Trials@uspto.gov
571-272-7822

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.

IPR2020-00712
Patent 8,738,148 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 1–18 ("the Challenged Claims") of U.S. Patent No. 8,738,148 B2 (Ex. 1001, "the '148 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 '148 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 '148 Patent

The '148 patent issued May 27, 2014, from an application filed on March 15, 2013, and is directed to a "[s]ystem for transcutaneous energy transfer." Ex. 1001, codes (21), (22), (45), (57). As background to the invention, the '148 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 2:1–3, 2:20–23. According to the '148 patent, "[f]or implanted medical devices, the efficiency at which energy is transcutaneously transferred is crucial." *Id.* at 3:3–4. The '148 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 3:4–3:26.

The '148 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 3:37–52. According to Patent Owner, the '148 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, 3:56–4:15, 20:65–22:18, Fig. 19).

Figure 3 of the '148 patent is reproduced below.

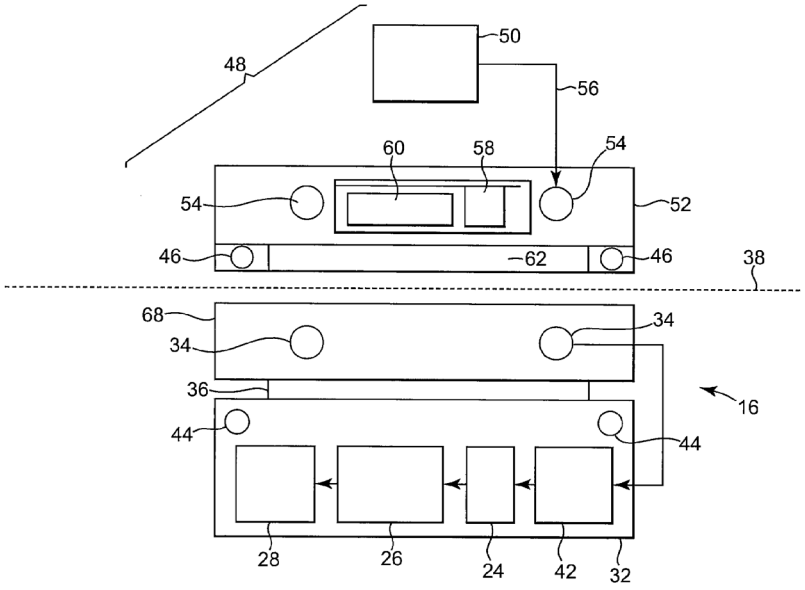

Fig. 3

Figure 3 illustrates implantable medical device 16 situated under cutaneous boundary 38, and associated external charging device 48. Ex. 1001, 6:2–5, 7:57–58, 8:21–23. 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 7:33–36, 7:60–8:3. 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 7:63–8:3, 8:21–8:25. "[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 7:63–8:3. "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 8:25–28.

Figure 19 of the '148 patent is reproduced below.

