## UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

## BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS, INC., Petitioner,

v.

MEDTRONIC, INC., Patent Owner.

IPR2020-00713 Patent 9,821,112 B2

Before JAMES A. TARTAL, ERIC C. JESCHKE, and ALYSSA A. FINAMORE, *Administrative Patent Judges*.

FINAMORE, Administrative Patent Judge.

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

## I. INTRODUCTION

Petitioner, Axonics, Inc.,<sup>1</sup> filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–22 of U.S. Patent No. 9,821,112 B2 ("the '112 patent") (Ex. 1001).<sup>2</sup> Pet. 1. On September 23, 2020, we granted institution of an *inter partes* review. Paper 11 ("Inst. Dec.").

With our authorization, Petitioner filed a Motion to Withdraw Grounds (Paper 18), whereby Petitioner sought to withdraw two of the eight grounds asserted in the Petition. Paper 18, 2. We granted Petitioner's Motion to Withdraw Grounds. Paper 19.

Patent Owner, Medtronic, Inc., filed a Response (Paper 22, "PO Resp."). Concurrently with the Response, Patent Owner filed a Disclaimer (Ex. 2027), by which Patent Owner disclaimed claims 8, 14, 15, 19, and 21 of the '112 patent. Ex. 2027, 1.

Petitioner filed a Reply (Paper 28, "Reply"). Patent Owner filed a Sur-reply (Paper 36, "Sur-reply").

Oral argument took place on June 17, 2021. We have entered the transcript (Paper 41, "Tr.").

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). In view of Patent Owner's disclaimer, claims 1–7, 9–13, 16–18, 20, and 22

<sup>&</sup>lt;sup>1</sup> During the trial, the name of Petitioner when the Petition was filed, Axonics Modulation Technologies, Inc., was changed to Axonics, Inc. *See* Paper 35.

<sup>&</sup>lt;sup>2</sup> 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 of the Petition. We consider Petitioner's reference to U.S. Patent No. 9,463,112 B2 to be a typographical error.

remain in this proceeding, and we conclude Petitioner has not proven, by a preponderance of the evidence, the unpatentability of claims 1–7, 16–18, and 22, but has proven, by a preponderance of the evidence, the unpatentability of claims 9–13 and 20.

#### II. BACKGROUND

#### A. Real Parties in Interest

Petitioner asserts that it is the real party in interest. Pet. 83; *see also* Paper 35 (notifying the Board of the name change from Axonics Modulation Technologies, Inc. to Axonics, Inc.). 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) ("the '324 patent IPR"). 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

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.

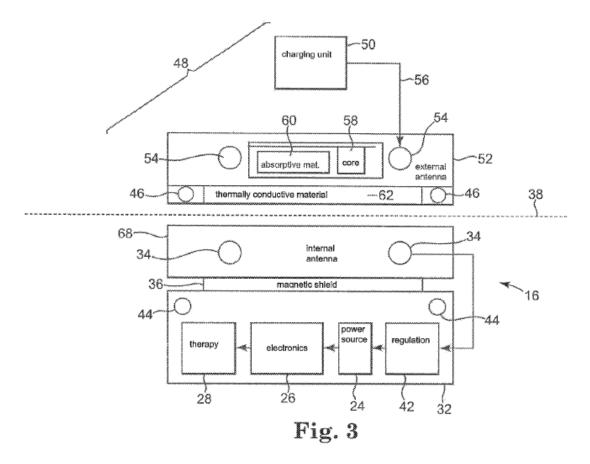


Figure 3 is a block diagram of implantable medical device 16 implanted subcutaneously, i.e., below cutaneous boundary 38, and associated external charging device 48. *Id.* at 7:40–43, 9:22–25, 9:53–55. Implantable medical device 16 includes housing 32 enclosing rechargeable power source 24 such as a 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, 9:25–36, 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. Effect of the Disclaimer

After institution of *inter partes* review, Patent Owner filed the Disclaimer disclaiming claims 8, 14, 15, 19, and 21 of the '112 patent. PO Resp. 1–2; Ex. 2027; *see also* 35 U.S.C. § 253(a) (providing that a patentee may "make disclaimer of any complete claim" in writing with the Patent and

Trademark Office, and such disclaimer "shall thereafter be considered as part of the original patent"). Patent Owner asserts that in light of the Disclaimer, claims 8, 14, 15, 19, and 21 are to be "treated as though they never existed." PO Resp. 17 n.9 (citations omitted). Patent Owner further argues that we should "not address the disclaimed claims in the Final Written Decision." *Id.* (citation omitted). Petitioner does not dispute the effect of the Disclaimer. *See* Reply 11–13, 18–22 (arguing that the challenged claims not disclaimed are unpatentable).

We agree with Patent Owner that we should not address the patentability of claims 8, 14, 15, 19, and 21 in this Decision. *See* PO Resp. 17 n.9. Rather, we treat claims 8, 14, 15, 19, and 21 as if they never existed. *See Gunn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) ("A statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent."). We address the patentability only of the challenged claims not disclaimed. *See Intel Corp. v. VLSI Tech. LLC*, IPR2018-01040, Paper 36, 16 (PTAB Feb. 12, 2020) ("Consistent with other Board decisions in which some, but not all, challenged claims have been disclaimed after institution, we address the patentability only of the remaining claims.").

## E. Challenged Claims

Of the challenged claims not disclaimed, claims 1 and 18 are independent. Ex. 1001, 21:63–22:7, 23:22–24:5. Independent claim 1 is 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.

*Id.* at 21:63–22:7.

Independent claim 18 recites a medical system similar to that of

independent claim 1, and recites various means-plus-function limitations.

*Id.* at 23:22–24:5. Claims 2–7 and 22 depend from independent claim 1. *Id.* at 22:8–28, 28, 24:26, 27

at 22:8–28, 24:26–27.

Claims 9–13, 16, and 17 depend from independent claim 8. Id.

at 22:41-67, 23:10-21. Claim 20 depends from independent claim 19. Id.

at 24:18–23. Independent claims 8 and 19, now disclaimed, are similar to independent claim 1, but do not recite sensing temperature specifically at the external charging device. *Id.* at 22:29–40, 24:6–17.

# F. Asserted Grounds of Unpatentability and Evidence

In view of the withdrawn grounds and the disclaimed claims, as set forth above in section I, Petitioner challenges claims 1-7, 9-13, 16-18, 20, and 22 on the following six grounds:

Challenged Claims	35 U.S.C. § <sup>3</sup>	References
1–3, 7, 16–18, 22	103(a)	Barreras '313 <sup>4</sup> , Taylor <sup>5</sup> , Barreras <sup>6</sup>
46	103(a)	Barreras '313, Taylor, Barreras, Wang <sup>7</sup>
9–11, 13	103(a)	Barreras '313, Barreras, Wang
9–11, 13	103(a)	Torgerson <sup>8</sup> , Barreras, Wang
12, 20	103(a)	Barreras '313, Barreras
12, 20	103(a)	Torgerson, Barreras

<sup>&</sup>lt;sup>3</sup> The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended certain sections of this statute, including §§ 102 and 103, and the effective date of the relevant amendment is March 16, 2013. The '112 patent claims priority to several applications, some of which were filed before March 16, 2013 (Ex. 1001, code (60)), and there is no dispute that the challenged claims of the '112 patent have an effective filing date before March 16, 2013. Accordingly, we apply the pre-AIA version of the statute.

<sup>&</sup>lt;sup>4</sup> Barreras, Sr. et al., US 5,733,313, issued Mar. 31, 1998 ("Barreras '313") (Ex. 1010).

<sup>&</sup>lt;sup>5</sup> Taylor et al., US 6,685,638 B1, issued Feb. 3, 2004 ("Taylor") (Ex. 1011). <sup>6</sup> Barreras et al., WO 00/69012, published Nov. 16, 2000 ("Barreras") (Ex. 1007).

<sup>&</sup>lt;sup>7</sup> Wang et al., US 5,702,431, issued Dec. 30, 1997 ("Wang") (Ex. 1008).
<sup>8</sup> Torgerson et al., WO 01/83029 A1, published Nov. 8, 2001 ("Torgerson") (Ex. 1005).

In support of its asserted grounds of unpatentability, Petitioner relies on a Declaration of Michael Colvin (Ex. 1003). Patent Owner deposed and cross-examined Dr. Colvin and submits a transcript of the deposition (Ex. 2024).

Patent Owner proffers a Declaration of Dr. Matthew Haller (Ex. 2022). Petitioner deposed and cross-examined Dr. Haller and submits a transcript of the deposition (Ex. 1020).

