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Paper No. 8
Date: September 23, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00680
Patent 8,457,758 B2

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

TARTAL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Axonics Modulation Technologies, Inc. ("Petitioner") filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–12 ("the Challenged Claims") of U.S. Patent No. 8,457,758 B2 (Ex. 1001, "the '758 patent"). Paper 1 ("Pet."). Medtronic, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . 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). Moreover, a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the Challenged Claims. Accordingly, we authorize an *inter partes* review to be instituted as to the Challenged Claims of the '758 patent on the grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

II. BACKGROUND

A. The '758 Patent

The '758 patent issued June 4, 2013, from an application filed on August 16, 2011, and is directed to a "[s]ystem for transcutaneous energy transfer." Ex. 1001, codes (21), (22), (45), (57). As background to the invention, the '758 patent explains that "[s]everal systems and methods have been used for transcutaneously inductively recharging a rechargeable used in an implantable medical device," including "the use of inductive coupling involve[ing] the placement of two coils positioned in close proximity to each other on opposite sides of the cutaneous boundary." *Id.* at 1:65–67, 2:16–19. According to the '758 patent, "[f]or implanted medical devices, the efficiency at which energy is transcutaneously transferred is crucial." *Id.* at 2:66–67. The '758 patent further explains that inductive coupling "has a tendency to heat surrounding components and tissue," which limits "the amount of energy transfer which can be accomplished per unit time," that a patient's mobility is impaired during charging, and that the amount of charging "can be limited by the amount of time required for charging," thereby limiting "the size of the internal power source." *Id.* at 2:67–3:25.

The '758 patent states that "[a]lignment of an external primary coil with the internal secondary coil is important in achieving efficiency in transcutaneous energy transfer," that "it is not always easy for the user to know when the primary and secondary coils are properly aligned," and that, even when aligned, "the physical package containing the primary coil with the protrusion of the implanted medical device may not result in optimum alignment of the primary and secondary coils," because the coils may not be centered in the package and "even perfect alignment of the packages may result in actual misalignment of the primary and secondary coils."

Id. at 3:33–48. According to Patent Owner, the '758 patent solved the problem of proper alignment "through an inventive system including an external power source that, among other things, automatically varies the power output of the external charging device to generate a predetermined current through the internal power source as a function of a value associated with the current passing through the internal power source." Prelim. Resp. 3–4 (citing Ex. 1001, 3:52–4:12, 20:63–22:15, Fig. 19).

Figure 3 of the '758 patent is reproduced below.

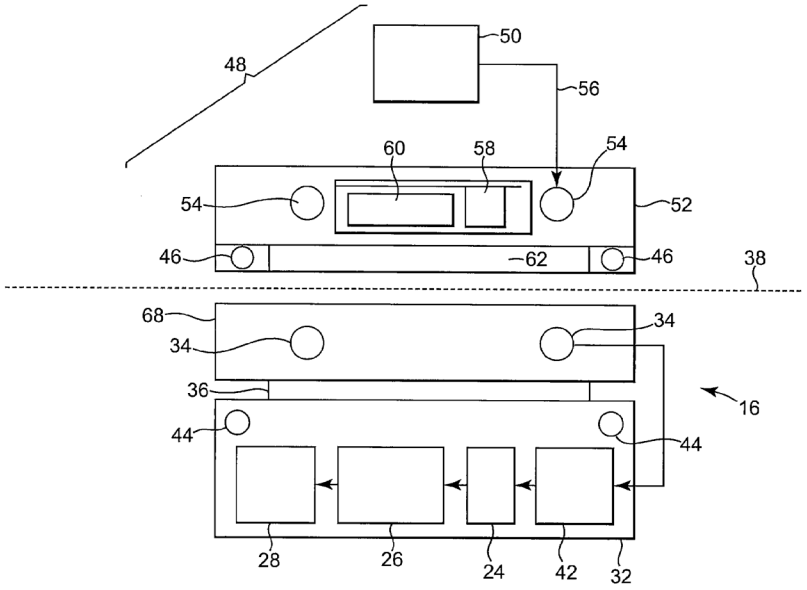

Fig. 3

Figure 3 illustrates implantable medical device 16, situated under cutaneous boundary 38, and associated external charging device 48. Ex. 1001, 6:1–4, 7:55–56, 8:19–21. Implantable medical device 16 includes rechargeable power source 24, which powers electronics 26 and therapy module 28 "in a conventional manner," charging regulation module 42, and internal telemetry coil 44. *Id.* at 7:31–34, 7:57–8:1. External charging device 48 with external telemetry unit 46, charging unit 50, and external antenna 52 is used to charge rechargeable power source 24 of implantable medical

device 16 while implantable medical device 16 is in place in a patient. *Id.* at 7:60–8:1, 8:19–8:23. "[I]nternal telemetry coil 44 [is] configured in [a] conventional manner to communicate through external telemetry coil 46 to an external programming device (not shown), charging unit 50 or other device in a conventional manner in order to both program and control implantable medical device and to externally obtain information from implantable medical device 16 once implantable medical device has been implanted." *Id.* at 7:60–8:1. "Charging unit 50 contains the electronics necessary to drive primary coil 54 with an oscillating current in order to induce current in secondary coil 34 when primary coil 54 is placed in the proximity of secondary coil 34." *Id.* at 8:23–26.

Figure 19 of the '758 patent is reproduced below.

