UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

Case IPR2019-00678
Patent No. 7,774,069

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 7,774,069 UNDER 35 U.S.C. § § 311–319 AND 37 C.F.R. § 42.100 *ET SEQ.*

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I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics" or "Petitioner") respectfully petitions for initiation of *inter partes* review of claims 5 through 9 of U.S. Patent No. 7,774,069 ("the '069 patent"), Ex. 1001, in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq*. ("Petition"). The '069 patent generally relates to a system for charging the battery inside a medical device that is implanted beneath the skin of a patient. The '069 patent describes such transcutaneous energy transfer system as having an external power source which includes a primary inductive coil, and an implanted medical device which includes a secondary inductive coil and an internal rechargeable power source. Placing the external power source in proximity of the implanted medical device generates, via inductive coupling, a charging current in the internal power source. '069, Abstract. The '069 patent admits that such systems were generally known in the art and characterizes much of the functionality of the claimed system as implemented "in a conventional manner." Ex. 1001, 7:16-6. The purported novelty it claims relates to optimizing the battery charging process by improving alignment between the primary coil and the secondary coil with "[a]n alignment indicator [that] reports the alignment as a function of the current generated in the internal power source." Ex. 1001, Abstract. As explained herein, however, the '069 patent did not disclose anything new. Indeed, such systems for transcutaneous

energy transfer, including those with the claimed alignment indicator feature, had been known, written about and in widespread use for decades prior to the filing date of the ’069 patent. The ’069 patent adds nothing to the art and its claims should be found unpatentable as anticipated and/or obvious.

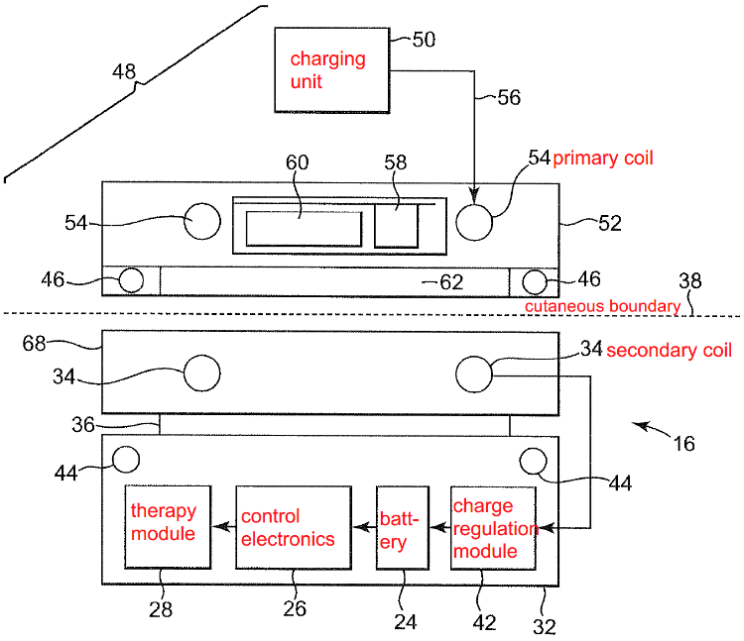
II. OVERVIEW OF THE ‘069 PATENT

A. Background and Summary of the ‘069 Patent

The ‘069 patent issued August 10, 2010, from Application No. 11/119,361 filed April 29, 2005, and does not claim priority to any earlier application. The ‘069 patent is therefore subject to the *pre*-America Invents Act (“AIA”) provisions of 35 U.S.C. §§ 102 and 103.

The ‘069 patent relates generally to a system for charging the battery inside a medical device that is implanted beneath the skin of a patient. The ‘069 patent describes such transcutaneous energy transfer system as having two main components: 1) an implantable device that includes a therapy module that stimulates tissue of the patient, electronics for driving the therapy module, and a rechargeable battery that powers the device; and 2) an external charging device that transcutaneously provides power to recharge the battery in the implantable device when placed in proximity of the implanted device.

FIG. 3 of the '069 patent, an annotated version of which is reproduced herein, is a block diagram of the system showing an implantable medical device 16 positioned under cutaneous boundary 38, and an external charging device 48. Implantable medical device 16 includes "a rechargeable power source 24, such as a Lithium ion battery, that powers electronics 26 and therapy module 28 ***in a conventional manner***." Ex. 1001, 7:16-20 (emphasis added).[1] "Therapy module 28 is coupled to [the patient] ***also conventionally***." Exhibit 1001, 7:19-20 (emphasis added). Similarly, "charging regulation [module 42] and therapy control [electronics 26 and therapy module 28] ***is conventional***." Ex. 1001, 7:45-47 (emphasis added). That is, "[e]lectronics 26 help provide control of the charging



[1] Per the '069 patent, "implantable medical device 16" of FIG. 3 "is similar to the embodiment illustrated in FIG. 2" except for breaking charging regulation module 42 off into a separate block form electronics 26. Ex. 1001, 7:42-45.

rate of rechargeable power source 24 ***in a conventional manner***." Ex. 1001, 7:29-30 (emphasis added). "Implantable medical device 16 also has "internal telemetry coil 44 configured ***in conventional manner*** to communicate through external telemetry coil 46 to [the charging unit 50] ***in a conventional manner*** in order to both program and control" implantable medical device 16 … ." Ex 1001, 7:46-51 (emphasis added).

The charging of internal battery 24 is controlled by external charging device 48 which includes a charging unit 50 that drives external primary coil 54 to induce current in internal secondary coil 34 when external primary coil 54 is placed in the proximity of internal secondary coil 34. Ex. 1001, 8:4-12. "Typically, efficiency of energy transfer will be greatest when primary coil 54 of charging unit 50 is transcutaneously optimally aligned with secondary coil 34 of implantable medical device 16." 'Ex. 1001, 19:31-34. An "alignment indicator 150 functionally provides active feedback to [the person] responsible for positioning primary coil 54 during charging of rechargeable power source 24." Ex. 1001, 19:45-48. "In a preferred embodiment, the alignment indication is based upon the amount of current actually flowing through rechargeable power source 24. It is to be recognized and understood, however, that it is not necessary that the current measured actually be the current passing through rechargeable power source 24. Alternatively, an alignment measurement may be made by measuring a value, e.g.,

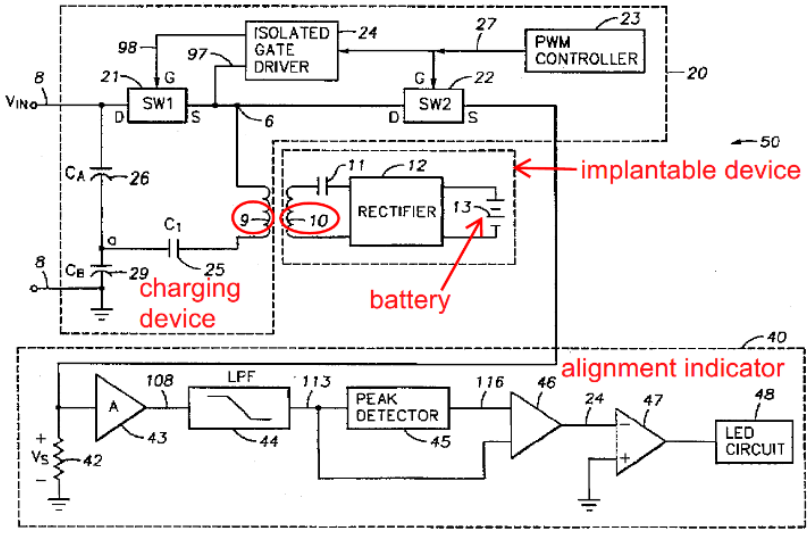
current or voltage, associated with, e.g., proportional to, the current passing through rechargeable power source 24." Ex. 1001, 20:46-54.

B. Prosecution History of the '069 Patent

The '069 patent issued after lengthy prosecution involving numerous Office Actions and significant amendments to the claims. A copy of the file history can be found at Exhibit 1002.

In relevant parts, in an Office Action dated November 14, 2007, the Examiner rejected the claims as anticipated by U.S. Patent No. 5,690,693 to Wang et al. ("Wang '693"). An annotated FIG. 3 of Wang '693 is reproduced herein.