Additionally, Patent Owner provides evidence of objective indicia of non-obviousness of the claimed invention. Patent Owner identifies this evidence in its Response. PO Resp. 57–62.

#### III. ANALYSIS

#### A. Testimonial Evidence

Patent Owner maintains that we should give Dr. Colvin's testimony little or no weight because it is inconsistent and unreliable. PO Resp. 62–65. Petitioner replies that the "the record is clear that Dr. Colvin always gave honest and truthful testimony at his deposition." Reply 24.

Petitioner urges that Dr. Haller's testimony is entitled to little weight because it is contradicted by the prior art and based on an incorrect understanding of the claims. *Id.* at 23–24. Patent Owner argues Dr. Haller's testimony is reliable. Sur-reply 25–27.

As set forth in our Trial Practice Guide<sup>9</sup>, we generally permit testimony where the declarant's scientific, technical, or other specialized

<sup>&</sup>lt;sup>9</sup> USPTO, *Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019*, https://www.uspto.gov/TrialPracticeGuideConsolidated ("TPG"); *see also* Office Patent Trial Practice Guide, November 2019

knowledge will help the Board understand the evidence or to determine a fact in issue. TPG 34 (citing Fed. R. Evid. 702(a)). Given their education and experience with the charging of implantable medical devices (Ex. 1003  $\P\P$  4–11; Ex. 2022  $\P\P$  3–9), we find Dr. Colvin's testimony and Dr. Haller's testimony helpful in deciding factual issues in this proceeding. Moreover, when assigning weight to a declarant's testimony, we consider the underlying facts or data upon which the testimony is based. TPG 40–41. In our analysis of the asserted grounds of unpatentability, we weigh Dr. Colvin's testimony and Dr. Haller's testimony accordingly.

## B. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art ("POSITA") 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 medical implantable 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 proposes its own level of ordinary skill in the art. PO Resp. 5–6. According to Patent Owner, a POSITA "would have had at least a bachelor's degree in a relevant field (e.g., electrical, mechanical, or biomedical engineering) with at least two years of experience with the design of components (e.g., circuitry) for implantable medical devices and associated external devices (e.g., a charging unit)." *Id.* (citing Ex. 2022 ¶ 14). Patent Owner further contends "[m]ore education can substitute for practical experience and *vice versa.*" *Id.* at 6 (citing Ex. 2022 ¶ 14).

Edition, 84 Fed. Reg. 64,280 (Nov. 21, 2019) (notifying the public of the availability of the Consolidated Trial Practice Guide).

Patent Owner "disagrees with Petitioner's definition as it is too generic and does not require design experience." *Id.* Patent Owner, however, does not explain why the level of ordinary skill in the art requires experience with designing the components for implantable medical systems, as opposed to experience, in general, with implantable medical systems. Moreover, Petitioner defines the level of ordinary skill in the art in two ways. One way expressly requires design experience. The other is an alternative thereto, and Patent Owner acknowledges education can substitute for experience. We see no meaningful distinction between Petitioner's proposed level of ordinary skill in the art and that of Patent Owner.

Petitioner's proposed level of ordinary skill in the art finds support in the evidence. 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 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.

In view of the foregoing, the evidence reflects Petitioner's proposed level of ordinary skill in the art, which does not differ significantly from Patent Owner's proffered level of ordinary skill in the art. Our analysis of the asserted grounds of unpatentability does not turn on which of the parties' definitions for the level of ordinary skill in the art we apply, and we adopt Petitioner's definition of the level of ordinary skill in the art.

#### C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C.

282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Furthermore, we expressly construe the claims to the extent necessary to determine whether Petitioner has proven that the challenged claims are unpatentable. *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 also proposes a construction for "programmable limit" and disagrees with Petitioner's proffered construction of this term. PO Resp. 8–15. Patent Owner additionally argues: "The Board can resolve the parties' dispute in this proceeding without construing 'programmable limit' because none of the prior art arguments offered below implicate the meaning of 'programmable limit.' The same is true for the means plus function terms." *Id.* at 7 (citations and footnote omitted).

We agree with Patent Owner that we need not expressly construe the claim term "programmable limit" or the means-plus-function limitations in independent claim 18 to resolve the dispute. For the reasons set forth in our analysis of the asserted grounds of unpatentability, we determine that no claim term requires an express construction for us to ascertain whether Petitioner has shown the challenged claims to be unpatentable.

D. 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 would have been obvious over Barreras '313, Taylor, and Barreras.<sup>10</sup> Pet. 58–73; Reply 2–13. Patent Owner argues Petitioner's proposed combination of Barreras '313, Taylor, and Barreras would not have resulted in all of the claim limitations. PO Resp. 34–47; Sur-reply 15–19. Patent Owner also argues that there would not have been a motivation to combine the teachings of the references as Petitioner proposes. PO Resp. 19–34; Sur-reply 3–14.

We begin our analysis of this asserted ground of unpatentability with an overview of each of Barreras '313, Taylor, and Barreras. We then discuss the parties' contentions for each of the claims. For the reasons below, Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claims 1–3, 7, 16–18, and 22 would have been obvious over the combined teachings of Barreras '313, Taylor, and Barreras.

1. Barreras '313

Barreras '313 relates to "an implantable medical device including a rechargeable back-up power source and a charging unit for recharging the

<sup>&</sup>lt;sup>10</sup> In the Petition's listing of the asserted grounds, Petitioner does not identify claims 16 and 17 with respect to the asserted ground based on Barreras '313, Taylor, and Barreras. Pet. 18. In the arguments for this asserted ground, however, Petitioner addresses these claims. *Id.* at 58, 72–73; Reply 19. Accordingly, we understand the asserted ground based on Barreras '313, Taylor, and Barreras includes claims 16 and 17, and we consider the omission of these claims from this asserted ground in the Petition's listing of the asserted grounds to be a typographical error. *See also* Inst. Dec. 46 (addressing claims 16 and 17 with respect to the asserted ground based on Barreras '313, Taylor, and Barreras).

back-up power source via RF coupling." Ex. 1010, 1:8–11. An implanted medical device and charging unit are shown in Figure 1, reproduced below.

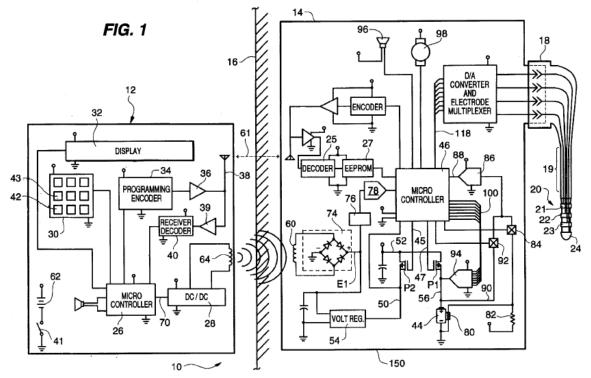


Figure 1 is a block electrical schematic circuit diagram of an implantable, rechargeable tissue stimulator system comprising an implanted receiver and transmitting unit. *Id.* at 7:6–9. As shown in Figure 1, rechargeable tissue stimulator system 10 includes comprises transmitter 12 and receiver 14 surgically implanted beneath patient's skin 16. *Id.* at 7:33–38. 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 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. Taylor

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.

Second transmitter 130 is shown in Figure 2B, reproduced below.

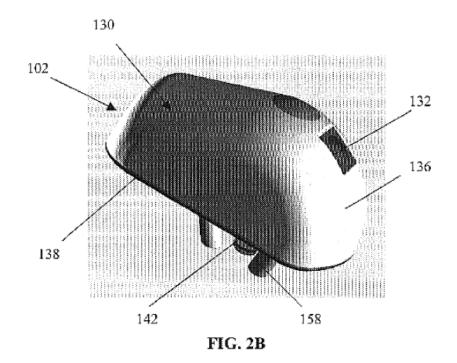


Figure 2B is an enlarged view of the second transmitter. *Id.* at 4:52–53. Second transmitter 130 comprises housing 136 enclosing transmitter assembly 134. *Id.* at 7:60–62. Housing base 138 includes a plurality of feet 158 for resting and balancing housing 136 against the patient and over the implanted 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.

3. Barreras

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.

## 4. Independent claim 1

#### a. Undisputed limitations

Independent claim 1 recites "[a] medical system, comprising: an implantable medical device; [and] an external charging device configured to transcutaneously transfer energy to the implantable medical device," i.e., limitation 1.0. 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 inductor 60 of implanted receiver 14. Pet. 64–65 (citing Ex. 1010, 8:39–60, 12:6–9, Fig. 6).