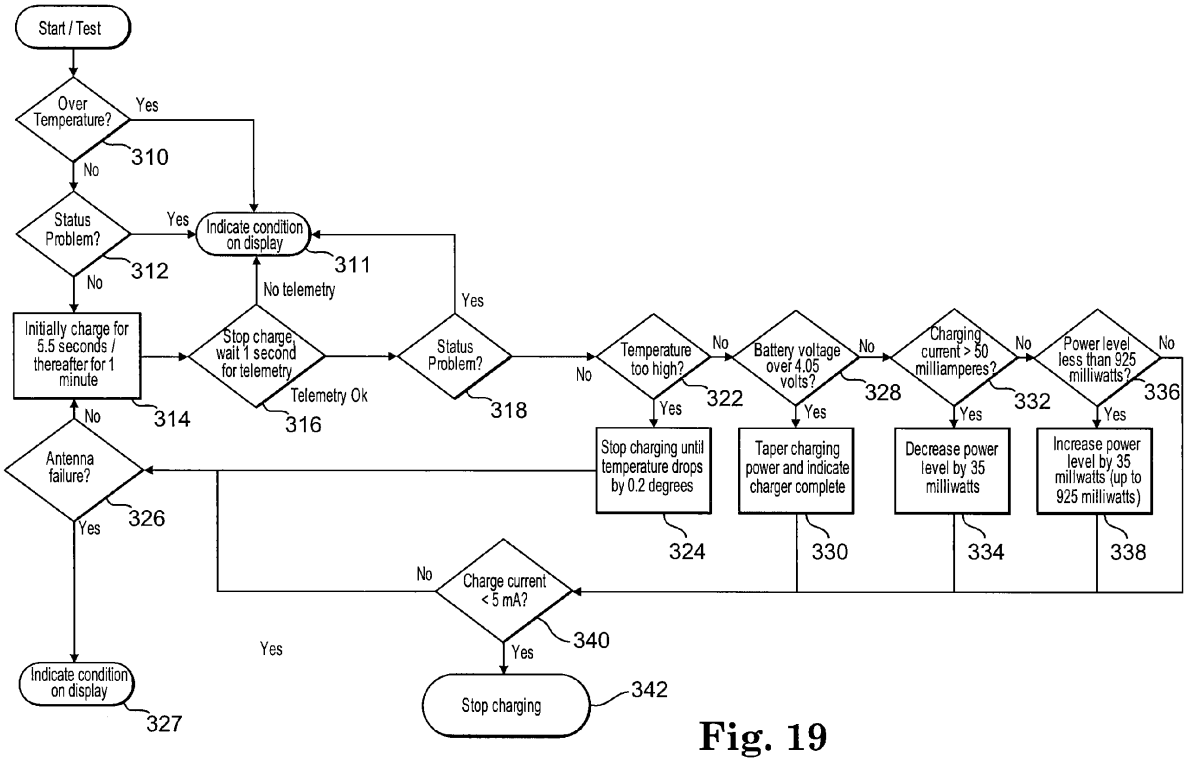

Fig. 19

Figure 19 is a flow chart illustrating the operation of charging unit 50 to charge an implantable medical device. *Id.* at 6:42–43, 21:27–28. The steps shown in Figure 19 are described in the '148 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. 21:28–22:17.

B. Illustrative Claim

Petitioner challenges claims 1–18 of the '148 patent. Claims 1, 3, 6, 7, 9, 12, 13, 15, and 18 are independent. Claim 2 depends from claim 1, claims 4 and 5 depend from claim 3, claim 8 depends from claim 7, claims 10 and 11 depend from claim 9, claim 14 depends from claim 13, and claims 16 and 17 depend from claim 15. Ex. 1001 22:28–25:25. 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 battery and a secondary coil operatively coupled to said internal battery, 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 battery;
> wherein said external power source automatically varies its power output based on a value measured in said implantable medical device and associated with said current passing through said internal battery.

Ex. 1001, 22:28–46.

C. Asserted Grounds of Unpatentability

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

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–18	102	Schulman[1]
1–4, 7–10, 13–16	102	Fischell Article[2]
5, 6, 11, 12, 17, 18	103[3]	Fischell Article, Fischell '260[4]

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 '148 patent as a subject of *Medtronic, Inc. v. Axonics Modulation Technologies, Inc.*, Case No. 8:19-cv-02115-DOC-JDE (C.D. Cal.). Pet. 97; 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 IPR2020-00680 concerning U.S. Patent No. 8,457,758 B2 ("the '758 patent"). Pet. 97; Paper 4, 2. The '148 patent issued from an application that was a continuation of an application that issued as the '758 patent. Ex. 1001, code (60). The '758 patent issued from an application that

[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] 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 '148 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).
[4] U.S. Patent No. 3,888,260 (issued June 10, 1975) (Ex. 1007, "Fischell '260").

was a continuation of an application that was a division of an application that issued as the '069 patent. *Id.*

E. Real Parties in Interest

Petitioner identifies no additional real parties in interest. Pet. 96. 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. 8. 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 '148 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 and in is consistent with the definitions 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. 7. 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 Fischell '260, 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.