In a response filed on February 19, 2008, the Applicant acknowledged that: "Wang et al '693 discloses a transcutaneous energy transmission device for implantable medical device. The transcutaneous energy transmission device has a primary coil **[9]** which is configured to energize a secondary coil **[10]** in an implantable medical device when placed in proximity of the secondary coil (column 8, line 51 – column 9, line 1). When switch 22 is opened, the current through the primary coil is directed to alignment indicator circuit 40 (column 8,



line 51 through column 9, line 15).” Exhibit 1002, p. 241 of 429 (reference numerals in bold added for clarity). Applicant then argued that instead of reporting the alignment as a function of the current associated with the internal power source, Wang ‘693 discloses measuring the current associated with the external power source. Exhibit 1002, p. 241 of 429.

Unpersuaded, the Examiner issued a final rejection on May 9, 2008, pointing out that Wang ‘693, at column 9, lines 1-15, does teach that “the current of the internal power source is correlated to the alignment indicator reporting alignment … .” Exhibit 1002, p. 232 of 429.

Applicant then responded, in an amendment filed August 6, 2008, by amending independent claim 1 as follows: “a current ~~associated with~~ through said internal power source,” and independent claim 21 as follows: “a current ~~in said~~ through said internal power source.” Applicant relied on the amended language in its attempt to distinguish Wang ‘693, arguing that “Wang et al ‘693 does not show, disclose or suggest, and in fact teaches away from reporting the alignment of the primary and secondary coils as a function of the current through the internal power source. Instead Wang et al ‘693 specifically discloses measuring the current associated with the external power source.” Exhibit 1002, pp. 206 of 429.

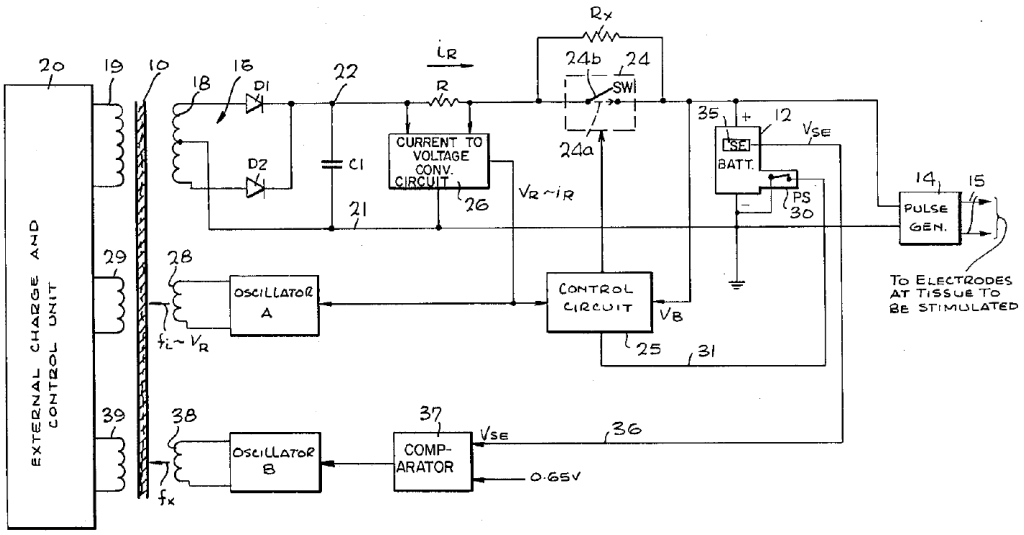
In a subsequent Office Action dated October 8, 2008, the Examiner continued to reject the claims based on Wang ‘693 explaining that the claim “does

not require the internal current to be measured, or even utilized in the determination of alignment." The Examiner referenced the following passage in the pending application: "It is to be recognized and understood, however, that it is not necessary that the current measured actually be the current passing through rechargeable power source 24. Alternatively, an alignment measurement may be made by measuring a value, e.g., current or voltage, associated with, e.g., proportional to, the current passing through rechargeable power source 24." (This passage appears in the '069 patent at 20:48-54.) The Examiner then concluded that "as long as the current utilized to determine alignment is associated with, or proportional to, the internal current, it reads on the claim." Exhibit 1002, pp. 188-189 of 429.

The Applicant, in a response dated January 7, 2009, further amended claims 1 and 21 as follows: "measuring said current and reporting said alignment ~~as a function of~~ based on said current." Exhibit 1002, pp. 172 and 174 of 429. The Applicant then relied on the amended language in its attempt to distinguish Wang '693, arguing that the measured current in Wang '693 is not "through the internal power source." Exhibit 1002, pp. 176-177 of 429.

Once again the Examiner rejected the amended claims in an Office Action dated February 19, 2009, this time as anticipated by U.S. Patent No. 4,082,097 to Mann et al. ("Mann '097"). The Examiner explained that Mann '097 discloses a

system for transcutaneous energy transfer as claimed including "an alignment indicator that is operatively coupled to the internal power source that measures a current i_R that is the current flowing through the internal power source." Exhibit 1002, p. 160 of 429. FIG. 1 of Mann '097 is reproduced herein.



In response, the Applicant argued, in an amendment filed October 19, 2009, that while Mann '097 discloses a recharging system including an external coil 19 that induces a current in an internal coil 18 with an alignment indicator which indicates proper alignment of external coil 19 with internal coil 18, it does not disclose that "the external power source varies its power output in order to generate a predetermined current in the internal power source." Exhibit 1002, p. 80 of 429.

The Examiner did not find the Applicant's argument persuasive and issued a final rejection in an Office Action dated January 27, 2010. After setting forth the operation of the system in Mann '097, the Examiner concluded that "the power

output from the external power source is varied in order to achieve a predetermined current." Exhibit 1002, p. 63 of '429.

The '069 patent was ultimately allowed after the Applicant amended the rejected claims to add the limitation "automatically" as follows: "wherein said external power source automatically varies its power output in order to generate a predetermined current in said internal power source." The Applicant then argued that Mann '097 does not disclose that "the external power source automatically varies its power output in order to generate a predetermined current in the internal power source. Rather, the user is merely informed that the alignment of the coils is off by the particular lights which are illuminated." Exhibit 1002, p. 54 of 429 (emphasis in original). It should be noted that Mann '097 does in fact teach varying the power output by the external charger based on feedback signal received from the implanted device (i.e., automatically) in order to generate a predetermined current in the internal power source . At column 10, lines 24 to 34, for example, Mann '097 discloses that a voltage Vi "whose amplitude is related to the charging current amplitude … is used as a feedback signal to the charge power source in the [external] console to control the power provided by the power source, so that when the charge head 55 is properly aligned against the skin with respect to the implanted pacer the charging current is at a desired amplitude … ."

III. PROPOSED CLAIM CONSTRUCTION

Axonics provides proposed constructions under Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) for the term "measuring said current" recited in claim 5 of the '069 patent. The remaining terms should be given their plain and ordinary meaning.

A. "Measuring said Current"

Independent claim 5 of the '069 patent recites "generating a current through said internal power source" followed by "measuring said current." In the context of the '069 patent and its prosecution history, the phrase "measuring said current" should be construed to mean "measuring the actual current through the internal power source."

With respect to the "current" that is measured as recited in claim 5, the '069 patent includes the following broadening language: "It is to be recognized and understood, however, that it is not necessary that the current measured actually be the current passing through rechargeable power source 24. Alternatively, an alignment measurement may be made by measuring a value, e.g., current or voltage, associated with, e.g., proportional to, the current passing through rechargeable power source 24." Ex. 1001, 20:48-54. During prosecution, however, there were at least two instances where Applicant submitted amendments and

remarks that compel limiting the measured current to the actual current through, not a current associated with, the internal power source.

As discussed in greater detail above under section II.B., in response to an Examiner rejection based on prior art Wang '693, Applicant amended independent claim 1 as follows: "thereby generating a current ~~associated with~~ through said internal power source." In its attempt to distinguish Wang '693, Applicant argued that "Wang et al '693 does not show, disclose or suggest, and in fact teaches away from reporting the alignment of the primary and secondary coils as a function of the current through the internal power source. Instead Wang et al '693 specifically discloses measuring the current associated with the external power source." Exhibit 1002, p. 206 of 429 (emphasis in original). By deleting the words "associated with" and replacing them with "through" when characterizing the current through the internal power source, Applicant expressly limited the scope of the phrase to the actual current through the internal power source, relinquishing any broader scope that might have been otherwise contemplated by the above broadening language in the detailed description of the '069 patent.