Independent claim 1 further recites that the external charging device comprises "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. Ex. 1001, 22:1–3. Petitioner argues Barreras '313 discloses thermistor 80 in implanted receiver 14. Pet. 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 also recites that the external charging device comprises "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. 1003 ¶ 203; Ex. 1007, 13:1–5). Petitioner also argues that external transmitter 12 of Barreras '313 includes a micro controller for regulating charging based on temperature, and that the micro controller is connected to a random-access memory (RAM). *Id.* at 70. According to Petitioner, it would have been obvious to store the variable maximum temperature that informs charging regulation on the RAM of Barreras '313. *Id.* 

Patent Owner does not dispute Petitioner's contentions with respect to limitations 1.0, 1.1, and 1.3. Petitioner's arguments and Dr. Colvin's testimony find support in Barreras '313, Taylor, and Barreras. Barreras '313 discloses external transmitter 12 transcutaneously transfers energy to implanted receiver 14, which includes thermistor 80 for regulating the energy transfer. Ex. 1010, 8:35–43, 8:56–9:5, Figs. 1, 6. External transmitter 12 includes micro controller 26 connected to a RAM, and micro controller 26 is used, via software, to regulate the amount of energy to be coupled into receiver 14. *Id.* at 7:48–52, Fig. 6. Taylor teaches an external transmitter having a thermistor. Ex. 1011, 9:16–21, 16:23–26. Barreras teaches a temperature maximum that is a software-loaded variable. Ex. 1007, 13:1–3. In view of the foregoing, Petitioner has persuasively

identified limitations 1.0, 1.1 and 1.3 in its proposed combination of Barreras '313, Taylor, and Barreras.

#### b. Control circuit to control the transfer of energy

Independent claim 1 recites that the external charging device comprises "a control circuit configured to compare the measured temperature to a programmable limit and control the transfer of energy based on the comparison," i.e., limitation 1.2. Ex. 1001, 22:4–6. 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. 1003 ¶ 202; Ex. 1010, 5:57–63, 7:48–52, 8:43–49, 8:56–9:5); Reply 11–12. Petitioner further argues it would have been obvious for a POSITA 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. Pet. 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 argues that the relied-upon references, alone or in combination, do not disclose the control of the transfer of charging energy based on the temperature of the external charging device, as limitation 1.2 requires. PO Resp. 34–41; Sur-reply 15–17. Patent Owner maintains that limitation 1.2 does not recite the control circuit and temperature sensor as separate pieces, but instead requires an interaction between the control circuit and the temperature sensor in the external charging device. PO Resp. 35 (citing Ex. 2022 ¶ 80); Sur-reply 15. Per Patent Owner, none of the references disclose the recited interaction of the control circuit

controlling the transfer of charging energy based on the output of the temperature sensor in the external charging device, and, as a result, combining the references would not result in the subject matter of limitation 1.2. PO Resp. 35–36 (citing Ex. 2022 ¶ 80); Sur-reply 15. Patent Owner alleges that microcontroller 26 of Barreras '313 does not disclose the recited control circuit because the system of Barreras '313 does not have a temperature sensor in transmitter 12 that microcontroller 26 could use to control charging energy. PO Resp. 36 (citing Ex. 2022 ¶ 81). Patent Owner also alleges that Taylor does not teach controlling the transfer of charging energy because Taylor's system does not transcutaneously transfer charging energy. Id. at 36–41; Sur-reply 15–17. According to Patent Owner, Taylor teaches using its transmitter to generate magnetic force to physically move implanted valve components rather than transferring charging energy to them (PO Resp. 40 (citing Ex. 2022 ¶¶ 85–91); Sur-reply 16–17), and Taylor's teaching of displaying a message to a clinician when the system overheats is not controlling the transcutaneous transfer of charging energy based on a measured temperature (PO Resp. 40–41 (citing Ex. 2022 ¶ 92); Sur-reply 15–16). Additionally, Patent Owner insists that Dr. Colvin admits there is no charging energy in Taylor. PO Resp. 37–38 (citing Ex. 2024, 128:17–129:13, 142:23–143:17, 143:19–21); Sur-reply 17.

Patent Owner's arguments address Barreras '313 and Taylor individually, whereas Petitioner is relying on the combined teachings of Barreras '313, Taylor, and Barreras to result in the subject matter of limitation 1.2. "[T]he test for obviousness is what the *combined teachings* of the references would have suggested to those having ordinary skill in the art." *In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012) (emphasis added)

(citing *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). Petitioner proposes to combine the system disclosed in Barreras '313, which includes an external charging device having circuitry for controlling the transcutaneous transfer of charging energy based on the measured temperature of a temperature sensor in the implanted medical device, with Taylor's teaching of measuring temperature with a temperature sensor in the external device and Barreras's teaching of comparing a monitored temperature to a programmable limit. Pet. 62–64, 67–69.

Contrary to Patent Owner's argument, Petitioner is not relying on the control circuitry of Barreras '313 and the temperature sensor of Taylor as separate components, nor is Petitioner relying on Taylor for teaching controlling the transcutaneous transfer of charging energy based on a measured temperature. Rather, Petitioner argues Barreras '313 discloses a system including an external charging device with circuitry that interacts with a temperature sensor in the implanted medical device by controlling the transcutaneous transfer of charging energy based on the measured temperature. Pet. 67–68; Reply 11–12. According to Petitioner, the disclosed system in Barreras '313 differs from the subject matter recited in limitation 1.2 only in that the recited system controls the transfer of charging energy based on the measured temperature of a temperature sensor in the implanted medical device, not in the external charging device, and does not compare the measured temperature to a programmable limit, and Petitioner argues Taylor and Barreras teach the recited subject matter missing from Barreras '313. Pet. 67–69; Reply 11–12.

Barreras '313 discloses that transmitter 12 includes micro controller 26 for communicating with implanted receiver 14 and regulating

the amount of RF energy to be coupled to implanted receiver 14, and that the current level used to recharge rechargeable power source 44 is regulated as a function of the measured temperature of thermistor 80 adhered to rechargeable power source 44 of implanted receiver 14. Ex. 1010, 7:48–59, 8:56–9:5, Figs. 1, 6; see also id. at claim 4 (claiming rechargeable battery having a temperature sensor "coupled via said RF signal transmitting means to said first control means of said transmitting unit whereby the level of transmitted RF energy can be reduced proportionally to the reduction in charging rate of the rechargeable battery in said receiving unit"). Taylor teaches that transmitters 120, 130 include a temperature sensor to ensure the coils, which generate a magnetic field to energize a stepper motor of an implanted shunt valve 50, do not over heat. Ex. 1011, 6:51-59; see also id. at 16:23–26 ("A thermistor such as a PT100 can be incorporated in the transmitter to assure that the temperature of the legs 158 does not exceed the requirements for brief patient contact as defined in EN60601."). Barreras teaches comparing a monitored temperature to an unsafe value, which is a software-loaded variable. Ex. 1007, 13:1-3.

In view of the foregoing, Petitioner has demonstrated that Barreras '313 discloses a system including an external charging device with circuitry for controlling the transcutaneous transfer of charging energy based on the measured temperature of a temperature sensor in an implanted medical device. Petitioner also has demonstrated that Taylor teaches measuring temperature with a temperature sensor in an external device and that Barreras teaches comparing a monitored temperature to a programmable limit. Petitioner has persuaded us that its proposed combination of Barreras '313, Taylor, and Barreras would result in a control circuit

configured to control the transfer of charging energy based on a comparison of the measured temperature of a temperature sensor on the external charging device to a programmable limit. Petitioner has shown limitation 1.2 in its proposed combination of Barreras '313, Taylor, and Barreras.

### c. Reasons for combining the teachings

## Petitioner argues that

it would have been obvious, for a POSITA 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 ¶¶ 195–196); *see also id.* at 66–67 (citing Ex. 1003 ¶ 201) (asserting a similar rationale for combining the teachings of

Barreras '313 and Taylor). Petitioner further argues "a POSITA would have strong motivation to utilize a software[-]loaded variable as the temperature maximum, as taught in Barreras, since this allows the temperature maximum to be updated to support differing charge regimens or to incorporate new or updated safety standards without any significant manufacturing changes." *Id.* at 64 (citing Ex. 1003 ¶¶ 197–198); *see also id.* at 69 (citing Ex. 1003 ¶ 202) (asserting a similar rationale for combining the teachings of Barreras '313 and Barreras).

Patent Owner maintains a POSITA would not have been motivated to modify the system of Barreras '313 to include a temperature sensor located on an external transmitter, as Taylor teaches, for three reasons. PO Resp. 19–34; Sur-reply 3–14. First, Patent Owner argues the system of

Barreras '313 did not need a temperature sensor on the transmitter to comply with the 41°C limit set forth in the safety standards. PO Resp. 21, 23–27; Sur-reply 3–5, 11–12. Second, Patent Owner argues a POSITA would not have expected overheating of the transmitter of Barreras '313. PO Resp. 27–30; Sur-reply 6–10. Third, Patent Owner argues Taylor's temperature sensor in the transmitter would not have motivated a POSITA to include a temperature sensor in the transmitter of Barreras '313. PO Resp. 30–34.