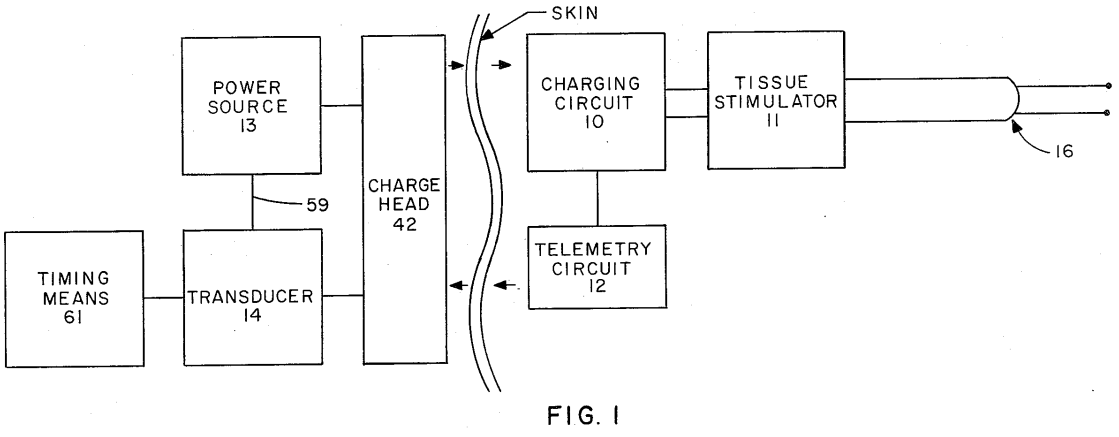

FIG. 1

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.

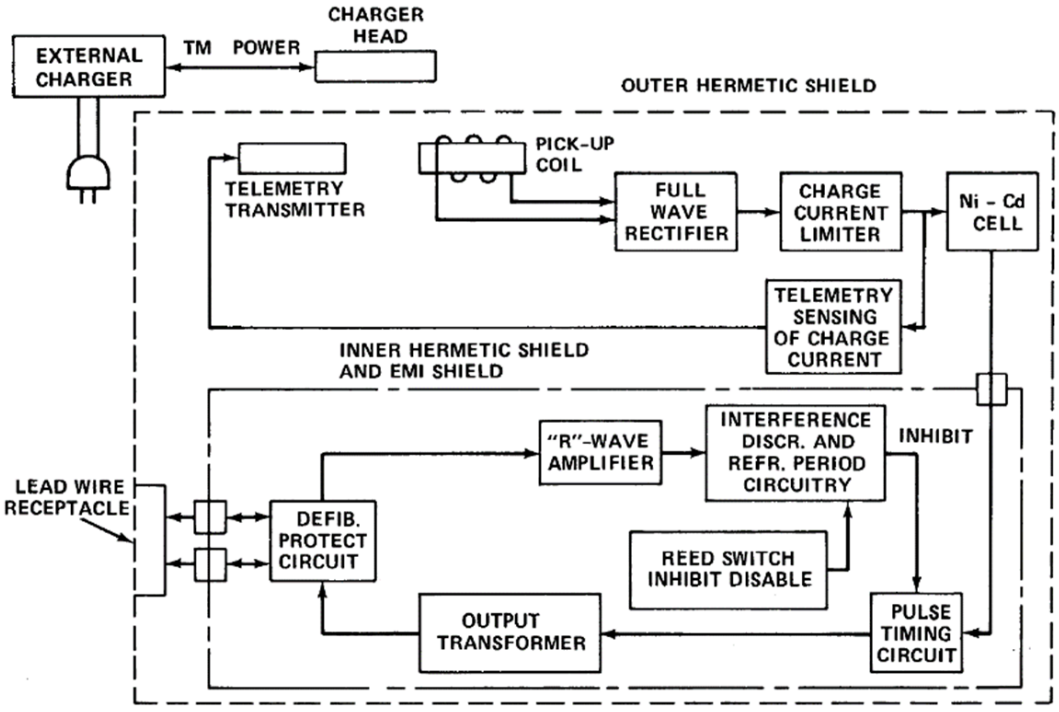

Fig. 8 Block diagram of rechargeable demand pacemaker

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. 50–51.

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 Fischell '260

Fischell '260, titled Rechargeable Demand Inhibited Cardiac Pacer and Tissue Stimulator, generally relates to a "demand inhibited cardiac pacer or human tissue stimulator" that uses a rechargeable battery and "provides accurate telemetry indication as to when such recharging of the unit's battery is taking place." Ex. 1007, codes (54), (57). The demand inhibited cardiac pacer or human tissue stimulator of Fischell '260 includes "double hermetic sealing" which provides an "effective electromagnetic shield for the internal

electronic components . . . without severely attenuating the alternating magnetic field that is utilized to recharge the pacer or stimulator battery." *Id.* at 1:59–2:3.