More specifically directed to the claim term "measuring said current," in a subsequent Office Action, the Examiner pointed precisely to the same broadening passage from the '069 patent (20:48-54) in maintaining the rejection of the claims first pointing out that the claim "does not require the internal current to be

measured, or even utilized in the determination of alignment," and then concluding that "as long as the current utilized to determine alignment is associated with, or proportional to, the internal current, [prior art Wang '693] reads on the claim." Exhibit 1002, pp. 188-189 of 429. Acquiescing to the Examiner's characterization, in its response Applicant further amended the claims introducing the term "measuring said current" and then relied on the amended language arguing that the measured current in Wang '693 is not "through the internal power source." Exhibit 1002, pp. 176-177 of 429. *See, e.g.*, *Convolve, Inc. v. Compaq Computer Corp.*, 812 F.3d 1313, 1324 (Fed. Cir. 2016) (limiting acoustic noise to "seek acoustic noise" based on claim amendments and arguments to overcome prior art stating that acoustic noise in the claim is limited to noise generated by the seek function while the prior art discloses acoustic noise generated by a spindle motor); *Energy Trans. Grp., Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1359-60 (Fed. Cir. 2012) (finding patentee relinquished scope of patent method of cancelling feedback "that involve[s] 'determining'—rather than 'measuring'—phase and amplitude").

Based on these instances of claim amendments and the accompanying arguments made by the Applicant during prosecution, the phrase "measuring said current" must be construed to mean "measuring the actual current through the internal power supply" and not a current associated with or proportional to the

actual current. *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1335 (Fed. Cir. 2004) (claim construction must take into account "the prosecution history to determine whether the patentee relinquished claim coverage by amendment or through argument to overcome or distinguish a reference").

IV. FACTUAL BACKGROUND

A. Declaration of Evidence

This Petition is supported by the declaration of Dr. Dorin Panescu (Ex. 1003). Dr. Panescu earned a B.S. in Electronics and Telecommunications from the Polytechnic Institute of Timisoara, Romania in 1985, and a M.S. and a PhD. in Electrical and Computer Engineering from the University of Wisconsin-Madison in 1991 and 1993, respectively. Dr. Panescu has over 25 years of direct technical experience in electrical medical device technology including systems with implantable medical devices like those in the claims at issue. Dr. Panescu is an inventor on over 170 issued U.S. patent and is the author of over 150 industry publications. Additional details regarding Dr. Panescu's background are provided in Exhibit 1004.

B. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") is a hypothetical person presumed to know the relevant prior art, including the references discussed in this Petition. *See, e.g.*, *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013)

("[T]he knowledge of [a person of ordinary skill in the art] is part of the store of public knowledge that must be consulted when considering whether a claimed invention would have been obvious."). A POSITA at the time of the claimed 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.

V. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS FOR CANCELLATION (37 C.F.R. § 42.22(A) AND 42.104(B))

The Board is requested to find that there is a reasonable likelihood that Axonics will establish that each of claims 5 through 9 of the '069 patent is invalid in light of the teachings of the following references, alone or in combination with each other:

- U.S. Patent No. 3,942,535, issued March 9, 1976 ("Schulman"), Ex. 1005.
- "A Long-Lived, Reliable, Rechargeable Cardiac Pacemaker", by R.E. Fischell et al., published 1975, ("Fischell"), Ex. 1006.
- U.S. Patent No. 6,227,204, issued May 8, 2001, ("Baumann"), Ex. 1007.

Each of the listed references was published more than one year before the '069 patent's priority date of April 29, 2005, and is therefore prior art under pre-

AIA 35 U.S.C. §102(b). Schulman and Fischell were not before the examiner during prosecution of the ’069 patent, and while Baumann was disclosed by the Applicant, Baumann was not substantively raised during prosecution.

As discussed in greater detail under Section II.A., the ‘069 patent generally describes a system for transcutaneous energy transfer between an implanted medical device with an internal power source (rechargeable battery) and an external power source (charging device). The external power source includes a primary coil and the implanted medical device includes a secondary coil. Placing the external power source in proximity of the implanted medical device generates, via inductive coupling, a charging current in the internal power source. Ex. 1001, Abstract. The ‘069 patent admits that such systems were generally known in the art and characterizes much of the functionality of the claimed system as being implemented “in a conventional manner.” Ex. 1001, 7:16-64. The purported novelty it claims relates to “[a]n alignment indicator [that] reports the alignment as a function of the current generated in the internal power source.” Ex. 1001, Abstract.

The listed prior art references similarly address systems for transcutaneous energy transfer with alignment indicators and optimized methods for recharging of batteries in implanted devices. Schulman is directed to a rechargeable implantable medical device with external charging controlled by telemetered maximum

charging current indicating optimal charging alignment. Fischell discloses a system including a rechargeable implantable cardiac pacemaker that telemeters sensed battery charge current to an external charger, based on which alignment of the external charger with the implanted pacer is optimized. Baumann discloses an improved system and method for charging of rechargeable batteries of implanted medical devices by transcutaneous transmission of power from an external charging device. Petitioner therefore respectfully requests that the Board cancel the challenged claims of the ’069 patent based on the following grounds:

- Ground 1: Claims 5 and 8 are unpatentable as anticipated by Schulman.
- Ground 2: Claims 5 and 8 are unpatentable as anticipated by Fischell.
- Ground 3: Claims 6, 7 and 9 are unpatentable as obvious over Schulman in view of Bauman.
- Ground 4: Claims 6, 7 and 9 are unpatentable as obvious over Fischell in view of Bauman.

The scope and content of the references and their application to the claims are more specifically discussed below under the separate grounds for unpatentability.

A. Ground 1: Claims 5 and 8 are unpatentable as anticipated by Schulman

1. Schulman

U.S. Patent No. 3,942,535 to Joseph H. Schulman ("Schulman"), Ex. 1005, issued on March 9, 1976, claiming priority to parent application filed on September 27, 1973. With an issue date nearly three decades before the earliest priority date of the '069 patent (April 29, 2005), Schulman qualifies as prior art under 35 U.S.C. §102(b).

Schulman discloses "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. "A constant current power source acting through an induction coil externally located with respect to a living patient is used to induce current flow in a charging circuit located beneath the skin of the patient." Ex. 1005, Abstract. In connection with FIG. 1, reproduced herein, Schulman describes "a rechargeable tissue stimulating system comprising a charging circuit 10 including a telemetry circuit 12 and a tissue stimulator 11 including a catheter 16, all designed for implantation into the body of a living patient. The system further includes a power source 13 with a 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." Ex. 1005, 3:42-50.

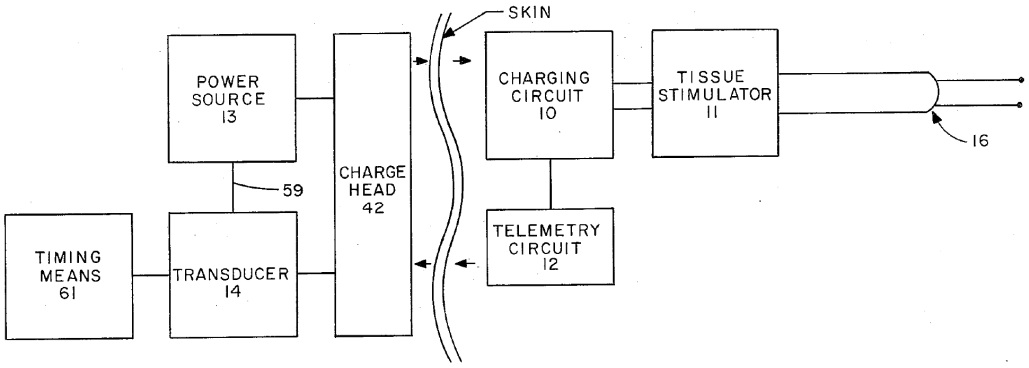


FIG. 1

Schulman further teaches that the "external electrical charging power source [includes] an induction coil for positioning external to a living subject and proximate to the induction coil of the implantable charging circuit" and that the telemetry circuit in the implantable device detects "the magnitude of charging current receive by" the internal battery and reports it to the external power source. Ex. 1005, 2:37-46. The transducer in the external charging source converts the received signal into an "electrical control signal" that is used to "adjust the strength of the magnetic field applied to said implantable charging circuit." Ex. 1005, 2:46-52.