Regarding Patent Owner's first argument, Patent Owner relies on Dr. Haller's testimony that the need to satisfy safety standards did not mean a POSITA would have included a temperature sensor in a heat-producing device. PO Resp. 25 (citing Ex. 2022 ¶ 61). Patent Owner contends Dr. Colvin admits that a heat-producing device, such as an implant or an external charging device, could satisfy the 41°C limit set without a temperature sensor in the device. PO Resp. 24 (citing Ex. 2024, 97:8–22); Sur-reply 4, 11–12. Patent Owner further contends that, while Dr. Colvin was Chief Scientist at Advanced Bionics, Advanced Bionics certified to the Food and Drug Administration (FDA) that the Precision 1.0 recharger, which did not include a temperature sensor, complied with the 41°C limit. PO Resp. 25–26 (citing Ex. 2022 ¶ 63; Ex. 2024, 32:24–33:3, 51:23–52:12, 67:5–68:5); Sur-reply 5 (citing Ex. 2022 ¶ 28, 68); see also Sur-reply 12 (arguing the absence of a temperature sensor in Precision 1.0 confirms the hindsight in Petitioner's obviousness analysis). Patent Owner also contends that, like the Precision 1.0 recharger, the associated patient remote control contacted a patient's skin and lacked a temperature sensor. PO Resp. 26 (citing Ex. 2022 ¶ 33; Ex. 2024, 53:18–25).

With respect to Patent Owner's second argument, Patent Owner asserts that the conventional thinking at the time of the invention was an implanted device was expected to overheat but a transmitter for recharging the implanted device was not, and that this conventional thinking is demonstrated by Barreras '313, Torgerson, and Barreras each disclosing a system having a temperature sensor in the implanted device but not in the external device, the lack of a temperature sensor in the FDA-approved Precision 1.0 recharger, and Dr. Colvin's testimony. PO Resp. 27–29 (citing Ex. 1005, 10:19–23; Ex. 1007, 12:34–13:8, Fig. 4; Ex. 1010, 8:56–9:5, Fig. 1; Ex. 2022 ¶¶ 66–68; Ex. 2024, 141:14–142:6). Patent Owner also asserts the Board already concluded in the '324 patent IPR that Petitioner failed to provide evidence that a POSITA would have expected overheating of the transmitter of Barreras '313. Sur-reply 6 (citing Ex. 2019<sup>11</sup>, 12–13).

In regard to Patent Owner's third argument, Patent Owner alleges "[s]imply because Taylor's device had a temperature sensor that Taylor thought was necessary in the context of the function of its device (which magnetically adjusts and acoustically monitors valves and is not even a recharger), does not mean that the same considerations apply to the Barreras '313's recharger 12." PO Resp. 30–31 (citing Ex. 2022 ¶ 73). Patent Owner also alleges "[a] POSITA designing or implementing an inductively coupled recharging system for a medical device like Barreras '313 would have very different concerns about heat generation than an engineer designing a system with electromagnets for valve adjustment like Taylor." *Id.* at 32 (citing Ex. 2022 ¶ 74–75).

<sup>&</sup>lt;sup>11</sup> Axonics Modulation Technologies, Inc. v. Medtronic, Inc., IPR2020-00714, Paper 11 (PTAB Sept. 15, 2020) (Ex. 2019).

Petitioner's reasoning for modifying the system disclosed in Barreras '313 to include a temperature sensor on the external transmitter, as Taylor teaches, is based on Dr. Colvin's opinion that compliance with safety standards prescribing a 41°C limit for any medical or dental equipment part in contact with a patient would have motivated a POSITA to add a temperature sensor to the external transmitter of Barreras '313. Dr. Colvin, however, admits that an external transmitter without a temperature sensor can comply with the safety standards if the external transmitter, under normal use conditions and under fault condition, does not exceed the prescribed temperature limit, i.e., overheat. Ex. 2024, 97:8–22.

Dr. Haller testifies that a POSITA would not have expected the external transmitter of Barreras '313 to overheat in view of the conventional thinking regarding a transmitter that charges a device implanted just below the skin and enclosed in a metallic housing, such as the transmitter of Barreras '313. Ex. 2022 ¶¶ 20–27. According to Dr. Haller:

At the time of the invention, it was understood that eddy currents on the metal surface of the implanted device were the primary source of heat generated during recharging. Specifically, it was understood that eddy currents in the conductive metallic housing (called a "can") of the implanted medical device would generate heat that could cause the implant to reach unsafe temperatures transcutaneous recharging. The conventional during understanding at that time was that the surface temperature of the implant, resulting from eddy currents, among other factors, would remain hotter than the surfaces of the external recharger during recharging. Eddy currents did not cause similar heating on the surface of the external recharger because the housing could be made from plastic, a material with very low thermal and electrical conductivity.

*Id.*  $\P$  21 (citation and footnote omitted). Dr. Colvin similarly explains that eddy currents in the metallic housing of an implanted device result in heat buildup in the implanted device, not the transmitter:

[O]ver the last 20 or 30 years most implants are encased in a titanium metallic can and the external recharger[s] are usually encapsulated in plastic. So if something was to heat up between the charger and the implantable device it's usually the [e]ddy currents induced in the implanted can is where you get most of the heat built up.

Ex. 2024, 141:21–142:6.

Petitioner replies that overheating was a known problem in the art. Reply 6–7. According to Petitioner, Carbunaru<sup>12</sup> demonstrates it was known in the art at the time of the invention to control an external transcutaneous charging device based on a temperature output of a temperature sensor in the external charging device, specifically for the purpose of preventing overheating to comply with the applicable safety standards. *Id.* at 7 (citing Ex. 1003 ¶¶ 83–84). Petitioner further replies that Dr. Haller distinguishes Barreras '313 from Carbunaru based on implant depth and titanium enclosures, both of which are beyond the scope of the claimed invention. *Id.* at 7–11.

Petitioner, however, conflates the obviousness requirements of motivation to combine and reasonable expectation of success, which are distinct inquiries. *See, e.g., Intelligent Bio–Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (explaining "two different legal concepts—reasonable expectation of success and motivation to combine"). Reasonable expectation of success contemplates the likelihood of success in

<sup>&</sup>lt;sup>12</sup> Carbunaru et al., US 2004/0098068 A1, published May 20, 2004 ("Carbunaru") (Ex. 2008).

combining the references to meet the limitations of the claimed invention, and failure to consider the appropriate scope of the claimed invention in evaluating a reasonable expectation of success constitutes a legal error. *Id.* In contrast, motivation to combine considers whether there would have been a suggestion or motivation to make the proposed combination of references. *Id.* at 1368. Although the scope of the claimed invention limits the requirement for reasonable expectation of success, the requirement of motivation to combine is not so limited. *Id.* ("While [the deblocking of the prior art's azidomethyl group] is irrelevant to a finding that there was no reasonable expectation of success in meeting the claims of the '537 patent, which do not require quantitative deblocking at all, it is central to a finding of no motivation to combine.").

Petitioner also replies that Matsuki<sup>13</sup> teaches overheating is a concern for a transmitter charging a device implanted just below the skin (Reply 8 (citing Ex. 1025, Figs. 3, 7)), and that Wang '665<sup>14</sup> teaches overheating is a problem for a transmitter charging a device implanted just below the skin and enclosed within a metal housing (*id.* at 10 (citing Ex. 2021, 5:58–62)). Matsuki regards computer simulation of the temperature rise on transcutaneous energy transmission by a pair of spiral coils separated by a subcutaneous layer having a certain thickness. Ex. 1025, 3334, Fig. 1. Matsuki evaluates temperature rise on transcutaneous energy transmission by a pair of spiral coils, not by a transmitter and an implanted medical

<sup>13</sup> Matsuki et al., Simulations of Temperature Rise on Transcutaneous Energy Transmission by Non-contract Energy Transmitting Coils, 29 IEEE Transactions on Magnetics 3334 (Nov. 1993) (Ex. 1025).
<sup>14</sup> Wang et al., US 5,991,665, issued Nov. 23, 1999 ("Wang '665") (Ex. 2021).

device, much less an implanted medical device enclosed in a metal housing. Wang '665 teaches overheating is a concern for an implanted device, not an external transmitter for charging the implanted device. According to Wang '665, housing 14 encloses induction coil 24 for transferring energy to implantable medical device 25. Ex. 2021, 5:18–24, Fig. 2. Housing 14 includes fan 26 for dissipating via convention the heat generated by can 41 of the implanted medical device 25. *Id.* at 6:54–59, Fig. 2. Wang '665 teaches that induction coil 24 having relatively low AC resistance reduces heat generation, but is silent regarding induction coil 24 of housing 14 overheating.