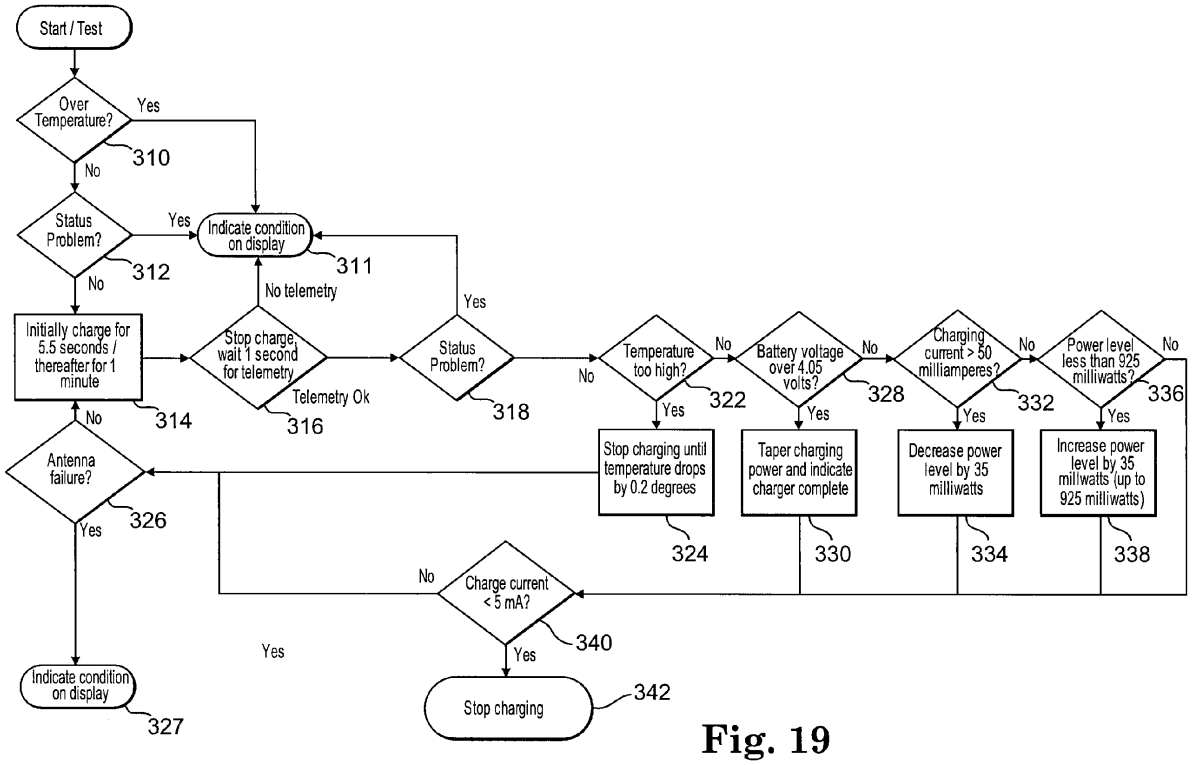

Fig. 19

Figure 19 is a flow chart illustrating the operation of charging unit 50 to charge an implantable medical device. *Id.* at 6:42–43, 21:24–25. The steps shown in Figure 19 are described in the '758 patent as follows:

- at step 310, charging unit 50 determines "whether external antenna 52 is over the temperature limit set for charging operation," where the "temperature limit can help prevent patient 18 from being exposed to temperatures that are higher than desired";
- at steps 311 to 313, "[i]f external antenna 52 of charging unit 50 is over temperature, an alert condition is indicated," "[i]f external antenna [52] is not over the temperature limit, charging unit 50 then checks . . . for a status problem with charging unit 50," and "[i]f a status problem is found, an alert condition is indicated";
- at steps 314 and 316, "[i]f a status problem is not found, charging unit 50 initially charges . . . rechargeable power source 24 of implantable medical device 16 for 5.5 seconds," and "[c]harging unit 50 then stops charging and waits . . . one second to check for reception of a telemetry signal from implantable medical device 16," such as "the value of the current flowing through secondary coil 34," and "[i]f no telemetry signal is detected, an alert condition is indicated," returning the operation to step 311;
- at step 318, "[i]f telemetry is received, charging unit 50 then checks . . . for a status problem with implantable medical device 16," and "[i]f a status problem is detected, an alert condition is indicated," returning the operation to step 311;
- at step 322, "[i]f no status problem exists, charging unit 50 checks . . . to determine if the temperature is too high," and [i]f an over temperature condition is detected, charging is stopped and a status

indication is displayed until the temperature drops below a predetermined level";

- at step 328, "[i]f no over temperature condition exists, charging unit 50 checks . . . to determine if the voltage across rechargeable power source 24 is over a voltage at which the charging rate should begin to decrease, e.g., 4.05 volts";
- at steps 330 and 332, "[i]f the voltage across rechargeable power 24 is greater than 4.05 volts, then charging unit 50 begins to taper charging power," but "[i]f the voltage across rechargeable power source 24 is not over 4.05 volts, charging unit 50 checks . . . to determine whether the charging current through rechargeable power source 24 is over a current rate that is not desirable, e.g., 50 milliamperes";
- at step 334, "[i]f the charging current is over 50 milliamperes, then the charging power level is decreased . . . by an appropriate [amount], e.g., by 35 milliwatts";
- at steps 336 and 338, "[i]f the charging current is not over 50 milliamperes, charging unit 50 checks . . . to determine if the charging power level is less than [an] appropriate amount, e.g., 925 milliwatts," and "[i]f the power level is less than 925 milliwatts, the charging power level is increased . . . by 35 milliwatts, up to a maximum of 925 milliwatts";
- at steps 340 and 342, "[i]f the charge current is below . . . five (5) milliamperes, then charging unit 50 stops . . . charging and indicates that charging is complete, e.g., by lighting the charging complete indicator light," and "[i]f not, [operation returns to step 314 and] charging unit 50 then charges . . . rechargeable power source for one (1) minute and then

conducts the aforementioned tests, checks and actions as performed after the initial 5.5 second charge."

Id. at 21:24–22:14.

B. Illustrative Claim

Petitioner challenges claims 1–12 of the '758 patent, each of which is independent. Pet. 1; Ex. 1001, 22:25–26:30. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

> 1. A system for transcutaneous energy transfer, comprising:
> an implantable medical device having componentry for providing a therapeutic output, said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, said implantable medical device adapted to be implanted in a patient; and
> an external power source having a primary coil, said external power source providing energy to said implantable medical device when said primary coil of said external power source is placed in proximity of said secondary coil of said implantable medical device and thereby generating a current, having a value, passing through said internal power source:
> wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source:
> wherein said external power source automatically varies its power output based on a measured current associated with said current passing through said internal power source.

Ex. 1001, 22:25–46.

C. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 5, 9	102	Schulman[1]
1, 5, 9	102	Fischell Article[2]
1–12	102	Baumann[3]
2–4, 6–8, 10–12	103[4]	Schulman, Baumann
2–4, 6–8, 10–12	103	Fischell Article, Baumann

Pet. 9–10. Petitioner relies on the supporting Declaration of Dr. Dorin Panescu, dated March 2, 2020. Ex. 1003.