Figure 1a of Fischell '260 is reproduced below:

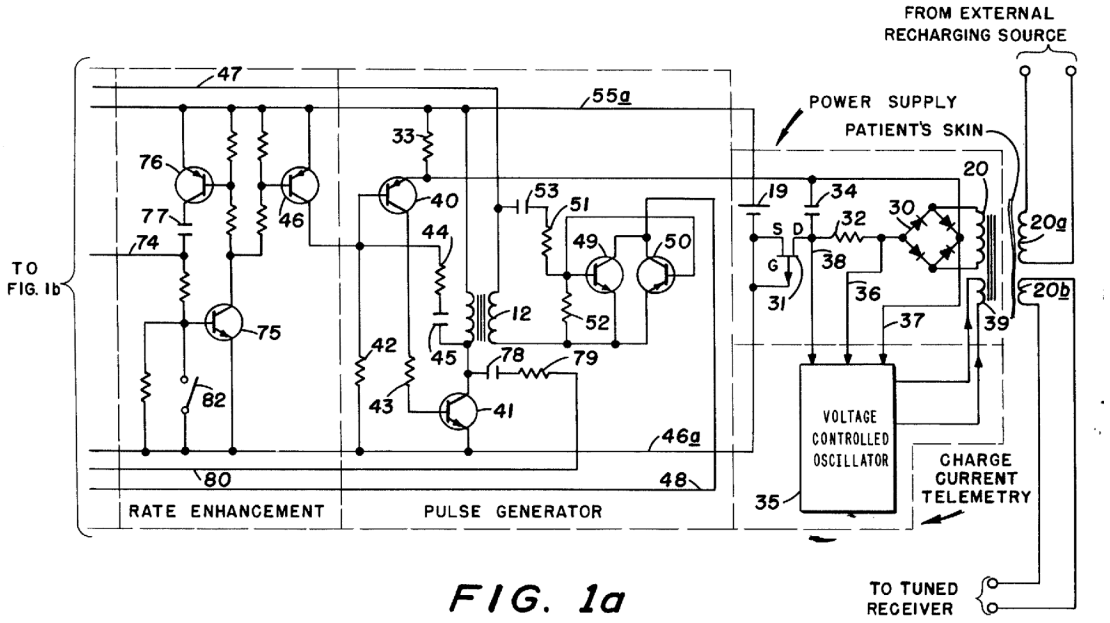

FIG. 1a

Fischell '260 Figure 1a, together with Figure 1b (not reproduced), is a schematic diagram of circuitry utilized in a rechargeable demand inhibited cardiac pacer. *Id.* at 3:27–31. As shown in Figure 1a, electrical power for the electronic circuitry of the proposed pacer unit is provided by single cell rechargeable nickel-cadmium battery 19 and "is maintained in an acceptable operating condition by recharging energy inductively coupled through the patient's skin from a suitable external source of recharging energy by means of the ferrite core input transformer 20 and the illustrated recharge head 20a." *Id.* at 6:40–50. Petitioner identifies recharge head 20a as an "external coil" and input transformer 20 as an "internal coil." Pet. 79. Fischell '260 states that "[t]he input recharging energy developed across the illustrated upper secondary winding of the input transformer 20 is rectified at

the conventional full-wave diode bridge rectifier 30," and that the "output recharging current available at the diagonals of the rectifier 30 is applied to the battery 19 through a series recharging circuit comprising a conventional field effect transistor current limiter 31, current monitoring resistor 32, and a small (e.g., 3 ohm) voltage drop resistor 33." Ex. 1007, 6:50–59. "A voltage controlled oscillator 35 . . . receive[s] operating supply voltage from the output of the full wave rectifier bridge 30," and is "also connected . . . to receive a control voltage signal developed across the current monitoring resistor 32." *Id.* at 6:66–7:3. "As a result, the output frequency generated by the oscillator 35 varies in accordance with the value of recharging current being supplied to the battery 19." *Id.* at 7:3–6. "The output frequency telemetry signal from the oscillator 35, when detected by a suitable external receiving unit (not shown) via the winding 20b, thus provides accurate indications both that recharging is taking place and the precise value of the recharging current." *Id.* at 7:10–15.

E. Alleged Anticipation by Schulman

Petitioner contends that claims 1–18 of the '148 patent are anticipated by Schulman. Pet. 11–49. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 68–91, 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. Prelim. Resp. 8–20.

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. 14 (citing Ex. 1005, 1:7–11).