Unlike Carbunaru, Matsuki, and Wang '665, the system of Barreras '313 includes a transmitter for charging an implanted receiver enclosed in a metallic housing. Ex. 1010, 3:15–17 (describing the disclosed system provides RF coupling through a titanium-encased receiver). We credit Dr. Haller's unrebutted testimony as to the conventional thinking regarding a transmitter that charges an implanted device enclosed in a metallic housing, which was that the implanted device was expected to overheat, but the transmitter was not, due to the eddy currents in the metallic housing of the implanted device. In view of the foregoing, Petitioner has not persuaded us that safety standards prescribing a 41°C limit to prevent overheating would have motivated a POSITA to modify the system disclosed in Barreras '313 to include a temperature sensor on the external transmitter, as Taylor teaches.

#### d. Conclusion of independent claim 1

Petitioner has demonstrated each limitation of independent claim 1 in its proposed combination of Barreras '313, Taylor, and Barreras. Petitioner,

however, has not persuaded us that a POSITA would have had a reason to combine the teachings of these references as Petitioner proposes. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–62; Sur-reply 14–15), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claim 1 would have been obvious over combined teachings of Barreras '313, Taylor, and Barreras.

5. Independent claim 18

Petitioner relies on the same reasoning for combining the teachings of Barreras '313, Taylor, and Barreras to result in the subject matter of independent claim 18 as for combining the teachings of these references to result in the subject matter of independent claim 1. Pet. 62–64. For the reasons discussed above in section III.D.4.c, Petitioner's reasoning is not persuasive. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–62; Sur-reply 14–15), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claim 18 would have been obvious over combined teachings of Barreras '313, Taylor, and Barreras.

6. Claims 2, 3, 7, 16, 17, and 22

For the reasons discussed above in section III.D.4.c, Petitioner has not persuaded us that a POSITA would have had a reason to combine the teachings of Barreras '313, Taylor, and Barreras to result in the subject matter of independent claim 1, from which claims 2, 3, 7, 16, 17, and 22 depend. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–62; Sur-reply 14–15), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of

dependent claims 2, 3, 7, 16, 17, and 22 would have been obvious over combined teachings of Barreras '313, Taylor, and Barreras.

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

Petitioner challenges claims 4–6 of the '112 patent under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Barreras '313, Taylor, Barreras, and Wang. Pet. 73–74; Reply 19–21. Patent Owner argues this asserted ground of unpatentability fails for the same reasons as the asserted ground based on Barreras '313, Taylor, and Barreras with respect to independent claim 1. PO Resp. 47. Patent Owner also argues that Petitioner has not shown a POSITA would have combined the teachings of Barreras '313, Taylor, Barreras, and Wang as Petitioner proposes. *Id.* at 47–50; Sur-reply 19–22. For the reasons below, Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claims 4–6 would have been obvious over the combined teachings of Barreras '313, Taylor, Barreras, and Wang.

Petitioner relies on Wang for teaching the subject matter exclusive to claims 4–6. Pet. 43–47, 74 (referencing the arguments regarding claims 4–6 with respect to the asserted ground based on Torgerson, UL 544, Barreras, and Wang, now withdrawn). However, for the reasons discussed above in section III.D.4.c, Petitioner has not persuaded us that a POSITA would have had a reason to combine the teachings of Barreras '313, Taylor, and Barreras to result in the subject matter of independent claim 1, from which claims 4–6 depend. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–62; Sur-reply 14–15), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of

dependent claims 4–6 would have been obvious over combined teachings of Barreras '313, Taylor, Barreras, and Wang.

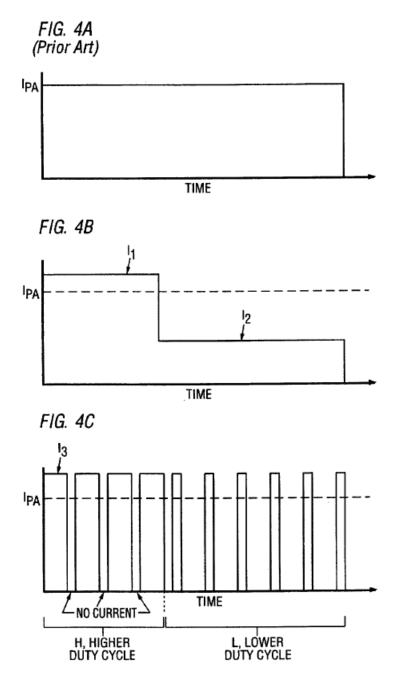
#### F. Obviousness Based on Barreras '313, Barreras, and Wang

Petitioner challenges claims 9–11 and 13 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Barreras '313, Barreras, and Wang. Pet. 81–82; Reply 19–21. Patent Owner argues that Petitioner has not shown a POSITA would have combined the teachings of Barreras '313, Barreras, and Wang as Petitioner proposes. PO Resp. 50–53; Sur-reply 19–22.

As we discuss Barreras '313 and Barreras above in sections III.D.1 and III.D.3, respectively, we begin our analysis of this asserted ground of unpatentability with an overview of Wang, and then discuss the parties' contentions for each of the claims. For the reasons below, Petitioner has shown, by a preponderance of the evidence, that the subject matter of claims 9–11 and 13 would have been obvious over the combined teachings of Barreras '313, Barreras, and Wang.

1. Wang

Wang relates to "an external energy transmission device for recharging batteries inside an implantable medical device." Ex. 1008, 1:19–21. 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, 7:48–53. 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.



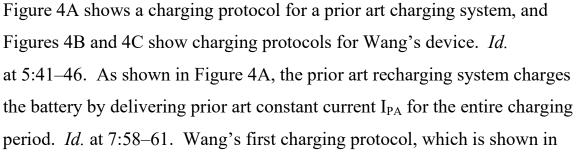


Figure 4B, delivers charging current  $I_1$ , which is higher than prior art constant current  $I_{PA}$ , for a first predetermined period of time and then delivers lower current  $I_2$ , which is lower than prior art constant current  $I_{PA}$ , for the remainder of the charge cycle. *Id.* at 4:45–53, 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. Claim 9

#### a. Undisputed limitations

Beginning with the limitations of independent claim 8, from which claim 9 depends, independent claim 8 recites "[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 argues Barreras '313 discloses an implantable, rechargeable stimulator system 10 comprising external transmitter 12 that transcutaneously transfers energy from output inductor 64 to inductor 60 of implanted receiver 14. Pet. 76–77 (citing Ex. 1010, 8:39–60, 12:6–9, Fig. 6).

Independent claim 8 next 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 Barreras '313 discloses using thermistor 80 in implanted receiver 14 to regulate the charging of rechargeable power source 44 to restrict temperature rise. Pet. 77 (citing Ex. 1010, 8:56–9:5).

Independent claim 8 also recites "obtaining a programmable limit from a memory," i.e., limitation 8.2. Ex. 1001, 22:36. 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. Pet. 78 (citing Ex. 1007, 13:1–5).

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 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. Pet. 78–79 (citing Ex. 1003 ¶ 223–224).

The last limitation of independent claim 8 recites "controlling the transfer of energy based on the comparison," i.e., limitation 8.4. Ex. 1001, 22:39–40. Petitioner argues 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 argues 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).

Turning to claim 9, it recites "wherein controlling the transfer of energy based on the comparison comprises adjusting a rate at which energy is transcutaneously transferred to the implantable medical device based on

the comparison." Ex. 1001, 22:41–44. For this limitation of claim 9, Petitioner relies on Wang's charging protocols. Pet. 43–47, 82 (referencing the arguments regarding claims 4–6 with respect to the asserted ground based on Torgerson, UL 544, Barreras, and Wang, now withdrawn). Petitioner argues Wang's first charging protocol produces charging current at either a high or low level to provide efficient charging without an excessive temperature rise in the implanted device. *Id.* at 43 (citing Ex. 1008, 4:45–53, Fig. 4B). Petitioner also argues Wang's second charging protocol provides relatively high charging current that is periodically interrupted. *Id.* (citing Ex. 1008, 4:66–5:7, Fig. 4C). According to Petitioner, Wang teaches first and second charging protocols that adjust the rate at which energy is transferred to the implantable device to limit the temperature rise of the implanted device during charging. *Id.* at 44 (citing Ex. 1003 ¶ 154).