D. Related Proceedings

The parties identify the '758 patent as a subject of *Medtronic, Inc. v. Axonics Modulation Technologies, Inc.*, Case No. 8:19-cv-02115-DOC-JDE (C.D. Cal.). Pet. 107; Paper 4, 2. The parties also identify as related matters IPR2020-00678 concerning U.S. Patent Number 7,774,069 B2 ("the '069 patent") and IPR2020-00712 concerning U.S. Patent No. 8,738,148 B2 ("the '148 patent"). Pet. 107; Paper 4, 2. The '758 patent issued from an application that was a continuation of an application that was a division of

[1] U.S. Patent No. 3,942,535 (issued March 9, 1976) (Ex. 1005, "Schulman").
[2] Fischell et al., *A Long-Lived, Reliable, Rechargeable Cardiac Pacemaker*, *Engineering in Medicine*, 357 (Schaldach et al. eds., 1975) (Ex. 1006, "the Fischell Article").
[3] U.S. Patent No. 6,227,204 B1 (issued May 8, 2001) (Ex. 1007, "Baumann").
[4] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on March 16, 2013. Because the application that issued as the '758 patent states that it was filed before March 16, 2013, we apply the pre-AIA versions of these statutes. *See* 35 U.S.C. § 100(i).

an application that issued as the '069 patent. Ex. 1001, code (60). The '148 patent issued from an application that was a continuation of the application that issued as the '758 patent.

E. Real Parties in Interest

Petitioner identifies no additional real parties in interest. Pet. 107. Patent Owner states that it is the real party in interest, that "Medtronic plc is the ultimate parent of Medtronic, Inc.," 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." Paper 4, 1 n.1.

III. ANALYSIS

A. Legal Standards

A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under § 103 that

requires consideration of four factors: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Id.* at 17–18; *KSR*, 550 U.S. at 407. At this stage of the proceeding, neither party presents evidence or argument directed to secondary considerations.

B. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

Petitioner contends that a person of ordinary skill in the art at the time of the invention "would have had at least a bachelor's degree in electrical engineering or an equivalent as well as at least five years of experience in the industry working with implantable medical devices such as cardiac pacemakers or defibrillators." Pet. 7. Patent Owner does not dispute Petitioner's asserted level of ordinary skill at this stage of the proceeding. Prelim. Resp. 2, n.1.

For purposes of this Decision, we find that the '758 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of appropriate skill reflected in these references is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355

(Fed. Cir. 2001). Accordingly, for purposes of this decision on institution, we adopt Petitioner's asserted level of ordinary skill in the art.

C. Claim Construction

"In an *inter partes* review proceeding, a claim of a patent . . . shall be construed 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). That standard "includ[es] construing 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.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). "When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009).

Neither party proposes an express construction for any claim term. Petitioner asserts that "all claim terms should be given their plain and ordinary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history." Pet. 6. Patent Owner states that "the Board need not construe any terms because neither party has proposed any terms for construction and construction is unnecessary to resolve any underlying controversy." Prelim. Resp. 4. We find that no term requires express construction for purposes of this Decision. *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))).

D. Scope and Content of the Prior Art

Petitioner relies on Schulman, the Fischell Article, and Baumann, each of which we briefly summarize in relevant part below.

1. Summary of Schulman

Schulman, titled Rechargeable Tissue Stimulating System, generally "relates to a rechargeable tissue stimulating system for providing a charge to a voltage source implanted in a living being, and for regulating recharging of the voltage source through the use of a telemetry circuit." Ex. 1005, 1:7–11. Schulman describes the use of an induction coil external to the patient that "is used to induce current flow in a charging circuit located beneath the skin of the patient" and "external means" that "modulate the strength of the charging magnetic field, as well as provide visual or audio indication of proper charging as well as the proper positioning of the external power source with respect to the implanted charging circuit, completion of the proper charging interval to restore the amount of current used, and improper charging." *Id.* at code [57].

Figure 1 of Schulman is reproduced below.

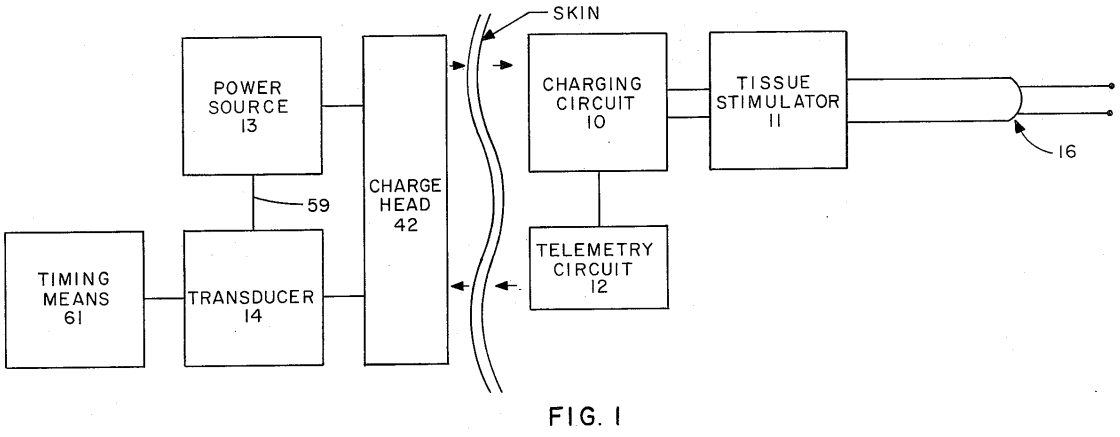

FIG. 1

Figure 1 is a block diagram of a rechargeable tissue stimulating system of Schulman. *Id.* at 3:16–17, 3:42–46. The system includes charging

circuit 10, with telemetry circuit 12 and tissue stimulator 11, for implantation in the body. *Id.* at 3:42–46. External to the patient, the system further includes power source 13 with transducer 14 "in the form of a detector circuit for recharging and for verifying the charging condition of the implanted portions of the tissue stimulating system," charge head 42, and timing means 61. *Id.* at 3:47–53. "The output of transducer 14 is used to control the power oscillator output energy and is used to drive the timing means 61, which includes a timing and indicator circuit." *Id.* at 3:55–58.

2. Summary of the Fischell Article

The Fischell Article, titled "A Long-lived, Reliable, Rechargeable Cardiac Pacemaker," describes a cardiac pacemaker system with a "rechargeable cell specifically adapted for use at body temperature." Ex. 1006, 357. The system includes an external device with a charger head that transfers energy to a pickup coil in the implant in order to recharge the battery. *Id.* at 372 (disclosing "the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil"), Fig. 8.