> *an implantable medical device having componentry for providing a therapeutic output, said implantable medical device having an internal battery and a secondary coil operatively coupled to said internal battery, 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 battery") and induction coil 17 (a "secondary coil") supplying power to battery 15. *Id.* at 14–16 (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 battery;*

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 (corresponding to 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 16–19 (citing Ex. 1005, 2:36–40, 3:59–62, 4:11–13, 6:17–19, 7:29–33, 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 measured in said implantable medical device and associated with said current passing through said internal battery* [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 19–20 (citing Ex. 1005, 4:63–66). Petitioner's contention is supported by Dr. Panescu, who explains as follows:

> Schulman refers to resistor R9 as "current sampling resistor" because resistor R9 provides a measure of the charging current that is supplied to internal battery 15. Schulman, 6:17–19. It is in response to the magnitude of this charging current, as sampled by R9, that the frequency of the multivibrator circuit (made up, in part, of transistors Q2 and Q3) is controlled. Schulman, 4:36–42. This frequency is then telemetered back to the external power source via coil 18. Schulman, 4:45–53.

Ex. 1003 ¶ 75. Petitioner further contends that the "current passing through resistor R8 tracks the current through R9 and is equal to the current passing through battery 15," and that the current passing through and the voltage across resistor R8 measure the same "value" in accordance with Ohm's law, which defines voltage as current times resistance. Pet. 21–22. Petitioner argues that Schulman teaches varying the output of the external power source 13 by telemetry feedback based on a value measured in the implantable device associated with the current passing through internal battery 15 because "[t]ransistor Q7 measures the current through (or voltage

across) R8 and regulates the current passing through R9 to attain a predetermined charging current." Pet. 20–22 (citing Ex. 1005, 5:2–35, 6:19–38; Ex. 1003 ¶¶ 75–88).

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, a single annotated drawing. . . , and unsupported assertions." Prelim. Resp. 8–13. 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.

More specifically, Patent Owner argues that it is unclear whether Petitioner relies on a value across resistor R8 or a value across resistor R9 as the recited "value measured" of claim 1. *Id.* at 10. Patent Owner also argues that Petitioner is "inconsistent" and "contradictory" as to how Schulman measures current across various proceedings. Prelim. Resp. 10 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, that the "current passing through resistor R8 tracks the current through R9 and is equal to the current passing through battery 15," and that "the current passing through resistor R8 and the voltage across it measure the same 'value,'" because of the relationship between voltage and current defined by Ohm's law. Pet. 19–22. 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 (disclosing "[c]harging 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's contention that Dr. Panescu's testimony that "[f]or most of the charging operation, the current through R8 tracks the current through R9" conflicts with Petitioner's contentions in the Petition presents an issue better suited for resolution on a full record. *See* Prelim. Resp. 14 n.4 (quoting Ex. 1003 ¶ 79).

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 by creating a magnetic field when the 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. 17 (citing Ex. 1003 ¶¶ 56, 57, 73, 74).

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. 13–22.

2. Independent Claims 3, 6, 9, 12, 13, 15, and 18

Like claim 1, claims 3 and 6 are directed to a "system," whereas claims 9 and 12 are directed to "[a]n external power source" with similar features as claim 1. Ex. 1001, 22:28–46, 22:50–23:3, 23:12–33, 23:55–24:6, 24:15–34. Claims 13, 15, and 18 are directed to "[a] method of transcutaneous energy transfer" with similar features as claim 1. *Id.* at 24:35–48, 24:52–67, 25:9–25. Patent Owner's arguments in opposition are largely similar to the arguments Patent Owner raises with regard to claim 1. *See, e.g.*, Prelim. Resp. 16–17 (arguing Petitioner's analysis of limitations of claims 13 and 15 is the same as claim and "deficient for at least the same reasons given" with respect to claim 1).

Each of claims 3, 6, 9, and 12 recite "wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal battery." Petitioner notes that "the only difference" between this limitation and the similar limitation in claim 1 is that this limitation "deletes the words 'measured in said implantable medical device and.'" Pet. 22. Petitioner argues that this limitation of claims 3, 6, 9, and 12 is disclosed by Schulman for the same reasons as provided for the similar limitation of claim 1. *Id.* at 23. Specifically, Petitioner asserts that "Schulman teaches automatically (via telemetry feedback) varying the power output of the external power source 13 based on a value (current or voltage across a resistor) associated with the charging current that passes through internal battery 15." *Id.* (citing Ex.