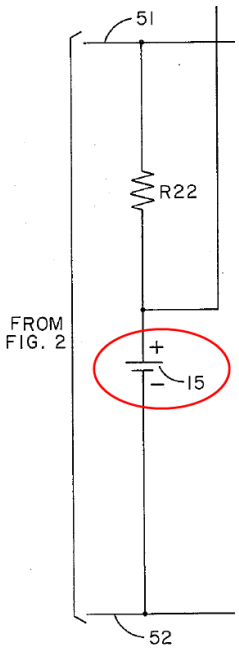
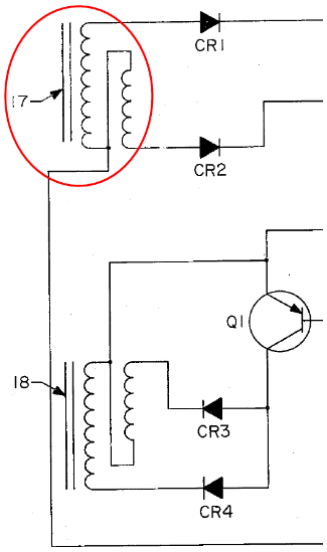
With respect to alignment, Schulman teaches that as "the induction coils of the power source are moved closer to a proper charging relationship with respect to the induction coil of the implanted charging circuit, … the frequency of magnetic field strength peak amplitude will increase." Ex. 1005, 6:28-32. When "this frequency increases sufficiently to indicate that the maximum charging current" has been reached, the "electrical control signal generated in transducer 14 by the

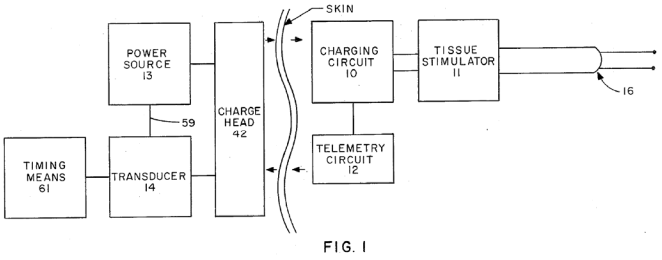
magnetic output signal from telemetry circuit 12 will produce changes in the regulation of the power source 13." Ex. 1005, 6:32-38. Among these changes are "altering the condition of the charging status indicating light emitting diodes … to indicate that proper charging of the tissue stimulating system is occurring." Ex. 1005, 6:38-45.

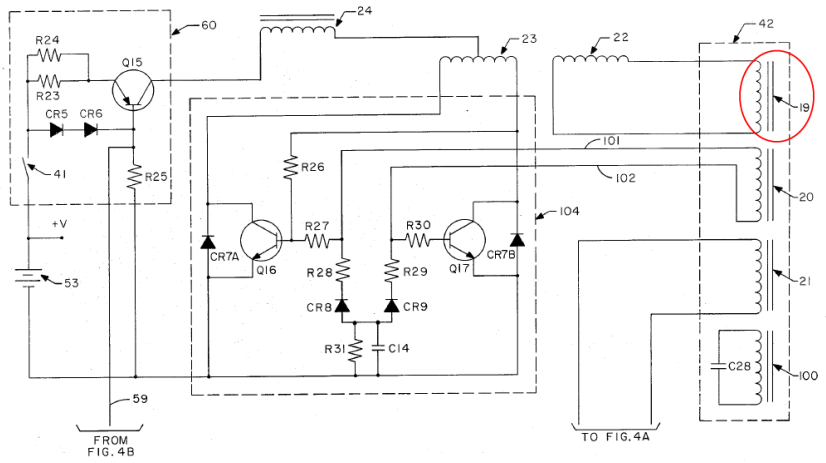
2. Applying Schulman to Claims 5 and 8

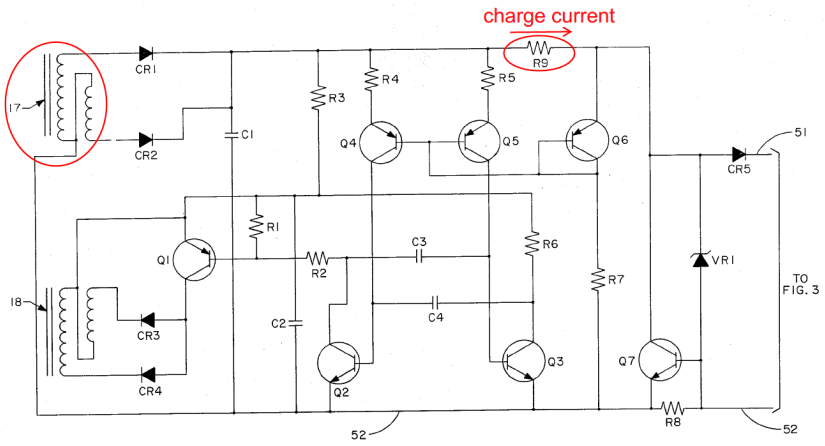
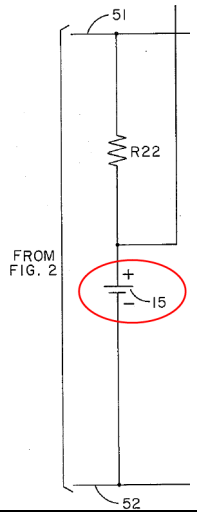
Schulman teaches every limitation of claims 5 and 8 of the '069 patent, as set forth in greater detail in the following charts.

	Claim 5	Schulman
5.0	A system for transcutaneous energy transfer, comprising:	*Petitioner does not here advocate that the preamble limits the scope of the claim.* "This invention 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 telemetry circuit." [Ex. 1005, 1:7-11, emphasis added]
5.1(a)	an implantable medical device having componentry for providing a therapeutic output,	"In a broad aspect this invention is a rechargeable tissue stimulating system comprising: ***an implantable electrical tissue stimulator including*** a rechargeable d.c. voltage source for powering an electronic generator used for applying electrical pulses ***to stimulate living tissue in order to maintain bodily functions of a living subject*** into which it is implanted." [Ex. 1005, 2:27-33, emphasis added]

	Claim 5	Schulman
5.1(b)	said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source,	"An implantable electrical tissue stimulator including a rechargeable d.c. voltage source" [Ex. 1005, 2:28-30] *Partial view of FIG. 3 reproduced herein shows "rechargeable d.c. voltage" or "battery 15" ("*internal power source"*) and connects between leads 51 and 52.*  "The charging circuit is illustrated in FIG. 2 and includes two induction coils 17 and 18. The output leads 51 and 52 from the induction coil 17 are rectified and are connected to the tissue stimulator of FIG. 3." [Ex. 1005, 59-62]  *Partial views of FIG. 2, reproduced herein shows "induction coil 17" ("*secondary coil"*). See Ex. 1003, ¶¶ 65-66 & 82-83.*
5.1(c)	said implantable medical device	"Referring now to FIG. 1, there is illustrated a rechargeable tissue stimulating system comprising a charging circuit 10 including a telemetry circuit 12 and a

	Claim 5	Schulman
	adapted to be implanted in a patient;	tissue stimulator 11 including a catheter 16, ***all designed for implantation into the body of a living patient***." [Ex. 1005, 3:42-46, emphasis added]  FIG. 1
5.2(a)	an external power source having a primary coil,	"[A]n external electrical charging power source including an induction coil." [Ex. 1005, 2:36-40]
5.2(b)	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	"[A]n external electrical charging power source including an induction coil for positioning external to a living subject and proximate to the induction coil of the implantable charging circuit." [Ex. 1005, 2:36-40] "Returning to the [external] power source illustrated in FIG. 4, a current control means 60 produces a constant current flow at its output into the induction coil 24." [Ex. 1005, 9:7-11] "This current flow is transformer coupled to the secondary 22 and connected from there to the ***coil 19 on the charging head***." [Ex. 1005, 7:46-48, emphasis added]

