicitly a temperature sensor located in the external transmitter, and asserts Taylor teaches an external transmitter having legs to contact a patient and a thermistor to assure the temperature of the legs does

not exceed the requirements for brief patient contact defined in the EN60601 safety standard. *Id.* at 66 (citing Ex. 1011, 9:16–21, 16:23–27).

Independent claim 1 further recites "a memory configured to store the programmable limit," i.e., limitation 1.3. Ex. 1001, 22:7. Petitioner relies on Barreras's software-loaded variable for teaching the recited "programmable limit," and argues a software-loaded variable would necessarily be stored in memory. Pet. 69–70 (citing Ex. 1007, 13:1–5; Ex. 1003 ¶ 203). Petitioner also argues that Barreras '313 discloses a micro controller, which is connected to random-access memory (RAM), for regulating charging based on temperature, and that it would have been obvious to store Barreras's variable maximum temperature that informs charging regulation on the RAM of Barreras '313. *Id.* at 70.

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions for claim limitations 1.0, 1.1, and 1.3. On the current record, Petitioner's arguments and Dr. Colvin's testimony find support in the cited references. In particular, Barreras '313 discloses external transmitter 12 transcutaneously transfers energy to implanted receiver 14 having thermistor 80 that is used to regulate the energy transfer (Ex. 1010, 8:35–43, 8:56–9:5, Figs. 1, 6), and Taylor teaches an external transmitter having a thermistor (Ex. 1011, 9:16–21, 16:23–27). Based on the current record and for purposes of this Decision, Petitioner has sufficiently identified limitations 1.0, 1.1, and 1.3 in the cited references.

b. Control circuit (limitation 1.2)

For the control circuit recited in limitation 1.2, Petitioner argues Barreras '313 discloses that both micro controller 26 of external transmitter 12 and micro controller 46 of implanted receiver 14 regulate

charging based on temperature. Pet. 67–68 (citing Ex. 1010, 5:57–63, 7:48–52, 8:43–49, 8:56–9:5; Ex. 1003 ¶ 202). Petitioner further argues it would have been obvious for a person of ordinary skill in the art to modify the control circuitry of Barreras '313 to control the transfer of energy based on the temperature of the external transmitter based on Taylor. *Id.* at 69. Petitioner acknowledges Barreras '313 does not expressly disclose a programmable limit, and relies on Barreras's software-loaded variable to teach the programmable limit. *Id.* at 68–69 (citing Ex. 1007 3:2–7, 13:1–5).

Patent Owner maintains that neither Barreras '313 nor Taylor discloses the recited control circuit. Prelim. Resp. 29–34. In particular, Patent Owner contends that no reference discloses the requisite interaction, namely controlling the energy transfer based on output of the temperature sensor on the external device. *Id.* at 32–34. We disagree with Patent Owner. As Petitioner correctly argues, Taylor teaches external transmitter 130 includes coils for magnetically energizing a stepper motor of the implanted shunt valve, as well as a thermistor for ensuring the coils do not generate too much heat. Pet. 60–62, 66; Ex. 1011, 6:48–59. As Taylor teaches an external transmitter that controls the transcutaneous transfer of energy, i.e., magnetic energization, based on output of the temperature sensor of the external transmitter, Petitioner, on this record and for purposes of institution, has sufficiently identified the control circuit recited in limitation 1.2.

c. Rationale

In regard to the combination of Barreras '313 and Taylor, Petitioner argues

> it would have been obvious, for a [person of ordinary skill in the art] to include a temperature sensor in the external charging device in Barreras '313, as taught in Taylor, to monitor the temperature and include control circuitry that controls transfer of energy based on the monitored temperature so that the external charging device does not exceed the mandated 41 °C to ensure compliance with the applicable safety standard.

Pet. 63 (citing Ex. 1003 ¶¶ 95–196); *see also id.* at 66–67 (citing Ex. 1003 ¶ 201) (asserting a similar rationale for combining the teachings of Barreras '313 and Taylor). Patent Owner contends Petitioner fails to demonstrate that a person of ordinary skill in the art would have been motivated to combine the teachings of Barreras '313 and Taylor because Petitioner provides no justification why controlling the energy transfer based on the output of a temperature sensor on the external charging device would have been the mechanism of choice for limiting the temperature of external device that is applied to patient's skin. Prelim. Resp. 34–35 (citing Ex. 2010 ¶ 49). Patent Owner further contends that

> [i]f controlling the energy transfer from the external device based on a sensed temperature of the external device was obvious at the time of the invention, a well-known company like Boston Scientific with infinite resources at its disposal would not sell rechargers without such a feature only to *later* add the claimed feature to the rechargers after they burnt patients.

Id. at 35 (citing Ex. 2005[6], 1, 6).