Patent Owner does not dispute Petitioner's contentions with respect to the limitations of independent claim 8 and claim 9 depending therefrom. Petitioner's arguments and Dr. Colvin's testimony find support in Barreras '313, Barreras, and Wang. Barreras '313 discloses external transmitter 12 transcutaneously transfers energy to implanted receiver 14, which includes thermistor 80 for regulating the energy transfer. Ex. 1010, 8:35–43, 8:56–9:5, Figs. 1, 6. External transmitter 12 includes micro controller 26 connected to a RAM, and micro controller 26 is used, via software, to regulate the amount of energy to be coupled into receiver 14. *Id.* at 7:48–52, Fig. 6. Barreras teaches comparing monitored temperature with the maximum temperature, which is a software-loaded variable. Ex. 1007, 13:1–3. Wang teaches charging protocols that vary a charge

current, which charges a battery in an implanted device, to limit temperature rise. Ex. 1008, 4:45–53, 4:66–5:7, 7:58–8:12, Figs. 4B–C. In view of the foregoing, Petitioner has persuasively identified the limitations of independent claim 8 and claim 9 depending therefrom in its proposed combination of Barreras '313, Barreras, and Wang.

#### b. Reasons for combining the teachings

Petitioner argues "a POSITA would be motivated to utilize the maximum temperature limit variable in Barreras within the temperature based control circuitry in Barreras '313 to ensure the temperature of the external charging devices meets applicable safety standards while allowing software revisions incorporating new improvements or changing standards." Pet. 75–76 (citing Ex. 1003 ¶ 210; Ex. 1007, 3:2–7). Petitioner also argues a POSITA would have used Wang's charging protocol for adjusting the rate of energy transfer "to ensure compliance with industry standards of temperature rise, as described in Wang." *Id.* at 82.

Patent Owner alleges Petitioner has not explained how Petitioner proposes to combine the teachings of Barreras '313 and Wang. Sur-reply 19–20. Patent Owner further alleges Petitioner has not shown a POSITA would have incorporated Wang's charging protocols into the method of Barreras '313 to comply with industry standards for temperature rise because Petitioner provides no evidence that incorporating Wang's charging protocols into the method of Barreras '313 would reduce peak temperature rise any better than the method of Barreras '313, which controls the transfer of energy based on temperature. PO Resp. 51–53; Sur-reply 20–22. Per Patent Owner, "[Petitioner] provides no evidence that incorporating Wang's predetermined charging schemes into . . . Barreras

'313 would be necessary, or even desirable, to ensure safe charging and ensure compliance with standards." PO Resp. 50 (citing Ex. 2022 ¶ 108).

Petitioner replies:

a POSITA would have been motivated to use high recharging energies to charge the implanted medical device more quickly, which risks a faster temperature rise in the system and potentially exceeding safe temperature limits; thus a POSITA would have utilized the claimed protocols taught in Wang to adjust the transfer of energy *based on* monitored temperature in systems with temperature sensors to ensure patient safety.

Reply 20 (citing Ex. 1003 ¶¶ 45–46). Petitioner further replies that the system of Barreras '313 monitors only the battery temperature, whereas Wang's charging protocols reduce peak temperature rises in the battery, the implantable device can, and the system as a whole. *Id.* (citing Ex. 1008, 7:48–8:8).

At the outset, we disagree with Patent Owner that Petitioner has not explained how Petitioner proposes to combine the teachings of Barreras '313 and Wang to result in the recited method. Petitioner relies on Barreras '313 for disclosing controlling the transfer of energy, and Petitioner proposes to modify this controlling to include Wang's charging protocols. Pet. 79, 82.

Turning to whether a POSITA would have incorporated Wang's charging protocols into the method of Barreras '313 to comply with safety standards, Wang teaches its charging protocols are able to deliver the same amount of energy to the battery in the same amount of time but with less peak temperature rise. Ex. 1008, 7:42–8:12, Figs. 4A–C. Wang therefore teaches its charging protocols improve the mitigation of temperature rise because the charging protocols do not sacrifice charging efficiency to reduce temperature rise.

In view of the foregoing, Petitioner has persuaded us that a POSITA would have incorporated Wang's charging protocols into the method of Barreras '313 to ensure compliance with industry standards for temperature rise. We are also persuaded that a POSITA would have used Barreras's programmable limit with the method of Barreras '313 to ensure the temperature of the external charging devices meets applicable safety standards while allowing software revisions incorporating new improvements or changing standards. Petitioner has demonstrated that a POSITA would have had a reason to combine the teachings of Barreras '313, Barreras, and Wang as Petitioner proposes.

#### c. Reasonable expectation of success

Patent Owner contends "[Petitioner] did not even allege, much less, present any evidence that a POSITA would have had a reasonable expectation of success regarding the proposed modifications." PO Resp. 56; Sur-reply 23–25. Patent Owner maintains Petitioner failed to explain why a POSITA would have had a reasonable expectation of success in modifying the system of Barreras '313 to include Barreras's programmable limit. PO Resp. 57. Patent Owner also contends Petitioner has not shown a POSITA would have had a reasonable expectation of success in modifying the method of Barreras '313 to include Wang's charging protocols. *Id.* at 53; Sur-reply 22.

Petitioner replies that Barreras teaches a temperature limit can be implemented as a software-loaded variable, and that Barreras '313 teaches a RAM on its external charging device to store software for use by its micro controller. Reply 5 (citing Ex. 1003 ¶¶ 41, 203). Petitioner further replies "it was a 'common charging protocol' at the time of the invention to

implement a duty cycle, or lower the charging current or rate of energy transfer in response to feedback regarding heating." *Id.* at 21 (citing Ex. 1003 ¶¶ 80–81).

We are persuaded that a POSITA would have had a reasonable expectation of success in combining the teachings of references to result in the claimed invention. Regarding modifying the system of Barreras '313 to include Barreras's programmable limit, in view of the external charging device of Barreras '313 having RAM storing software (Ex. 1010, 7:48-52, Fig. 6) and Barreras's temperature limit being a software-loaded variable (Ex. 1007, 13:1–3), Petitioner has demonstrated that a POSITA would have had a reasonable expectation of success in modifying the system of Barreras '313 to include Barreras's programmable limit. In regard to modifying the method of Barreras '313 to include Wang's charging protocols, Barreras '313 discloses "regulat[ing], as a function of temperature, the current level used to recharge the rechargeable power source 44" (Ex. 1010, 8:56–58), and discloses this regulation provides "a temperature-controlled, current-regulated charging system" (id. at 8:67–9:1). Wang teaches charging protocols that vary the current used to charge a battery to minimize peak temperature rises. Ex. 1008, 4:45–53, 4:66–5:7, 7:58–8:12, Figs. 4B–C. As both Barreras '313 and Wang teach varying charge current to regulate temperature, Petitioner has demonstrated that a POSITA would have had a reasonable expectation of success in modifying the method of Barreras '313 to include Wang's charging protocols.

#### d. Objective evidence of non-obviousness

We must always consider objective evidence of non-obviousness, also known as secondary considerations, when determining obviousness.

Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1349 (Fed. Cir. 2012). "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995). We use a two-step analysis in evaluating nexus between the claimed invention and objective evidence. Lectrosonics, Inc. v. Zaxcom, Inc., IPR2018-01129, Paper 33, 33 (PTAB Jan. 24, 2020) (precedential). We first consider whether the patent owner has demonstrated "that its products are coextensive (or nearly coextensive) with the challenged claims," resulting in a rebuttable presumption of nexus. *Id.* If not, the patent owner may still demonstrate nexus by showing that the evidence of objective evidence is the "direct result of the unique characteristics of the claimed invention." Id. (quoting Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1373–75 (Fed. Cir. 2019)). The patent owner may do so by demonstrating that the objective evidence is the result of some aspect of the claim not already in the prior art or the claimed combination as a whole. Id. (citing In re Kao, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011); WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1331 (Fed. Cir. 2016)).

Patent Owner relies on the failure of a conventional device, Advanced Bionics's Precision 1.0 recharger, to operate safely, which resulted in it burning patients, as objective evidence of non-obviousness. PO Resp. 57–62; Sur-reply 14–15. Patent Owner argues the Precision system included a temperature sensor in the implanted device, but not in the external recharger, and was expected to maintain a safe temperature below 41°C while transcutaneously transmitting charging energy. PO Resp. 59 (citing Ex. 2022 ¶ 28–29; Ex. 2024, 51:23–52:8). Patent Owner also argues that,

despite bench tests showing the Precision 1.0 recharger would not overheat, the Precision 1.0 recharger ultimately proved ineffective at controlling temperature and caused second and third degree burns on patients. *Id.* at 60–61 (citing Ex. 2005<sup>15</sup>, 1; Ex. 2020<sup>16</sup>, 1; Ex. 2022 ¶ 32). Patent Owner further argues that, after the failure of the Precision 1.0 recharger, Advanced Bionics redesigned the Precision recharger to include a temperature sensor. *Id.* at 61 (citing Ex. 2020, 1; Ex. 2022 ¶¶ 33–34; Ex. 2024, 54:2–15).