	Claim 5	Schulman
	coil of said implantable medical device	 FIG. 4 "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." [Ex. 1005, 7:29-33, emphasis added] *Schulman teaches an external power source providing energy to the implanted device 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. The energy transfer through the inductive coupling between external coil 19 and internal coil 17 is explained in greater detail below in connection with the alignment aspect of the claim. See Ex. 1003, ¶¶ 65-66 & 82-83.*

	Claim 5	Schulman
5.2(c)	and thereby generating a current through said internal power source;	"The charging circuit is illustrated in FIG. 2 and includes two induction coils 17 and 18. The output leads 51 and 52 from the induction coil 17 are rectified and are connected to the tissue stimulator of FIG. 3." [Ex. 1005, 3:59-62]. *Annotated FIG. 2 depicting internal charging circuit 10 is reproduced herein:*  "Charging current passes through the current sampling resistor R9 and through the diode CR5 to the tissue stimulator." [Ex. 1005, 4:11-13] "All current up to a maximum level will flow through the rectified output leads 51 and 52 to charge the battery 15." [6:17-19]  *Schulman teaches that the inductive coupling generates a "charging*

	Claim 5	Schulman
		current" that flows through the internal battery. See Ex. 1003, ¶¶ 65-66, 82-83.
5.3(a)	an alignment indicator, operatively coupled to said internal power source,	"As the induction coils of the power source are moved closer to a proper charging relationship with respect to the induction coil of the implanted charging circuit, 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. These changes include altering the condition of the charging status indicating ***light emitting diodes 26 and 27,*** and altering the activation status of the ***buzzer 28***." [Ex. 1005, 6:28-41, emphasis added] *Schulman teaches an alignment indication based on feedback from telemetry circuit that is coupled to the internal power source. See Ex. 1003, ¶ 96.* "The operator of the charging system is thereby appraised that the cell 15 is not being properly charged by the ***flashing yellow light from the light emitting diode 27 and by the intermittent buzzer 28. This is an indication*** to him to adjust the position of the charging head 42 containing the induction coils 19, 20 and 21 ***to more properly align*** these induction coils with the induction coils 17 and 18 of the charging circuit 10. Once proper

	Claim 5	Schulman
		alignment has been achieved, the yellow light 27 and the buzzer 28 will be rendered inactive and the green light 26 will be continuously lighted as long as the charging head 42 remains in place and at least the operating current is maintained through the resistor R9." [Ex. 1005, 9:44-57, emphasis added]
5.3(b)	measuring said current and reporting an alignment between said primary coil and said secondary coil based on said current; and	"As the induction coils of the power source are moved closer to a proper charging relationship with respect to the induction coil of the implanted charging circuit, the period t in FIG. 9 will decrease. That is, the frequency of magnetic field strength peak amplitude will increase when this frequency increases sufficiently to indicate that the ***maximum charging current across resistor R9 has been reached***. 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. These changes include altering the condition of the charging status indicating light emitting diodes 26 and 27, and altering the activation status of the buzzer 28." [Ex. 1005, 6:28-41, emphasis added] "None of this will affect the charging of the battery 15, however, ***unless the current flowing through resistor R9 drops below its operating level***. This will be sensed by the transducer circuit 14 which ***will deactivate the*** green

	Claim 5	Schulman
		light emitting diode 26 and activate the intermittent operation of the ***buzzer 28 and yellow light emitting diode 27***." [9:67-10:4, emphasis added] *Schulman teaches measuring the level of charging current into the internal battery and reporting alignment based on the level of that current. See Ex. 1003, ¶ 96.*
5.4	wherein said external power source automatically varies its power output in order to generate a predetermined current in said internal power source.	"***[A]ny current less than this maximum*** passing through resistor R9 ***is indicative of inadequate charging*** of the battery 15. It is the telemetry circuit 12 (previously described) which senses this condition and signals the condition back to the induction coil 21 by modulating the frequency of the amplitude peak fluctuation of the charging field … 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***. These changes include … generating a signal on circuit 59 to alter the output of the current control means 60." [Ex. 1005, 6:19-43, emphasis added] "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***

	Claim 5	Schulman
		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." [Ex. 1005, 7:20-33, emphasis added] "It should be noted, that when a current larger than the operating current exists through the resistor R9, … a current control signal on line 59 will act to reduce the intensity of the magnetic field, and thereby reduce the current flowing through the resistor R9." [Ex. 1005, 9:57-65, emphasis added] *Schulman teaches that the implanted charging circuit provides feedback via a telemetry circuit to automatically adjust the power that is output by the external power source in order to maintain battery charging current at a maximum operating level ("predetermined current"). See Ex. 1003, ¶¶ 85-95.*

Schulman similarly teaches all limitations of claim 8 as set forth in the chart below.

	Claim 8	Schulman
	The system as in claim 5 wherein said predetermined current in said internal power source comprises a maximum amount of current for charging said internal power source.	"All ***current up to a maximum level*** will flow through the rectified output leads 51 and 52 to charge the battery 15." [Ex. 1005, 6:17-19, emphasis added] "[A]ny current less than this maximum passing through resistor R9 is indicative of inadequate charging of the battery 15." [6:19-21] "[W]hen 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." [Ex. 1005, 7:25-29, emphasis added]

B. Ground 2: Claims 5 and 8 are unpatentable as anticipated by Fischell

1. Fischell

The book titled "Advances in Pacemaker Technology," edited by M. Schaldach and S. Furman and published in 1975, includes, in Chapter 5, the article titled "A LONG-LIVED, RELIABLE, RECHARGEABLE CARDIAC PACEMAKER" by R.E. Fischell, K.B. Lewis, J.H. Schulman, and J.W. Love ("Fischell"), Exhibit 1006. Fischell was accessible to public at least as of April 7,

1976, as evidenced by the declaration, Ex. 1008, of Rachel J. Watters, the librarian and Director of Wisconsin TechSearch, at the University of Wisconsin-Madison. With a publication date decades before the earliest priority date of the '069 patent (April 29, 2005), Fischell qualifies as prior art under 35 U.S.C. §102(b).

Fischell is directed at rechargeable cardiac pacemakers utilizing "[a] new rechargeable cell specifically adapted for use at body temperature" that improves the reliability of the pacemaker system. Ex. 1006, p. 357. After a brief description of the history of development of implantable rechargeable cardiac pacemakers, dating as far back as 1958, Fischell defines the design goals for the implantable rechargeable pacer system as one that "1. Did not use any life-limiting components. 2. Could be recharged by the patient at home. …" Ex. 1006, p. 358-359.

FIG. 8 of Fischell, reproduced herein, is 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"

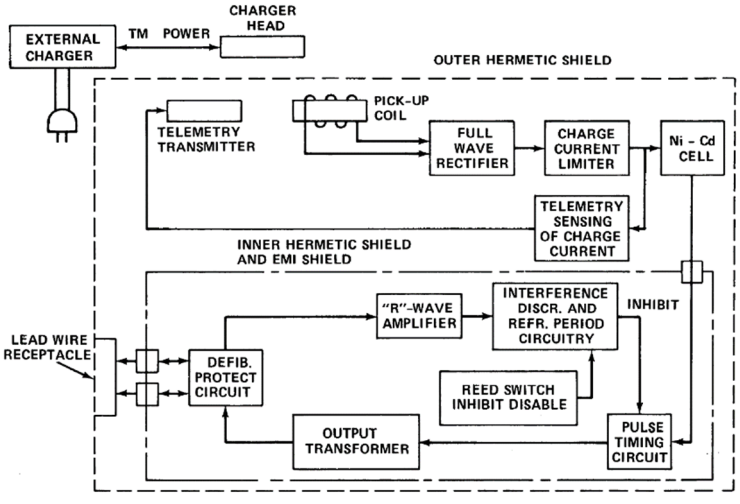


Fig. 8 Block diagram of rechargeable demand pacemaker

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, "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, pp. 372-373.

With respect to alignment, Fischell teaches that the patient puts on a Velcro vest and "locates the charger head onto the Velcro vest over the site of the implanted pacer until

a. the beeping sounds stops,

b. the amber light goes off, and

c. the green light comes on."