1003 ¶¶ 75–88). Patent Owner disputes Petitioner's assertion for the same reasons as claim 1, and further argues Petitioner's reference to "current or voltage" is "even more inscrutable" and that Petitioner does not explain which resistor is relied on or how current or voltage values "would be associated with the current 'passing through said internal battery.'" Prelim. Resp. 15–16. Petitioner unambiguously relies on the same analysis for the similar limitations in claims 3, 6, 9, and 12 as for claim 1, which we find sufficient for purposes of this Decision as explained above. *See* Pet. 15–16.

With regard to claims 3, 9, and 15, Patent Owner argues that Petitioner's analysis of the recited "signal proportional to said current" is ambiguous, conclusory, and dependent improperly incorporated testimony of Dr. Panescu. Prelim. Resp. 17–18. Patent Owner also argues that Petitioner fails to show that the current (or voltage) across R8 is proportional to the current through the battery 15. *Id.* at 18. Petitioner states in the Petition that "[t]he 'signal proportional' is the measured current through resistor R8 (1:1 proportion) or the measured voltage across R8 (proportional based on Ohm's law V=I*R)." Pet. 23 (citing Ex. 1003 ¶¶ 75–88). Patent Owner does not, on the current record, persuasively refute Petitioner's contention by merely asserting it is insufficient in light of the support provided by the testimony of Dr. Panescu.

With regard to claims 6, 12, and 18, Patent Owner notes that each claim recites automatically varying the power output of the external power sources "based on a measured voltage." Prelim. Resp. 19–20. Petitioner contends that the limitation is met for the same reason as its analysis of claims 1 and 3. Pet. 26, 35, 48–49. Petitioner argues that Schulman discloses "a measured voltage across resistor R8." *Id.* at 26 (citing Ex. 1003 ¶¶ 75–88). As Dr. Panescu explains, a person of ordinary skill "would

readily understand that the voltage across sampling resistor R9 is directly proportional to the current measured across resistor R9," and "[t]hese two signals, in other words, denote two ways of representing the same electric value." Ex. 1003 ¶ 76. We find on the current record Petitioner sufficiently explains how Petitioner contends that Schulman discloses to a person of ordinary skill in the art the "measured voltage," as claimed, and that Petitioner's arguments find support in the cited reference.

3. Independent Claim 7

As compared to the "system" recited in claim 1, claim 7 is directed to an "external power source," but the limitations of both claims are otherwise substantially the same. Ex. 1001, 22:28–46, 23:34–50. Petitioner contends claim 7 is anticipated by Schulman for largely the same reasons as claim 1, and Patent Owner raises the same arguments in opposition to both claims, which we address above. *See* Pet. 14–22, 27–31; Prelim. Resp. 8–14.

4. Dependent Claims 2, 4, 5, 8, 10, 11, 14, 16, and 17

Petitioner provides a claim chart explaining how it contends each of the additional limitations of claims 2, 4, 5, 8, 10, 14, 16, and 17 are disclosed by Schulman. Pet. 22, 24, 25, 31–34, 45–48. At this stage of the proceeding, Patent Owner does not raise arguments directed to claims 2, 4, 5, 8, 10, 11, 14, 16, or 17 apart from the arguments directed to the independent claim from which each of these claims depends. Prelim. Resp. 20. On the current record, Petitioner's arguments find support in the cited reference.

5. Showing of a Reasonable Likelihood

We have considered the evidence and argument presented by the parties and determine, for the reasons provided above, that the Petition at least provides the requisite showing, at this stage of the proceeding, that

Shulman discloses each limitation of claims 1 and 7 of the '148 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 and 7 are anticipated by Shulman.

F. Alleged Anticipation by the Fischell Article

Petitioner contends that claims 1–4, 7–10, and 13–16 of the '148 patent are anticipated by the Fischell Article. Pet. 49–76. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 92–98, 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 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. 20–29.

We find Petitioner has sufficiently shown for purposes of this Decision how it contends that the Fischell Article discloses the limitations of claims 1 and 7 of the '148 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. 49–57, 60–65 (citing, e.g., Ex. 1003 ¶¶ 60–62, 93–98). Patent Owner argues, for example, that Petitioner does not sufficiently explain how the Fischell Article discloses the varying limitation. Prelim. Resp. 21–25. 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 23 (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. 49–76.

Patent Owner's additional argument that citations in the Petition to declaration testimony is improper incorporation by reference is also not persuasive. *See* Prelim. Resp. 25–26. 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. 49–76.