Figure 8 of the Fischell Article is reproduced below.

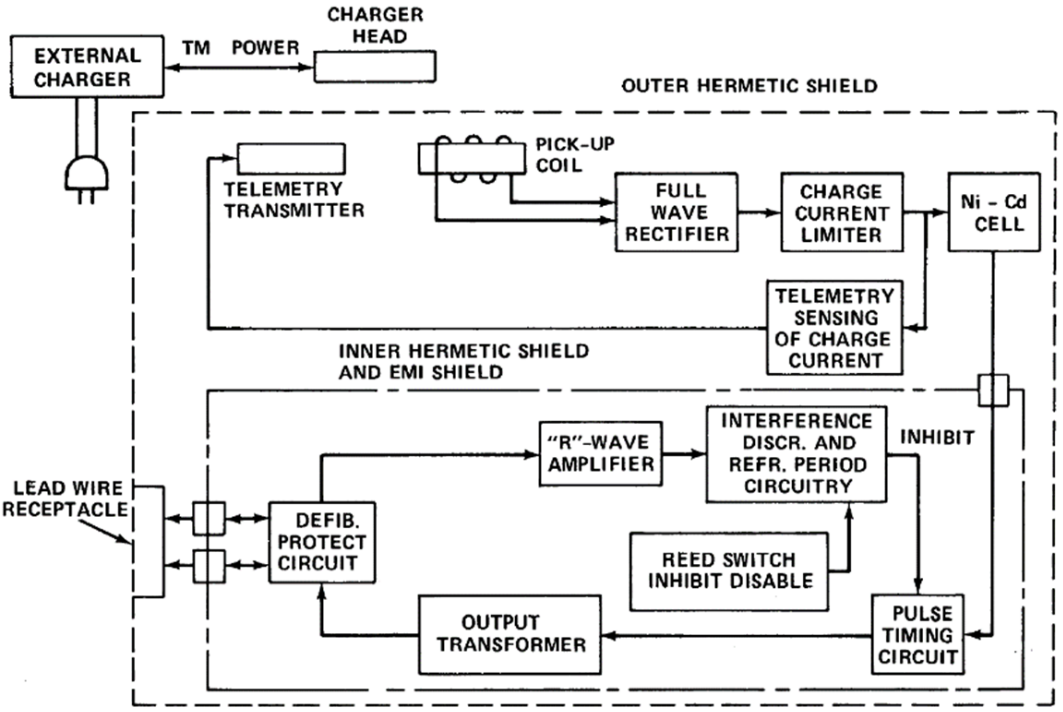

Fig. 8 Block diagram of rechargeable demand pacemaker

Figure 8 of the Fischell Article is a block diagram of the rechargeable cardiac pacemaker system described in the Fischell Article. *Id.* at 369. Petitioner describes the system shown in Figure 8 as follows:

> a block diagram of a rechargeable pacemaker system showing an "external charger" and a hermetically sealed rechargeable pacemaker or "pulse generator" that is implanted beneath the skin of the patient. The implantable device includes a "pick-up coil" that interfaces with an induction coil in the "charger head" of the external device, circuitry to convert the magnetic energy to current for charging an internal rechargeable battery, a "Ni-Cd cell," a block titled "telemetry sensing of charge current" that is coupled between the battery and a "telemetry transmitter" that transmits information back to the external charger. "When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil, a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery." Ex. 1006 at 372–373. The charger head of the external charger detects this frequency and "closed-loop controls the battery

> charge current" to bring it to a desired value (e.g., 40 mA). Ex. 1006 at 373.

Pet. 28–29.

A telemetry transmitter in the Fischell Article communicates back to the external device the charge current in the battery. *Id.* at 370–373 (disclosing "a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery"), Fig. 8 (noting a box for telemetry sensing of charge current), Table 3 (noting a "Battery charge current telemetry" item). If the battery is not charging properly due to misalignment (i.e., the current level is too low), the user is made aware by beeping and lights on the external device. *Id.* at 377–378. If the battery is receiving too much current, a feedback control system maintains charge at the appropriate level. *Id.* at 367 ("The charging circuit for the rechargeable pacer limits the charge (and overcharge) current into the battery to 40 mA."), 372 (disclosing "telemetry . . . to measure and control charge current into the battery"), 373 ("The external charg[ing] detects [the telemetry] and closed-loop controls the battery charge current to a value of 40 mA."), 378 ("A feedback control system in the charger maintains the battery charge current at the proper 40 mA level.")).

3. Summary of Baumann

Baumann, titled Device and Process for Charging of Rechargeable Batteries of Implants, generally "relates to a charging device for charging of rechargeable NiCd, Ni-metal hydride or lithium batteries of implants . . . by transcutaneous transmission of electric power from an external power transmission part to a power receiving part which forms a part of the implant." Ex. 1007, 1:7–19. Baumann explains that "[w]hen a battery is charged, only one part of the supplied electric power is converted into

charge," that "[a]nother part of this power is converted into heat on the internal resistance of the battery and is lost for charging," and that the "power loss can lead to an impermissible temperature rise of the implant housing, and thus, to damage of the surrounding tissue." *Id.* at 1:29–34. Baumann seeks to avoid such problems and further describes a process for charging implanted batteries where, in a first charging phase, "a relatively high charging current flows," and "after the cell voltage of the battery has reached a predetermined limiting charging voltage, in a second charging phase, the charging current is reduced compared to the charging current flowing at the end of the first charging phase." *Id.* at 1:20–27.

Figure 1 of Baumann is reproduced below.