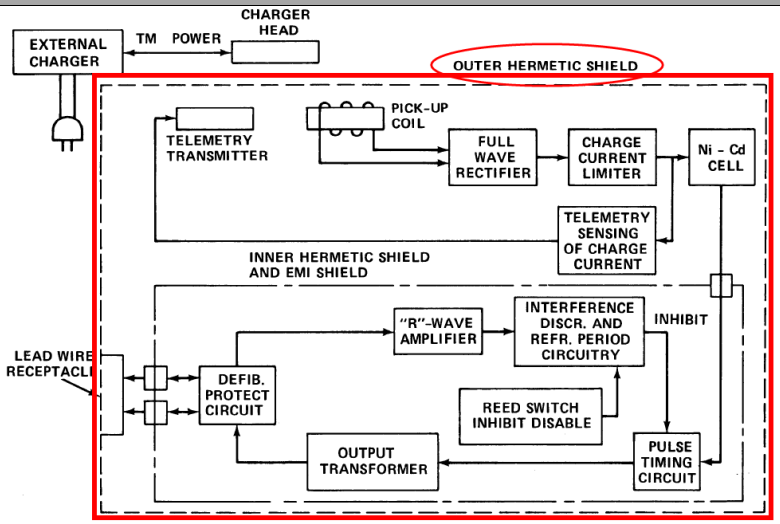
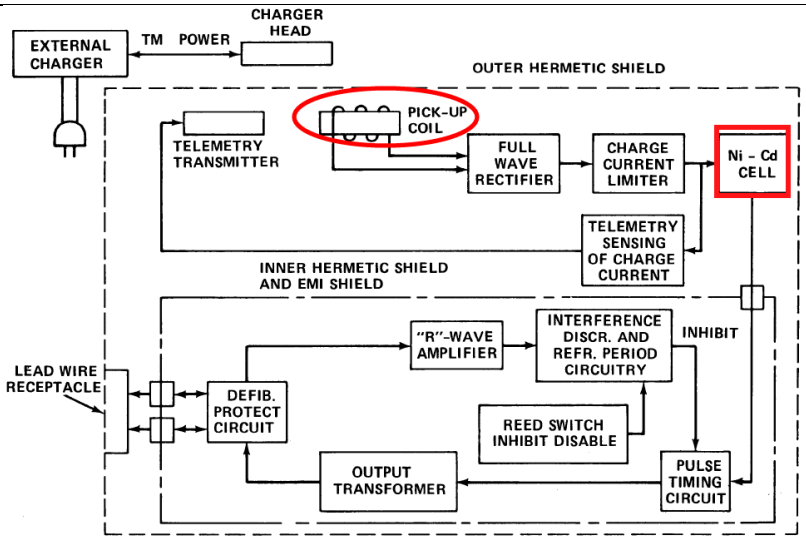
"The absence of the beeping noise and flashing amber light and the presence of the green light indicate to the patient that the nickel-cadmium cell is being charged at the proper level ... Should the charger head become misaligned during the charging process, the patient will be promptly informed of this fact by

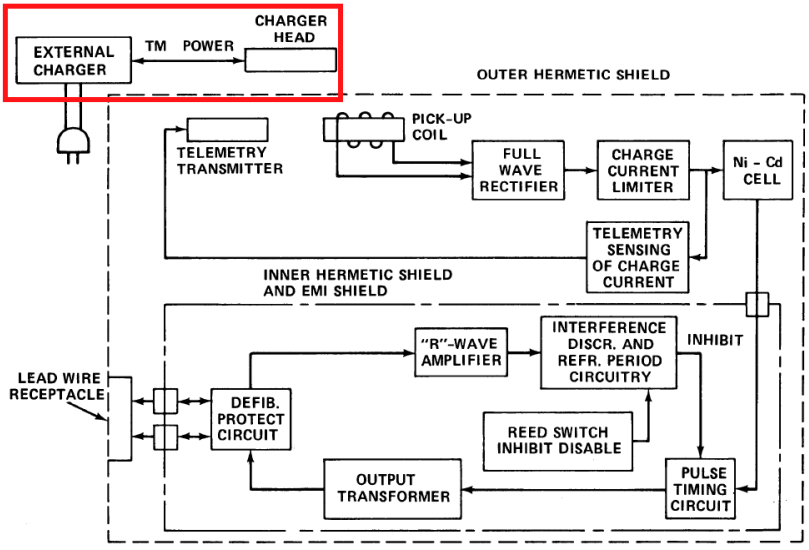
the reappearance of the beeping sound and the flashing amber light." Ex. 1006, pp. 377-378.

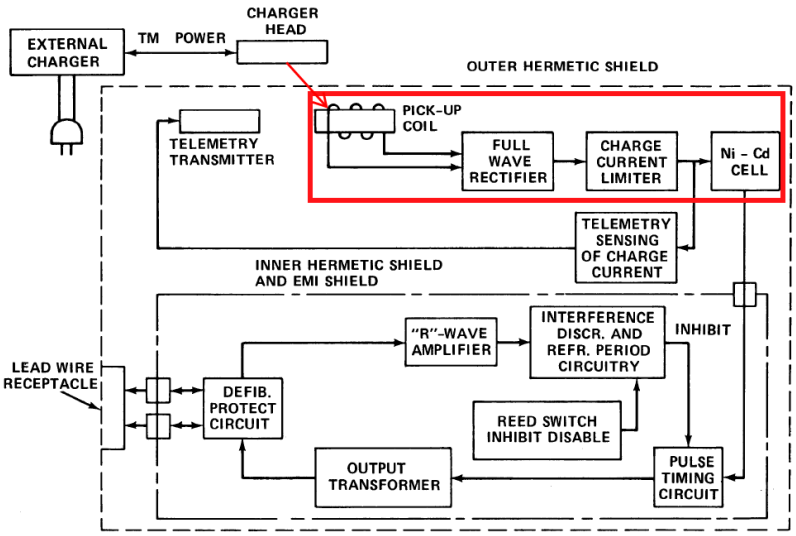
2. Applying Fischell to Claims 5 and 8

Fischell teaches every limitation of claims 5 and 8 of the '069 patent, as set forth in greater detail in the following charts.

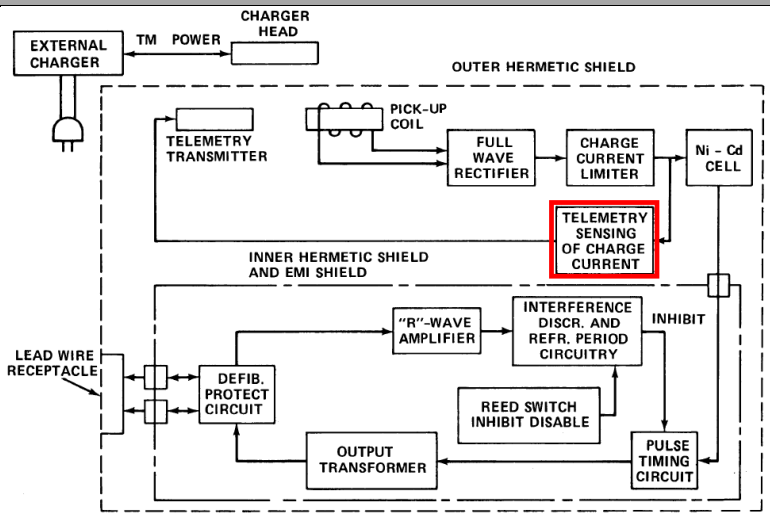
	Claim 5	Fischell
5.0	A system for transcutaneous energy transfer, comprising:	*Petitioner does not here advocate that the preamble limits the scope of the claim.*
5.1(a)	an implantable medical device having componentry for providing a therapeutic output,	"The concept of using a rechargeable cell for an ***implantable cardiac pacemaker*** is not new." Ex. 1006, p. 357, emphasis added] *FIG. 8 of Fischell, reproduced below, shows a "block diagram of rechargeable demand pacemaker" with a "Ni-Cd Cell" (battery) having an "outer hermetic shield" that is implanted in the body of a patient.*

	Claim 5	Fischell
		 Fig. 8 Block diagram of rechargeable demand pacemaker
5.1(b)	said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source,	 Fig. 8 Block diagram of rechargeable demand pacemaker "When the external charger applies an alternating magnetic field which is picked up through the intact skin by the ***pulse generator's pickup coil*** ..." [Ex. 1006, p. 372, emphasis added] "[O]ne can envision that the useful life of an implantable pacemaker would not be limited by cycle life if the ***nickel-cadmium cell*** is of the space type