We disagree with Patent Owner that there is no justification for controlling energy transfer to limit the temperature of the external device. Petitioner's rationale and Dr. Colvin's supporting testimony find support in

[6] U.S. Food & Drug Admin., *Class 2 Device Recall Precision Charger 1.0* (Oct. 31, 2008), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?ID=73737.

Taylor, which teaches controlling the transfer of energy to assure the temperature of the external transmitter does not exceed the requirements for brief patient contact defined in the EN60601 safety standard. Ex. 1011, 8:57–59, 9:17–21, 16:23–26.

To the extent Patent Owner is relying on secondary considerations of non-obviousness, arguments and evidence of secondary considerations are better evaluated in the context of a completed trial, when the record has been fully developed and the ultimate determination regarding patentability is made. Nonetheless, we have reviewed Patent Owner's arguments and evidence regarding secondary considerations and evaluated the arguments and evidence of non-obviousness with Petitioner's arguments and evidence of obviousness. Whenever this Decision states that Petitioner has demonstrated a reasonable likelihood of showing a claim is unpatentable, that statement indicates we have determined Petitioner's evidence is sufficient to meet the evidentiary burden for institution, notwithstanding Patent Owner's arguments and evidence regarding non-obviousness, including secondary considerations.

Turning to the combination of Barreras '313 and Taylor with Barreras, Petitioner's rationale is similar to that for combining Torgerson and Barreras. *Compare* Pet. 64, *with id.* at 48–49. At this stage of the proceeding, Patent Owner does not oppose Petitioner's rationale, which, as discussed in section III.E.3.c, finds support in Barreras.

d. Conclusion for independent claim 1

In view of the foregoing, Petitioner has shown persuasively each limitation of independent claim 1 in Barreras '313, Taylor, and Barreras. Petitioner also has articulated reasoning for why a person of ordinary skill

would have combined the teachings of these references in the manner set forth in the Petition.

3. Independent claim 18

Petitioner relies on its arguments for independent claim 1 for independent claim 18. Pet. 72–73. Patent Owner relies on its arguments for independent claim 1 for independent claim 18. Prelim. Resp. 29–36.

Patent Owner additionally argues Petitioner's arguments are deficient for independent claim 18, which recites various "means for" limitations. *Id.* at 10–11. According to Patent Owner, "Petitioner makes no attempt to map the prior art to the functions and the purported structure, as required" and "simply refers back to its analysis of claim 1." *Id.* We disagree with Patent Owner, as Petitioner's arguments for independent claim 1 contemplate both the functions and structures disclosed in the cited references. Pet. 64–70. For example, Petitioner argues Barreras discloses an implantable, rechargeable stimulator system 10 comprising external transmitter 12 that transcutaneously transfers energy from output inductor 64 to receiving inductor 60 of implanted receiver 14. Pet. 64–65 (citing Ex. 1010, 8:39–60, 12:6–9, Fig. 6).

In view of the foregoing, including the reasons set forth in section III.K.2, Petitioner has sufficiently identified each limitation of independent claim 18 in Barreras '313, Taylor, and Barreras. Petitioner also has articulated reasoning for why a person of ordinary skill would have combined the teachings of these references in the manner set forth in the Petition.

4. Dependent claims 2, 3, 7, 16, 17, and 22

Petitioner identifies the limitations of claims 2, 3, 7, 16, 17, and 22 in the cited references. Pet. 70–73. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for independent claims 1 and 18. Prelim. Resp. 29–36. On the current record, Petitioner's arguments find support in the cited references.

L. Obviousness Based on Barreras '313, Taylor, Barreras, and Wang

Petitioner identifies the limitations of claims 4–6 in Wang. Pet. 43–47; *see also id.* at 74 (referring to the arguments regarding Wang in the asserted ground based on Torgerson, UL 544, Barreras, and Wang). Petitioner also provides a rationale for combining the teachings of Barreras '313, Taylor, Barreras, and Wang. *Id.* at 74. At this stage of the proceeding, Patent Owner does not raise arguments for claims 4–6 apart from its arguments for independent claim 1. Prelim. Resp. 36. On the current record, Petitioner's arguments find support in Wang.

IV. CONCLUSION

For the reasons set forth above, Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the challenged claims of the '112 patent, and we institute an *inter partes* review based on the asserted grounds of unpatentability set forth in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (indicating that a decision whether to institute an *inter partes* review "require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in

the petition"). At this stage of the proceeding, however, we have not made a final determination as to the patentability of any challenged claim or any underlying factual or legal issue.

V. ORDER

In consideration of the foregoing, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, an *inter partes* review of the '112 patent is hereby instituted with respect to claims 1–22 of the '112 patent, on all grounds presented in the Petition; and

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

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