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. 23. We are satisfied that Petitioner's identification of a "power source" sufficiently informs Patent Owner how Petitioner contends 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 a proximally located 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. 54–55 (citing Ex. 1003 ¶¶ 60–62, 93, 94).

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. *See* Prelim. Resp. 24–25. 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 claims 13 and 15, for which Petitioner contends, and Patent Owner does not yet dispute, that "internal impedance is an inherent property of batteries." Pet. 70 (citing Ex. 1003 ¶ 90).

As to claims 3, 9, 13, and 15, Patent Owner generally asserts that Petitioner's contentions are insufficient for the same reasons raised with regard to claim 1. Prelim. Resp. 27–29. Patent Owner also argues in regard to claims 3, 9, and 15 the Petition fails to "explain why" the "'charge current' is a signal proportional to the current passing through the battery."

Id. at 28. Patent Owner, again, does not dispute Petitioner's contention so much as argue the explanation is insufficient, however, we find Petitioner's contention sufficient to show how Petitioner asserts the Fischell Article discloses the limitation at issue, as supported by Dr. Panescu. *See* Pet. 59 (citing Ex. 1003 ¶¶ 95–98) (stating "[t]he 'signal proportional' is the battery charging current as measured by the 'telemetry sensing of charge current' block, which passes through the internal battery (1:1 proportion)."). At this stage of the proceeding, Patent Owner does not raise arguments directed to claims 2, 4, 8, 10, 14, and 16 apart from the arguments directed to the independent claim from which each of these claims depends. Prelim. Resp. 29. On the current record, Petitioner's arguments find support in the cited reference.

G. Alleged Obviousness over the Fischell Article and Fischell '260

Petitioner contends dependent claims 5, 6, 11, 12, 17, and 18 of the '148 patent would have been obvious over the Fischell Article and Fischell '260. Pet. 77–96. Petitioner's contentions are supported by Dr. Panescu. Ex. 1003 ¶¶ 99–107, Ex. B. Each of these claims recites limitations directed to automatically varying the power output of the external power source "based on a voltage proportional to said current passing through said internal battery," (claims 5, 11, 17), or 'based on a measured voltage associated with said current passing through said internal battery (claims 6, 12, 18).

Petitioner argues as follows:

> [The] Fischell Article does teach "telemetry sensing of charge current" (i.e., the actual current passing through the battery) based on which the power supplied by the external power source is varied. Given that electrical current is commonly measured by measuring the voltage drop across a known resistor, according to

> Ohm's law, [the] Fischell Article inherently also teaches varying the power supplied by the external power source based on a voltage associated with or proportional to the current passing through the internal battery. Thus, even if it is argued that [the] Fischell Article does not inherently teach that limitation, it certainly suggests it.
>
> To remove doubts or arguments as to the invalidity of these remaining claims 5, 6, 11, 12, 17 and 18, Fischell '260, which provides detailed circuit implementation for the rechargeable demand pacemaker, is discussed herein. The combination of [the] Fischell Article and Fischell '260 renders these claims obvious.

Pet. 81–82. Petitioner contends that a person of ordinary skill "would have been motivated to combine the teachings of Fischell '260 with [the] Fischell Article to take advantage of the improvements offered by the detailed implementation of the rechargeable pacer offered by Fischell '260." *Id.* at 81 (citing Ex. 1003 ¶¶ 101–103).

Patent Owner argues that the asserted combination fails for the same reasons Patent Owner advances with regard to anticipation by the Fischell Article of the claims from which claims 5, 6, 11, 12, 17, and 18 depend. Prelim. Resp. 29–31, 34, 35. Patent Owner also argues that "Petitioner does not sufficiently explain why the voltage controlled oscillator receiving a control signal from across resistor 32 is a voltage proportional to the current passing through the internal battery." *Id.* at 30. With regard to Petitioner's rationale for the asserted combination, Patent Owner argues that "'improved' performance" is "insufficient for a motivation to combine," and that Petitioner fails to show the alleged improvement "could even be implemented in the Fischell Article such that there would be a reasonable expectation of success in the combination." *Id.* 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 and 7 of the '148 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 1–18 of U.S. Patent No. 8,738,148 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. 8,738,148 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

PETITIONER:

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

For PATENT OWNER:

Naveen Modi
Chetan R. Bansal
Quadeer Ahmed
PAUL HASTINGS LLP
naveenmodi@paulhastings.com
chetanbansal@paulhastings.com
quadeerahmed@paulhastings.com