Patent Owner contends that "[b]ecause Advanced Bionics solved the overheating problem by including a temperature sensor in the external recharger, as claimed in the '112 patent, the Precision 1.0 recharger's failure has a nexus to the claimed invention." *Id.; see also* Sur-reply 14 ("It is undisputed that Advanced Bionics solved the overheating problem in the Precision 1.0 recharger by including a temperature sensor in its redesigned recharger, as claimed in the '112 patent."). Patent Owner further contends "Advanced Bionics'[s] decision to not include a temperature sensor in the Precision 1.0 recharger and its ensuing recall for burning patients is quintessential evidence of non[-]obviousness of the claimed invention." PO Resp. 61 (citing *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012)); *see also* Sur-reply 15 (arguing *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation* supports the non-obviousness of the claimed invention).

<sup>&</sup>lt;sup>15</sup> Class 2 Device Recall Precision Charger 1.0, FDA (Oct. 31, 2008) (Ex. 2005).

<sup>&</sup>lt;sup>16</sup> Urgent Medical Device Recall, Boston Scientific (Sept. 22, 2008) (Ex. 2020).

Petitioner replies that Patent Owner has not shown a nexus between the claimed invention and the failure of the Precision 1.0 recharger. Reply 15–18. Petitioner argues that rechargers with temperature sensors were known in the art, as Carbunaru and Mann<sup>17</sup> demonstrate. *Id.* at 16–17. According to Petitioner, "[b]ecause there is no purported nexus between a *novel* feature of the claimed invention and the alleged failure of the Precision 1.0 recharger, this alleged secondary consideration is irrelevant." *Id.* at 17 (citing *In re Kao*, 639 F.3d at 1068). Petitioner also argues that, in contrast to *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, there is no indication Advanced Bionics tried and failed to make a recharger having a temperature sensor. *Id.* at 17–18.

In alleging nexus, Patent Owner characterizes the claimed invention as including a recharger having a temperature sensor. Claim 9, however, does not require such a recharger. Claim 9 depends from independent claim 8, which recites, *inter alia*, "transferring, via an external charging device, energy transcutaneously to an implantable medical device" and "sensing, via a sensor, a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device." Ex. 1001, 22:30–35. Neither independent claim 8, nor claim 9 depending therefrom, recites that the sensing occurs at the external charging device. Moreover, claim 9 requires a programmable limit, and Patent Owner's arguments regarding its objective evidence are silent regarding this claim limitation. Accordingly, Patent Owner has not shown that its objective evidence is coextensive or nearly coextensive with claim 9 or that the

<sup>&</sup>lt;sup>17</sup> Mann, US 6,275,737 B1, issued Aug. 14, 2001 ("Mann") (Ex. 1019).

objective evidence is the direct result of the unique characteristics of the claimed invention.

In view of the foregoing, Patent Owner has not demonstrated a nexus between the objective evidence and the claimed invention. Consequently, the objective evidence is entitled to minimal weight.

## e. Conclusion for claim 9

After considering the parties' arguments and weighing the evidence of obviousness and non-obviousness, Petitioner has persuaded us that the subject matter of claim 9 would have been obvious over Barreras '313, Barreras, and Wang. Petitioner has shown, by a preponderance of the evidence, that claim 9 is unpatentable.

#### 3. Claims 10, 11, and 13

Petitioner's arguments for claims 10, 11, and 13 are similar to its arguments for claim 9. Pet. 81–82; Reply 19–21. Patent Owner's arguments for claims 10, 11, and 13 are the same as its arguments for claim 9. PO Resp. 50–53; Sur-reply 19–22.

For the reasons discussed above in section III.F.2, Petitioner has persuaded us that the subject matter of claims 10, 11, and 13 would have been obvious over Barreras '313, Barreras, and Wang. Petitioner has shown, by a preponderance of the evidence, that claims 10, 11, and 13 are unpatentable.

#### G. Obviousness Based on Torgerson, Barreras, and Wang

Petitioner challenges claims 9–11 and 13 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Torgerson, Barreras, and Wang. Pet. 56–58; Reply 19–21. As discussed above in section III.F, Petitioner also challenges claims 9–11 and 13 under

35 U.S.C. § 103(a) in view of Barreras '313, Barreras, and Wang, and we find Petitioner has shown claims 9–11 and 13 are unpatentable on that ground. Having found claims 9–11 and 13 unpatentable, we do not reach this asserted ground alleging these claims are unpatentable under 35 U.S.C. § 103(a) in view of Torgerson, Barreras, and Wang. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

H. Obviousness Based on Barreras '313 and Barreras

Petitioner challenges claims 12 and 20 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Barreras '313 and Barreras.<sup>18</sup> Pet. 75–81; Reply 22. Patent Owner argues Petitioner's proposed combination of Barreras '313 and Barreras would not

<sup>&</sup>lt;sup>18</sup> In the Petition's listing of the asserted grounds, Petitioner identifies claims 16 and 17 with respect to the asserted ground based on Barreras '313 and Barreras. Pet. 18. In the arguments for this asserted ground, however, Petitioner does not address these claims. *Id.* at 75–81; Reply 22. Accordingly, we understand the asserted ground based on Barreras '313 and Barreras does not includes claims 16 and 17, and we consider the identification of these claims with respect to this asserted ground in the Petition's listing of the asserted grounds to be a typographical error. *See also* Inst. Dec. 38 (omitting claims 16 and 17 with respect to the asserted ground based on Barreras '313 and Barreras'.

have resulted in all of the claim limitations. PO Resp. 54-55;

Sur-reply 22–23. Patent Owner also argues that there would not have been a motivation to combine the teachings of the references as Petitioner proposes. PO Resp. 55–56. For the reasons below, Petitioner has shown, by a preponderance of the evidence, that the subject matter of claims 12 and 20 would have been obvious over the combined teachings of Barreras '313 and Barreras.

#### 1. Claim 12

## a. Undisputed limitations

We address Petitioner's arguments for the limitations of independent claim 8, from which claim 12 depends, in section III.F.2.a. For the reasons set forth in that section, Petitioner has persuasively identified the limitations of independent claim 8 in Barreras '313 and Barreras.

# b. Alternating between terminating and initiating the transcutaneous transfer of energy to the implantable medical device

Claim 12 recites "wherein controlling the transfer of energy based on the comparison comprises alternating between terminating the transcutaneous transfer of energy to the implantable medical device and initiating the transcutaneous transfer of energy to the implantable medical device." Ex. 1001, 22:58–63. For this limitation of claim 12, Petitioner argues that, in view of Barreras '313 disclosing regulating the transcutaneous transfer of energy based on temperature, the control circuitry of Barreras '313 necessarily would be capable of initiating and terminating energy transfer when the measured temperature exceeds the maximum temperature requirements. Pet. 71, 80 (referencing the arguments regarding claim 7 with respect to the asserted ground based on Barreras '313, Taylor,

and Barreras). Petitioner also relies on Barreras's power management module, which senses temperature and disconnects and reconnects charging circuit 60A based on the sensed temperature. *Id.* at 36 (citing Ex. 1007, 7:30–8:12), 71 (referencing the arguments regarding claim 7 with respect to the asserted ground based on Torgerson, UL 544, and Barreras, now withdrawn), 80 (referencing the arguments regarding claim 7 with respect to the asserted ground based on Barreras '313, Taylor, and Barreras); Reply 22.

Patent Owner argues that Barreras's connecting and disconnecting charging circuit 60A does not affect the transcutaneous transfer of energy between RF transmitting antenna 6 and RF receiving antenna 2. PO Resp. 54–55 (citing Ex. 1007, 7:2–7, 7:30–8:17, Fig. 4; Ex. 2022 ¶ 112); Sur-reply 22–23. Patent Owner further argues Barreras teaches that transcutaneous energy transfer can power the implant without simultaneously charging power source 10. PO Resp. 55 (citing Ex. 1007, 9:1–3).

Petitioner replies Barreras's external charging device transcutaneously transmits energy to induce the current that recharges the power source such that initiating or terminating the current to the power in turn initiates or terminates the transcutaneous transfer of energy. Reply 22 (citing Ex. 1007, 7:14–22, Figs. 1–2; Ex. 1003 ¶¶ 113–115). Petitioner acknowledges Barreras teaches that, in the RF position, transcutaneous energy transfer can power the implant without simultaneously charging power source, and replies that Barreras teaches a self position in which the transcutaneous energy transfer charges the power source. *Id.* (citing Ex. 1007, 9:1–10).