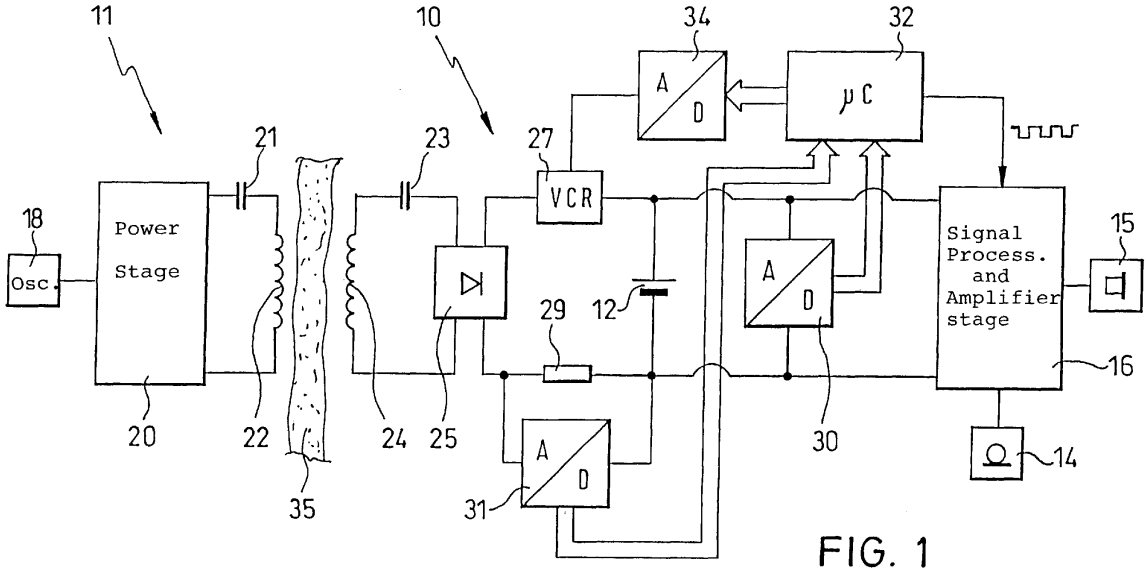

FIG. 1

Baumann Figure 1 "shows a schematic circuit diagram of an electronic hearing implant with a charging device." *Id.* at 3:47–49. The charging device illustrated in Figure 1 includes implantable power receiving part 10,

external power transmission part 11, and rechargeable battery 12. *Id.* at 3:60–65. Baumann further explains the following:

> A charging process begins with the external field coil 22 being placed on the outside of the skin 35 of the implant wearer such that it is aligned at least approximately with the implant coil 24. The electronic power stage 18, in interaction with the oscillator 18, . . . an alternating current supplies to the field coil 22 which has a frequency in the range from 40 kHz to 50 MHz. The alternating electromagnetic field produced by the field coil 22 transcutaneously induces in the implant coil 24 an alternating current which is rectified in the rectifier stage 25. The battery 12 is charged with the rectified charging current I_L, via the VCR 27 which is in series with the output of the rectifier stage 25, the instantaneous resistance value of the VCR 27, which is controlled by the microcontroller 32 via the D/A converter 34, determining the charging current I_L supplied to the battery from the rectifier stage 25. The size of the charging current I_L is determined from the voltage drop on the current measuring resistor 29, and a corresponding measured quantity travels to the microcontroller 32 via the A/D converter 31.

Ex. 1007, 4:36–55. Additionally, Baumann states that "[t]he means necessary to set the charging current I_L . . . can . . . be housed in an implantable power receiving part 10," or "it can also be in the external power transmission part 11 or distributed between both parts 10 and 11." *Id.* at 5:59–64. According to Baumann, battery charging "is regulated depending on the internal resistance of the battery," such that "the cell is charged only with as much energy as the electrochemical state allows, without excess gassing or heating of the cell occurring." Ex. 1007, 2:33–37. Baumann also discloses that when the voltage reaches a certain level it "sets back," or lowers, the current. Ex. 1007, 5:14–22 ("When monitoring of the cell voltage U_Z . . . indicates that the cell voltage has reached a limiting

[value] U_G, the microcontroller 32 . . . sets back the charging current I_L for a second charging phase T2."). Figure 3 of Baumann is reproduced below:

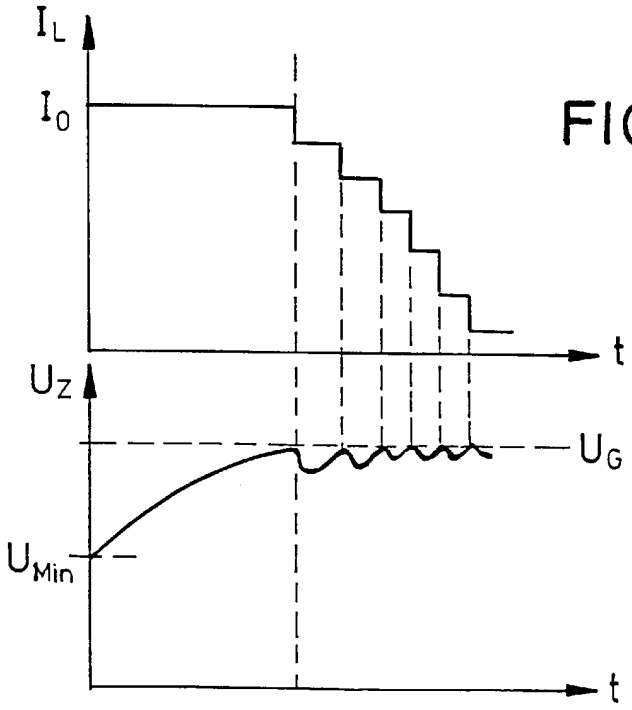

FIG. 3

Figure 3 depicts two graphs showing the relationship between charge current I_L over time, and battery voltage U_Z over time. *See id.* at 4:63–5:35. As shown in Figure 3, after the voltage U_Z hits a threshold value U_G, current I_L is varied in a stepwise function over time. *Id.* at 5:14–22.

E. Alleged Anticipation by Schulman

Petitioner contends that claims 1, 5, and 9 of the '758 patent are anticipated by Schulman. Pet. 12–27. Petitioner's contentions are supported by Dr. Panescu's testimony. Ex. 1003 ¶¶ 60–81, Ex. B. Patent Owner disputes these contentions, primarily with regard to whether Petitioner provided a sufficiently detailed explanation in the Petition of how the challenged claim limitations are mapped to the prior art, incorporated improperly expert testimony from a declaration into the Petition by

reference, and showed sufficiently in the Petition how Schulman discloses certain limitations, identified below as the "varying limitation" and the "measured current limitation." Prelim. Resp. 4–16.

1. Independent Claim 1

Petitioner provides an explanation of how Schulman allegedly discloses each limitation of claim 1, which we analyze below, along with Patent Owner's arguments in opposition.

A system for transcutaneous energy transfer, comprising:

To the extent the preamble is limiting, Petitioner contends, and Patent Owner does not yet dispute, that Schulman discloses a rechargeable tissue stimulating system corresponding to a system for transcutaneous energy transfer. Pet. 12 (citing Ex. 1005, 1:7–11).