	Claim 5	Fischell
		with hermetic sealing." [p. 364, emphasis added] *See highlighted components of FIG. 8, namely, pick-up coil 9 ("secondary coil") and Ni-Cd Cell ("internal power source)."*
5.1(c)	said implantable medical device adapted to be implanted in a patient;	"The concept of using a rechargeable cell for an ***implantable cardiac pacemaker*** is not new." [Ex. 1006, p. 357, emphasis added]
5.2(a)	an external power source having a primary coil,	 Fig. 8 Block diagram of rechargeable demand pacemaker "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, pp. 372-373]

	Claim 5	Fischell
		Fischell teaches that the external charger includes a "charger head" that "applies an alternating magnetic field" which would be through an inductive coil ("primary coil"). Fischell discloses an inductive coil for "charger head" of the rechargeable pacemaker in FIG. 6. [Ex. 1006, p. 368; see Ex. 1003, ¶¶ 99-100]
5.2(b)	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 through	 Fig. 8 Block diagram of rechargeable demand pacemaker "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, pp. 372-373] *As depicted in FIG. 8, Fischell teaches that the energy supplied by the external primary coil and picked up by the internal secondary "pick-up coil" is*

	Claim 5	Fischell
	said internal power source;	*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). See Ex. 1003, ¶¶ 99-100.*
5.3(a)	an alignment indicator, operatively coupled to said internal power source,	"The patient then locates the charger head onto the Velcro vest over the site of the implanted pacer until a. the beeping sounds stops, b. the amber light goes off, and c. the green light comes on." "The absence of the beeping noise and flashing amber light and the presence of the green light ***indicate to the patient that the nickel-cadmium cell is being charged at the proper level***." "Should the charger head become misaligned during the charging process, the patient will be promptly informed of this fact by the reappearance of the beeping sound and the flashing amber light." [Ex. 1006, pp. 377-378, emphasis added] *Fischell teaches that alignment indicator lights and beeping sounds operate in response to a charge level of the battery and are therefore operatively coupled to the battery. See Ex. 1003, pp. 103-104.*

	Claim 5	Fischell
5.3(b)	measuring said current and reporting an alignment between said primary coil and said secondary coil based on said current; and	 Fig. 8 Block diagram of rechargeable demand pacemaker *FIG. 8 explictly shows a block identified as the "telemetry sensing of charge current" whose input taps the node between the "charge current limiter" and the "Ni-Cd cell," and whose output is coupled to the "telemetry transmitter" block. Fischell, at Table 3, partially reproduced below, identifies telemetry of battery charge current occurring by means of an FM output from the pulse generator. See Ex. 1003, pp. 100-104.* **Battery charge current telemetry** — **by pulse rate measurement and by means of FM output from pulse generator** [Table 3, p. 370] "Two types of telemetry systems that can provide the doctor and the patient with valuable information are availble from the pacer, namely: a. telemetry by

	Claim 5	Fischell
		means of pulse rate to measure battery voltage, and b. ***telemetry*** by means of a frequency modulated signal from the pusle generator into the external charger ***to measure and control charge current into the battery***." [Ex. 1006, pp. 371-372, emphasis added] "The absence of the beeping noise and flashing amber light and the presence of the green light ***indicate to the patient that the nickel-cadmium cell is being charged at the proper level***. A feedback control system in the charger maintains the battery charge current at the proper 40 mA level, even though the charger head is varied considerably in its position relative to the implanted pulse generator." "Should the charger head become misaligned during the charging process, the patient will be promptly informed of this fact by the reappearance of the beeping sound and the flashing amber light." [Ex. 1006, p. 378, emphasis added] *Fischell teaches the activation of different lights indicating proper alignment based on the level of charge current into the battery. The proper level of charging is identified as a charge current through the battery having a value of 40 mA. Thus, via activation of different indicators lights, alignment is reported based on a measured current through the nickel-*

	Claim 5	Fischell
		cadmium cell. See Ex. 1003, pp. 103-104.
5.4	wherein said external power source automatically varies its power output in order to generate a predetermined current in said internal power source.	"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. The external charger detects this frequency (which is picked up by the charger head) and ***closed-loop controls the battery charge current to a value of 40 mA***." [Ex. 1006, pp. 372-373, emphasis added] "A ***feedback control system*** in the charger ***maintains*** the battery ***charge current at the proper 40 mA level***, even though the charger head is varied considerably in its position relative to the implanted pulse generator." [Ex. 1006, p. 378, emphasis added] *Fischell thus teaches a feedback telemetry system that automatically adjusts the power of the external charger in order to generate battery charge current at 40 mA ("predetermined current"). See Ex. 1003, ¶¶ 101-103.*

Fischell similarly teaches the limitation recited in claim 8 as set forth in the chart below.

	Claim 8	Fischell
	The system as in	"The charging circuit for the rechargeable pacer ***limits the charge (and overcharge) current*** into the

	Claim 8	Fischell
	claim 5 wherein said predetermined current in said internal power source comprises a maximum amount of current for charging said internal power source.	battery to 40 mA." [Ex. 1006, p. 367, emphasis added] "A feedback control system in the charger maintains the battery charge current at the proper 40 mA level." [Ex. 1006, p. 378]

C. Ground 3: Claims 6, 7 and 9 are unpatentable as obvious over Schulman in view of Baumann

1. Baumann

U.S. Patent No. 6,227,204 to Joachim Baumann et al. ("Baumann"), Exhibit 1007, titled "DEVICE AND PROCESS FOR CHARGING OF RECHARGEABLE BATTERIES OF IMPLANTS," issued on May 8, 2001, claiming priority to parent application filed on August 21, 1998. With an issue date nearly four years before the earliest priority date of the '069 patent (April 29, 2005), Baumann qualifies as prior art under 35 U.S.C. §102(b).

In an Information Disclosure Statement submitted on June 22, 2005, the '069 Applicant identified Baumann in a list that included 62 references. Baumann,

however, was never mentioned or argued in any office action or response, and therefore was never raised substantively at any point during prosecution by either the Examiner or the '069 Applicant. *See, e.g.*, *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2018-01247, 2019 WL 214935, at *18 (PTAB Jan. 15, 2019) (granting institution on grounds relying in prior art cited in Examiner's Notice of References Cited and presented to the Examiner in an Information Disclosure Statement when there was "no indication that the Examiner [] ever considered the combinations presented in the Petition").

Moreover, the combination of Schulman and Baumann was not at any point before the Examiner. *See, e.g.*, *ZTE (USA) Inc., v. Bell N. Research, LLC*, IPR2019-013652020 WL 698725, at *3 (PTAB Feb. 11, 2020) ("Although the Examiner considered Irvin during prosecution, . . . Irvin *in combination with Mullymäki and/or Bodin* is not the same or substantially the same prior art previously presented to the Office. Moreover, even if Mullym*ä*ki and/or Bodin were deemed to disclose the same subject matter as a reference [] previously considered by the Examiner, we consider the error by the Examiner in considering Irvin . . . to outweigh the fact that the same or similar art was before the Examiner during prosecution.").