Although Barreras teaches that transcutaneous energy can power the implant with or without charging the battery, Barreras expressly teaches that

the power management module disconnects and reconnects charging circuit during charging. According to Barreras:

This Power Management Module 11 incorporates distinctive circuitry and methods for operating same to: . . . (j) disconnect a charging circuit 60A from the power source 10 upon sensing a battery temperature exceeding a safe value *during charging*, (k) reconnect the charging circuit 60A to the power source upon the battery temperature dropping to a safe value *during charging* . . . .

Ex. 1007, 7:30–8:16 (emphases added). As the transcutaneous transfer of energy is used to charge the battery, disconnecting and reconnecting the charging circuit for the battery terminates and initiates the transcutaneous transfer of energy.

In view of the foregoing, Petitioner has persuaded us that Barreras teaches terminating and initiating the transcutaneous transfer of energy to the implanted medical device based on temperature, as the limitation of claim 12 requires. We are also persuaded that Barreras '313 inherently discloses the limitation of claim 12. Petitioner has shown the limitation of claim 12 in its proposed combination of Barreras '313 and Barreras.

c. Reasons for combining the teachings

Petitioner argues a POSITA would have been motivated to apply Barreras's teaching of terminating and initiating the transcutaneous transfer of energy based on temperature into the method of Barreras '313 to "provide more efficient and safe charging while ensuring the applicable safety standard is met." Pet. 71–72, 80 (referencing the arguments regarding claim 7 with respect to the asserted ground based on Barreras '313, Taylor, and Barreras). Patent Owner argues that UL 544<sup>19</sup> relates to the temperature

<sup>&</sup>lt;sup>19</sup> UL Standard for Safety for Medical and Dental Equipment,

of external devices in contact with a patient, not to implanted devices. PO Resp. 55 (citing Ex.  $1006^{20}$  § 36.2). According to Patent Owner, "[i]t is unclear how Barreras'[s] disclosure of controlling battery temperature in the implant would ensure compliance with UL 544 when only the recharger in . . . Barreras '313 would be subject to the safety standards set forth in UL 544." *Id.* at 55–56.

UL 544 prescribes "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 patient, shall not exceed 41°C (106°F)." Ex. 1006 § 36.2. This regulation regards any part applied to a patient and is not limited to any part applied externally to a patient. That notwithstanding, Petitioner's reasoning is premised on efficient and safe charging, not just compliance with UL 544.

In view of the foregoing, Petitioner has persuaded us that a POSITA would have incorporated Barreras's teaching of terminating and initiating the transcutaneous transfer of energy based on temperature into the method of Barreras '313 to provide more efficient and safe charging and ensure compliance with the applicable safety standard. Petitioner has demonstrated that a POSITA would have had a reason to combine the teachings of Barreras '313 and Barreras as Petitioner proposes.

UL 544 (Underwriters Laboratories Inc. ("UL") 1998) ("UL 544") (Ex. 1006).

<sup>&</sup>lt;sup>20</sup> Patent Owner cites to Exhibit 1005 in support of its argument premised on UL 544. PO Resp. 55. UL 544 is Exhibit 1006, not Exhibit 1005. Accordingly, we understand Patent Owner to be citing to Exhibit 1006, and we consider the citation to Exhibit 1005 to be a typographical error.

## d. Reasonable expectation of success

We address Patent Owner's allegation that Petitioner fails to demonstrate a POSITA would have had a reasonable expectation of success in combining the teachings of the references to result in the claimed invention in section III.F.2.c. For the reasons set forth in that section, Petitioner has persuaded us that a POSITA would have had a reasonable expectation of success in combining the teachings of references to result in the claimed invention.

### e. Objective evidence of non-obviousness

We address Patent Owner's objective evidence in section III.F.2.d. For the reasons set forth in that section, we find Patent Owner's objective evidence is entitled to minimal weight.

#### f. Conclusion for claim 12

After considering the parties' arguments and weighing the evidence of obviousness and non-obviousness, Petitioner has persuaded us that the subject matter of claim 12 would have been obvious over Barreras '313 and Barreras. Petitioner has shown, by a preponderance of the evidence, that claim 12 is unpatentable.

#### 2. Claim 20

Petitioner's arguments for claim 20, which depends from independent claim 19 that is similar to independent claim 8, are akin to its arguments for claim 12. Pet. 81; Reply 22. Patent Owner's arguments for claim 20 are the same as its arguments for claim 12. PO Resp. 50–53; Sur-reply 22–23.

For the reasons discussed above in section III.H.1, Petitioner has persuaded us that the subject matter of claim 20 would have been obvious over Barreras '313 and Barreras. Petitioner has shown, by a preponderance of the evidence, that claim 20 is unpatentable.

### I. Obviousness Based on Torgerson and Barreras

Petitioner challenges claims 12 and 20 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Torgerson and Barreras.<sup>21</sup> Pet. 47–56; Reply 22. As discussed above in section III.H, Petitioner also challenges claims 12 and 20 under 35 U.S.C. § 103(a) in view of Barreras '313 and Barreras, and we find Petitioner has shown claims 12 and 20 are unpatentable on that ground. Having found claims 12 and 20 unpatentable, we do not reach this asserted ground alleging these claims are unpatentable under 35 U.S.C. § 103(a) in view of Torgerson and Barreras. *See SAS Inst. Inc.*, 138 S. Ct. at 1359 (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc.*, 809 F. App'x at 990 (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

<sup>&</sup>lt;sup>21</sup> In the Petition's listing of the asserted grounds, Petitioner identifies claims 16 and 17 with respect to the asserted ground based on Torgerson and Barreras. Pet. 18. In the arguments for this asserted ground, however, Petitioner does not address these claims. *Id.* at 47–56; Reply 22. Accordingly, we understand the asserted ground based on Torgerson and Barreras does not includes claims 16 and 17, and we consider the identification of these claims with respect to this asserted ground in the Petition's listing of the asserted grounds to be a typographical error. *See also* Inst. Dec. 25 (omitting claims 16 and 17 with respect to the asserted ground based on Torgerson and Barreras).

# IV. CONCLUSION

For the reasons above, Petitioner has not proven, by a preponderance of the evidence, the unpatentability of claims 1-7, 16-18, and 22 but has proven, by a preponderance of the evidence, the unpatentability of claims 9-13 and 20.<sup>22</sup>

	35		Claims	Claims
Claims	U.S.C.	References	Shown	Not Shown
	§		Unpatentable	Unpatentable
1-3, 7, 16-18,	103(a)	Barreras '313,		1–3, 7, 16–18,
22	105(a)	Taylor, Barreras		22
		Barreras '313,		
4-6	103(a)	Taylor, Barreras,		4–6
		Wang		
9–11, 13	103(a)	Barreras '313,	9–11, 13	
		Barreras, Wang		
		Torgerson,		
9–11, 13	103(a)	Barreras,		
		Wang <sup>23</sup>		
12, 20	103(a)	Barreras '313,	12, 20	
		Barreras		
12, 20	103(a)	Torgerson,		
		Barreras <sup>24</sup>		
Overall			9–13, 20	1–7, 16–18,
Outcome				22

<sup>&</sup>lt;sup>22</sup> Should Patent Owner wish to pursue amendment of the claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding, 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

# V. ORDER

In consideration of the foregoing, it is:

ORDERED that claims 1–7, 16–18, and 22 of the '112 patent have not been shown to be unpatentable;

FURTHER ORDERED that claims 9–13 and 20 of the '112 patent have been shown to be unpatentable;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 318(b), upon expiration of the time for appeal of this Decision or the termination of any such appeal, a certificate shall issue canceling claims 9–13 and 20; and

FURTHER ORDERED that, as this is a Final Written Decision, a party seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

<sup>&</sup>lt;sup>23</sup> As explained above in section III.G, we do not reach this asserted ground of patentability for claims 9–11 and 13 because we have found these claims unpatentable on another ground.

<sup>&</sup>lt;sup>24</sup> As explained above in section III.I, we do not reach this asserted ground of patentability for claims 12 and 20 because we have found these claims unpatentable on another ground.

For PETITIONER: James Isbester Babak Sani KILPATRICK TOWNSEND & STOCKTON LLP jisbester@kilpatricktownsend.com bssani@kilpatricktownsend.com

For PATENT OWNER: Naveen Modi Chetan R. Bansal PAUL HASTINGS LLP naveenmodi@paulhastings.com chetanbansal@paulhastings.com