> *an implantable medical device having componentry for providing a therapeutic output, said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, said implantable medical device adapted to be implanted in a patient; and*

Petitioner contends, and Patent Owner does not yet dispute, that Schulman discloses an implantable electrical tissue stimulator corresponding to the recited "implantable medical device" with each of the recited features, including battery 15 (an "internal power source") and induction coil 17 (a "secondary coil") supplying power to battery 15. *Id.* at 12–14 (citing Ex. 1005, 2:27–33, 3:42–46, 3:59–62, Figs. 1–3).

> *an external power source having a primary coil, said external power source providing energy to said implantable medical device when said primary coil of said external power source is placed in proximity of said secondary coil of said implantable medical device and thereby generating a current, having a value, passing through said internal power source:*

Petitioner contends, and Patent Owner does not yet dispute, that Schulman discloses an electrical charging power source corresponding to the recited "external power source" with each of the recited features, including induction coil 19 (a "primary coil"), which provides energy to the implantable electrical tissue stimulator when placed in proximity of induction coil 17, thereby generating a current having a value. *Id.* at 14–16 (citing Ex. 1005, 2:36–40, 3:59–62, 6:17–19, 7:46–48, 9:9–11, Figs 2–4; Ex. 1003 ¶¶ 62, 67, 76, 79)

> *wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source* [the "varying limitation"];

With regard to the varying limitation, Petitioner contends that Schulman discloses the use of current sampling resistor R9 to control transistors Q2 and Q3, which control the telemetry frequency. *Id.* at 16–17 (citing Ex. 1005, 4:63–66). Petitioner, citing Dr. Panescu's testimony, explains that sampling resistor R9 measures the current passing through the internal battery to control the telemetry circuitry that communicates with the external power source. *Id.* at 17 (citing Ex. 1003 ¶¶ 67–80). Petitioner also contends that telemetry circuit 12 of Schulman relies on the current sampling of resistor R9 to signal induction coil 21 and that the "electrical control signal generated in transducer 14 by the magnetic output signal from the telemetry circuit 12 will produce changes in the regulation of the power

source 13." *Id.* at 17–18 (quoting Ex. 1005, 6:19–38). According to Petitioner, Schulman further explains as follows:

> Of course the electrical control signal on lead 59 from the transducer adjusts the current output from the current control means 60 to the induction coil 24 in order to adjust the strength of the magnetic field applied to the implanted charging circuit. That is, when the current passing through resistor R9 in the charging circuit exceeds a maximum operating level, the signal from circuit 59 will lower the output current from current control means 60. This lowered output current, through the use of induction coils 22, 23 and 24, results in a reduced magnetic field strength acting between the induction coils 19, 20 and 21 of the power source and induction coils 17 and 18 of the charging circuit.

Id. at 18 (quoting Ex. 1005, 7:20–33) (emphasis omitted). Petitioner argues, citing testimony from Dr. Panescu, that Schulman relies on telemetry feedback to automatically regulate the output of external power source 13 based on the measured current that passes through internal battery 15. *Id.* (citing Ex. 1003 ¶¶ 67–80).

Patent Owner argues that Petitioner provides "little to no explanation in the Petition" of how the varying limitation is disclosed by Schulman, and instead relies on "out of context quotations, minimally annotated figures, and conclusory assertions." Prelim. Resp. 8–10. To the contrary, we find Petitioner has sufficiently shown for purposes of this Decision how it contends Schulman discloses the varying limitation. Petitioner's contentions are supported not only by the portions of Schulman quoted in the Petition, but also by the cited testimony of Dr. Panescu. Patent Owner's additional argument that citing declaration testimony is improper incorporation by reference is also not persuasive in this case. *See* Prelim. Resp. 13–14. There is no requirement that Petitioner duplicate verbatim the entirety of a

declaration in the Petition to avoid an allegation of improper incorporation by reference. The Petition properly sets forth the arguments advanced by Petitioner and includes a concise summary of Dr. Panescu's supporting opinion with citation to a limited portion of Dr. Panescu's declaration. *See* Pet. 10–20.

Patent Owner also advances several more specific arguments, which we also find not persuasive on the current record. Patent Owner argues that Petitioner is "inconsistent" and "contradictory" as to how Schulman measures current across various proceedings and fails to explain how Schulman teaches measuring the current or why it is "through the battery." Prelim. Resp. 10–11, 11 n.3. We find the arguments not persuasive. There is no ambiguity in the Petition that Petitioner relies on sampling resistor R9 of Schulman to provide a measure of the charging current that passes through the internal battery. Pet. 17. Indeed, the record supports Petitioner's contention that Schulman discloses using resistor R9 to measure the current into the battery. *See, e.g.*, Ex. 1005, 4:11–12 ("Charging current passes through the current sampling resistor R9."); 4:66–5:2 ("[T]he initial current through resistor R9 is the charging current to the battery 15."); 5:35–38 ("As long as the current through resistor R9 remains at 40 milliamperes or above, charging of the battery 15 is considered to be proper."). \

For similar reasons, we reject on the current record Patent Owner's argument that Dr. Panescu's testimony is inconsistent and should be given "little to no weight," because the argument appears to take isolated statements out of context. *See* Prelim. Resp. 14, n.4. Patent Owner also argues that "the Petition fails to explain what disclosures from the quoted portions of Schulman it relies upon for teaching 'power output' of the power source 13." Prelim. Resp. 12. We are satisfied that Petitioner's

identification of a "power source" sufficiently informs Patent Owner how Petitioner contends Schulman discloses "power output" from the power source, particularly when coupled with Dr. Panescu's explanation, provided in the Petition, that "Schulman teaches external power source providing energy to the implanted device when induction coil 19 on the charging head of the external power source is placed in proximity of induction coil 17 of the implanted device." Pet. 15–16 (citing Ex. 1003 ¶¶ 62, 79).

> *wherein said external power source automatically varies its power output based on a measured current associated with said current passing through said internal power source* [the "measured current limitation"].

Petitioner contends that the measured current limitation "simply narrows the 'value' of the first wherein clause to 'measured current,' and does not require a separate measurement." Pet. 19–20 (additionally asserting as support that the Specification "does not describe two separate measurements"). Petitioner, therefore, relies on its analysis of the preceding varying limitation as likewise disclosing the measured current limitation. *Id.*

Patent Owner does not yet dispute Petitioner's contention that the measured current limitation only narrows the varying limitation. Prelim. Resp. 15–16. Instead, Patent Owner argues the Petition is deficient for the same reasons asserted with respect to the varying limitation discussed above. *See id.* Patent Owner also argues that the Petition is ambiguous because Petitioner asserts that Schulman discloses a "measured current or value," which is not necessarily limited to a "measured current." *Id.* at 16. For the reasons provided above, we find on the current record that Petitioner has sufficiently shown how it contends Schulman discloses the measured current limitation current, not merely a "value associated with the charging current."

2. Independent Claims 5 and 9

As compared to the "system" recited in claim 1, claim 5 is directed to "[a]n external power source" and claim 9 is directed to "[a] method of transcutaneous energy transfer," however, all three claims recite substantially similar features. *See* Ex. 1001, 22:25–46, 23:46–65, 24:61–25:10. Petitioner relies largely on the same analysis for all three claims. Pet. 12–27. Likewise, Patent Owner makes the same arguments in opposition with regard to claims 5 and 9 as it asserts with regard to claim 1. Prelim. Resp. 8–16. Petitioner has sufficiently shown for purposes of this Decision how it contends Schulman discloses the recited features of claims 5 and 9 for substantially the same reasons discussed above with regard to claim 1. We further find Patent Owner's arguments in opposition not persuasive for the reasons provided above with respect to claim 1.

3. Showing of a Reasonable Likelihood

We have considered the evidence and arguments presented by the parties and determine, for the reasons provided above, that the Petition provides the requisite showing, at this stage of the proceeding, that Shulman discloses each limitation of claims 1, 5, and 9 of the '758 patent. We further determine, based on the current record, that the Petition shows that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1, 5, and 9 are anticipated by Shulman.

F. Alleged Anticipation by the Fischell Article

Petitioner contends that claims 1, 5, and 9 of the '758 patent are anticipated by the Fischell Article. Pet. 27–45. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 82–91, Ex. B. Having found above a reasonable likelihood that Petitioner would prevail in showing at least one challenged claim is anticipated by Schulman, we focus our discussion of

Petitioner's allegations based on the Fischell Article on Patent Owner's arguments in opposition.

Patent Owner primarily argues that Petitioner failed to provide a sufficiently detailed explanation in the Petition of how the challenged claim limitations are mapped to the prior art, incorporated improperly expert testimony from a declaration into the Petition by reference, and failed to sufficiently show in the Petition how the Fischell Article discloses certain limitations. Prelim. Resp. 17–25.

We find Petitioner has sufficiently shown for purposes of this Decision how it contends that the Fischell Article discloses the limitations of claims 1, 5, and 9 of the '758 patent in the Petition, which is supported not only by the portions of the Fischell Article quoted in the Petition, but also by the cited testimony of Dr. Panescu. Pet. 27–45 (citing, e.g., Ex. 1003 ¶¶ 84–91, 109). Patent Owner argues, for example, that Petitioner does not sufficiently explain how the Fischell Article discloses the varying limitation. Prelim. Resp. 17–20. Patent Owner does not identify any specific deficiencies in what Petitioner does identify, but rather focuses on whether the explanation is sufficiently clear. *See, e.g.*, *id.* at 19–20 (asserting "there is simply insufficient explanation in the Petition"). We find the Petition sufficiently detailed in its description of how the Fischell Article allegedly discloses the varying limitation and sufficient for purposes of ascertaining whether a reasonable likelihood has been established. *See* Pet. 27–45.

Patent Owner's additional argument that citations in the Petition to declaration testimony are improper incorporation by reference is also not persuasive. *See* Prelim. Resp. 22–23. As explained above, there is no requirement that Petitioner duplicate verbatim the entirety of a declaration in the Petition to avoid an allegation of improper incorporation by reference.

The Petition properly sets forth the arguments advanced by Petitioner and includes a concise summary of Dr. Panescu's supporting opinion with citation to a limited portion of Dr. Panescu's declaration. *See* Pet. 27–45.

Patent Owner also argues that "the Petition fails to explain what disclosures from the quoted portions of the Fischell Article it relies upon for teaching 'power output' of the external charger." Prelim. Resp. 20. We are satisfied that Petitioner's identification of a "power source" sufficiently informs Patent Owner how Petitioner contends that the Fischell Article discloses "power output" from the power source, particularly when coupled with Dr. Panescu's explanation, provided in the Petition, that the Fischell Article "teaches that the external charger includes a 'charger head' that 'applies an alternating magnetic field' which would be through an inductive coil (primary coil)," and that the Fischell Article "teaches the energy supplied by the external primary coil and picked up by the internal secondary 'pick-up coil' is applied to a 'full wave rectifier,' the output of which goes through a 'charge current limiter' that in turn applies charge current to the internal battery (Ni-Cd cell)." Pet. 32–33 (citing Ex. 1003 ¶¶ 84, 85, 91).

The external charger charges the battery using a magnetic field to induce a current in the implant, which is the "power output" of the charger. *See* Ex. 1006, 372 (disclosing "the external charger applies an alternating magnetic field"), 378 (teaching "the charger maintains the battery charge current"). To the extent Patent Owner is arguing that an *ipsis verbis* usage of the phrase "power output" in the Fischell Article is required, we disagree. The disclosure of the Fischell Article is to be read by a person of ordinary skill in the art (who is familiar with electrical engineering and implantable medical devices), and the Petition sufficiently shows how Petitioner

contends that the Fischell Article discloses a feedback telemetry system that adjusts the power to maintain a specified current charge level. Similarly, Patent Owner's argument that "any attempt by Petitioner to rely on inherency in its analysis . . . fails" is not persuasive. What the Fischell Article discloses to a person of ordinary skill in the art is an issue for resolution at trial and distinct from whether a limitation of a challenged claim is inherent in the disclosure of the Fischell Article. Moreover, the only limitation Petitioner identifies as an inherent property concerns claim 9, for which Petitioner contends, and Patent Owner does not yet dispute, that "[i]t is an inherent property of batteries to have an internal resistance." Pet. 42 (citing Ex. 1003 ¶ 109).

With regard to the measured current limitation, Patent Owner does not yet dispute Petitioner's contention that it only narrows the varying limitation. Prelim. Resp. 24–25. Instead, Patent Owner argues the Petition is deficient for the same reasons asserted with respect to the varying limitation, that Petitioner "does not explain how a current is measured" in the Fischell Article, and that Petitioner "does not even clearly allege that it is a measured current." *Id.* Once again Patent Owner does not identify any specific deficiencies in what Petitioner does identify, but rather focuses on whether the explanation is sufficiently clear. We find on the current record that Petitioner has sufficiently shown how it contends that the Fischell Article discloses the measured current limitation. *See, e.g.*, Pet. 29–36.

G. Alleged Anticipation by Baumann

Petitioner contends that claims 1–12 of the '758 patent are anticipated by Baumann. Pet. 45–72. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 92–116, Ex. B. Having found above a reasonable likelihood Petitioner would prevail in showing at least one challenged claim

is anticipated by Schulman, we focus our discussion of Petitioner's allegations based on Baumann on Patent Owner's arguments in opposition.

Patent Owner primarily argues that Petitioner failed to provide a sufficiently detailed explanation in the Petition of how the challenged claim limitations are mapped to the prior art, incorporated improperly expert testimony from a declaration into the Petition by reference, and failed to sufficiently show in the Petition how Baumann discloses certain limitations. Prelim. Resp. 26–35. For substantially the same reasons explained above with respect to alleged anticipation by Schulman and by the Fischell Article, we find the Petition sufficiently shows how Petitioner contends Baumann anticipates each claim and does not improperly incorporate by reference testimony from a declaration. *See* Pet. 45–72.

More specifically, with regard to the varying limitation, Patent Owner argues that Petitioner's reliance on Baumann's express disclosure that the means to set the charging current may be housed in the external power transmission part 11 is insufficient because "Petitioner does not explain how such a system would work." Prelim. Resp. 28; *see also* Pet. 54 (citing Ex. 1007, 5:59–64). We are not persuaded by Patent Owner on the current record that the disclosure of Baumann is insufficient or not enabled. Prelim. Resp. 28–29. Petitioner concedes that Baumann does not expressly disclose "a telemetry system communicating information from the internal circuitry to the external charging unit," and instead asserts the disclosure was sufficient to enable a person of ordinary skill in the art. Pet. 54–55 (citing Ex. 1003 ¶ 102). Petitioner has sufficiently shown how it contends Baumann discloses the limitation, as supported by Dr. Panescu, for purposes of this Decision. Patent Owner also argues Petitioner's contentions with respect to certain limitations of dependent claims 2, 3, 6, 7, 10, and 11 are

insufficient. *See* Prelim. Resp. 30–35. We find Patent Owner's arguments concerning these dependent claims present fact-intensive issues better suited to resolution after development of a fuller record during trial.

H. Obviousness over Schulman and Baumann

Petitioner asserts the subject matter of dependent claims 2–4, 6–8, and 10–12 of the '758 patent would have been obvious over Schulman and Baumann. Pet. 72–90. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 117–130, Ex. B. Petitioner provides claim charts that in large part do no more than direct us to other portions of the Petition where Petitioner contends certain limitations are anticipated by Schulman or Baumann. Pet. 75–90. Using claim 2 as an example, Petitioner directs us to portions of the Petition addressing anticipation by Schulman for each limitation other than "wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle," for which we are directed to a different portion of the Petition addressing anticipation by Baumann. Pet. 75–78.

More generally, for all of the claims challenged under the combination, Petitioner explains how Baumann teaches "a two-phase charging protocol" and further contends that a person of ordinary skill in the art "would have been motivated to incorporate the teachings of Baumann into Schulman" both (1) "to not only realize decreased charging time, but to also improve on the safety and reliability features of the system," and (2) "in order to provide a charging process that charged batteries at an increased current, suitable for Ni-Cd batteries." *Id.* at 73–74 (citing Ex. 1003 ¶¶ 118–122); *see also id.* at 74–75 (asserting that a person of ordinary skill in the art "would have been able to modify Schulman's circuit to incorporate the main technical principals taught by Baumann").

Patent Owner first disputes Petitioner's contentions of what Schulman and Baumann disclose based on the same arguments Patent Owner raised with regard to anticipation by either Schulman or Baumann. Prelim. Resp. 35–36. Patent Owner also argues that Petitioner "does not describe why [a person of ordinary skill in that art] would be motivated to combine specific teachings of Baumann that are missing from Schulman with Schulman to yield the claimed invention," and that a "decreased charging time and/or improved safety and reliability is excessively generic, not explained, and insufficient." *Id.* at 37–39 (citation omitted). Patent Owner also asserts that Petitioner failed to show a reasonable expectation of success in the asserted combination of Baumann and Schulman. *Id.* at 39–41. On the current record, Petitioner's arguments find support in the cited references.

I. Obviousness over the Fischell Article and Baumann

Petitioner asserts the subject matter of dependent claims 2–4, 6–8, and 10–12 of the '758 patent would have been obvious over the Fischell Article and Baumann. Pet. 90–107. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 131–146, Ex. B. Petitioner provides claim charts that in large part do no more than direct us to other portions of the Petition where Petitioner contends certain limitations are anticipated by the Fischell Article or Baumann. Pet. 75–90. Petitioner also asserts substantially the same rationale for the asserted combination of the Fischell Article and Baumann as Petitioner asserts for the combination of Schulman and Baumann discussed above. *Id.* at 91–92.

Patent Owner first disputes Petitioner's contentions of what the Fischell Article and Baumann disclose based on the same arguments Patent Owner raised with regard to anticipation by either the Fischell Article or

Baumann. Prelim. Resp. 42–43. Patent Owner also argues that Petitioner "does not describe why [a person of ordinary skill in that art] would be motivated to combine specific teachings of Baumann that are missing from [the] Fischell [Article] with [the] Fischell [Article] to yield the claimed invention," and that a "decreased charging time and/or improved safety and reliability is excessively generic, not explained, and insufficient." *Id.* at 43–44 (citation omitted). Patent Owner also asserts that Petitioner failed to show a reasonable expectation of success in the asserted combination of Baumann and the Fischell Article. *Id.* at 45–46. On the current record, Petitioner's arguments find support in the cited references.

IV. CONCLUSION

Based on the evidence before us, we determine that Petitioner demonstrates a reasonable likelihood of prevailing at least on its assertion that independent claims 1, 5, and 9 of the '758 patent are unpatentable. Accordingly, *inter partes* review shall proceed in this case on all of the grounds raised in the Petition. *See SAS Inst.*, 138 S. Ct. at 1359–60 (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating that the decision whether to institute *inter partes* review requires "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim term and, thus, leaves undecided any remaining fact issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final written decision. *See Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting

that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing *id.* § 316(e)).

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–12 of U.S. Patent No. 8,457,758 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,457,758 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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