With respect to the substantive teachings of Baumann, with reference to FIG. 1, reproduced below, Baumann discloses "[a] device and a process for

charging of rechargeable NiCd, Ni-metal hydride or lithium batteries (12) of implants by transcutaneous transmission of electric power from an external power transmission part (11) to a power receiving part (10) which forms a part of the implant." Ex. 1007, Abstract. The charging device includes "a charging current detector (27, 32, 34)" that divides the charging of the internal battery (12) into two phases. *Id.*

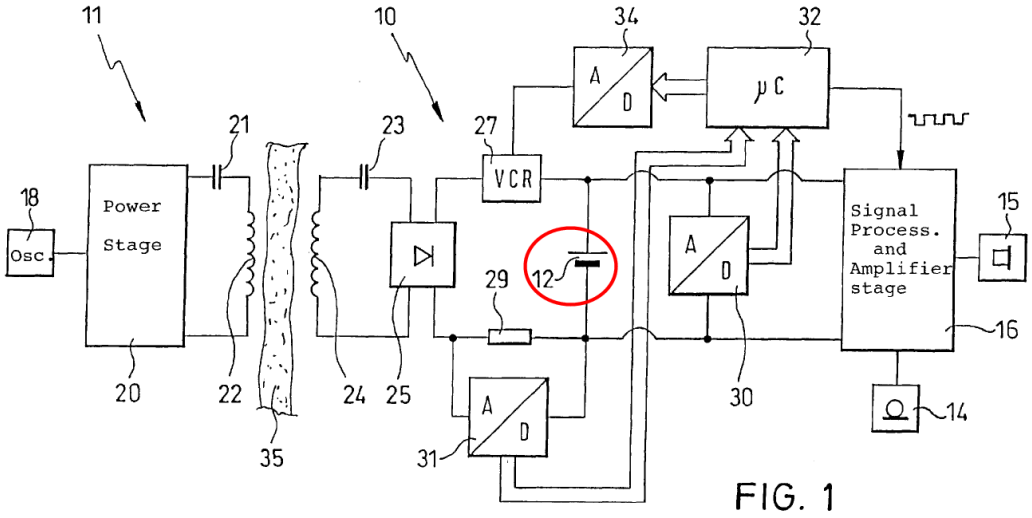


FIG. 1

As depicted in FIG. 3 of Baumann, "in a first charging phase (T1) [the charging current detector] allows a relatively high charging current (I_L) to flow and which, after the cell voltage (U_Z) of the battery has reached a predetermined limiting charging voltage (U_G), in a second charging phase (T2), reduces the charging current as compared to the

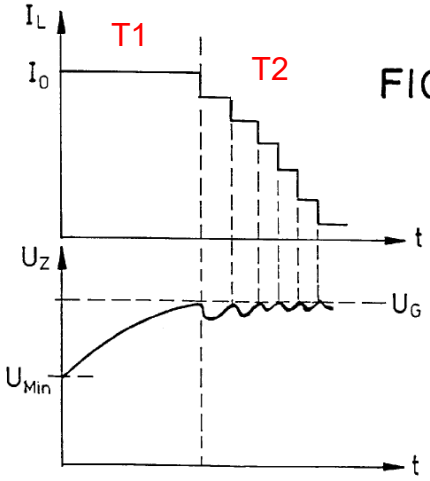


FIG. 3

charging current which flows at the end of the first charging phase." Ex. 1007, Abstract.

Baumann therefore teaches that the battery charging current varies as a function of the voltage of the battery, and further, that the battery charging current starts to decrease when voltage of battery reaches a predetermined limiting charging voltage U_G.

Baumann also teaches that: "the charging of the battery is regulated depending on the internal resistance of the battery. It is ensured that the cell is charged only with as much energy as the electrochemical state allows, without excess gassing or heating of the cell occurring. Older cells with increasing internal resistance, in this way, acquire less charge than new cells." Ex. 1007, 2:33-40.

2. The Combination of Schulman in view of Baumann

The Federal Circuit has found that motivation to combine two references exists in analogous art directed toward the same problem. *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011) (finding motivation to combine art regarding utility lighters and art cigarette lighters that both identify problem of making lighters more safe). Both Schulman and Bauman relate to the same field of rechargeable implanted medical devices. A POSITA would have been motivated to combine Schulman with Baumann for several reasons. Baumann discloses a battery charging protocol that maximizes charging speed while

minimizing risk of harmful charging condition. Ex. 1007, 2:15-22. This is achieved via a two phase charging protocol. These two phases include a constant current phase to achieve "charging as fast as possible" (Ex. 1007, 4:65-5:5 and FIG. 2), and a constant voltage phase with a limiting voltage "selected such that the battery cannot be damaged during charging" (Ex. 1007, 5:22-23 and FIG. 3).

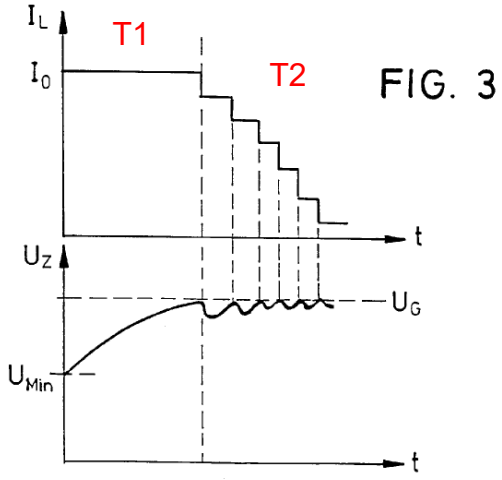
"[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). As in Baumann, Schulman includes a rechargeable battery in the implanted device. Schulman is similarly concerned with potentially harmful over-current and over-voltage conditions and provides safety features ("shunt current regulator") to maintain an acceptable charging current and to set a predetermined maximum battery voltage. Ex. 1005, 5:2-59. A POSITA would have been motivated to incorporate the teachings of Baumann into Schulman to not only realize decreased charging time, but to also improve on the safety and reliability features of the system.

Further, Schulman and Baumann described Ni-Cd batteries as being a type suitable for implantable device because of their larger charge capacity and long service life. Ni-Cd batteries were known for their reduced internal resistance and larger output current capabilities. Baumann teaches charging batteries with

significantly higher nominal capacity as compared to Schulman. A POSITA would have been motivated to incorporate the teachings of Baumann into Schulman in order to provide a charging process that charged batteries at an increased current, suitable for Ni-Cd batteries. A POSITA would have been able to modify Schulman's circuit to incorporate the main technical principals taught by Baumann. See Ex. 1003, ¶ 111.

3. Applying combination of Schulman and Baumann to Claims 6, 7 and 9

With respect to dependent claim 6, as demonstrated above under section V.A.2, Schulman teaches all of the limitations of its base claim, independent claim 5. Schulman arguably does not explicitly teach the relationship between the battery current and battery voltage as recited in claim 6. The combination of Schulman and Baumann, however, renders claim 6 obvious.

	Claim 6	Schulman combined with Baumann
	The system as in claim 5 wherein said predetermined current in said internal power source varies as a function of a voltage of said	 FIG. 3 "When … the cell voltage has reached a limiting

	Claim 6	Schulman combined with Baumann
	internal power source.	charging current* U_G, the microcontroller 32 … ***sets back the charging current I_L*** for a second charging phase T2 in appropriately chosen steps such that the cell voltage U_Z remains at least roughly constant for the further progression of the charging process, as depicted in FIG. 3." [Ex. 1005, 5:14-22] **It is unmistakable from the context and FIG. 3 that the use of "current" in this instance is a typographical error; U_G is identified as "limiting charging **voltage**" in all other instances in the specification. Accordingly, Baumann teaches that battery current varies as a function of battery voltage.* *Further, the use of the term "as" in the claim suggests that the inverse relationship between the battery voltage and battery current is continuous in the course of the change. However, the only instance where it could be argued the '069 patent describes the relationship between the battery charging current and battery voltage with any specificity is, with reference to the flow diagram in FIG. 19, at column 21, lines 38 to 43: "*If no over temperature condition exists, charging unit 50 checks (328) to determine if the voltage across

	Claim 6	Schulman combined with Baumann
		rechargeable power source 24 is over a voltage at which the charging rate should begin to decrease, e.g., 4.05 volts. If the voltage across rechargeable power 24 is greater than 4.05 volts, then charging unit 50 begins to taper charging power (330)." *That is, charging current does not decrease in a continuous manner as the battery voltage increases during charging, and instead "begins to taper" only after it is determined that the increasing battery voltage has reached a level that "is greater than 4.05 volts." This is precisely how Baumann's "charging current detector" operates. Accordingly, Baumann teaches that the battery current declines as voltage of the battery increases. See Ex. 1003, ¶¶ 113-115.*

- **Claim 7**

	Claim 7	Schulman combined with Baumann
	The system as in claim 6 wherein said predetermined current in said internal power	*This limitation further recites that current decreasing as voltage increases. This is precisely what is taught by Baumann as demonstrated in the chart immediately above for claim 6. See, above claim 6 under Ground 3.*

	Claim 7	Schulman combined with Baumann
	source declines as said voltage of said internal power source increases during a charging cycle.	

- **Claim 9**

Claim 9 is dependent on claim 8 which is dependent on claim 5. Both claims 5 and 8 have been shown, under Section V.A.2, to be anticipated by Schulman. Baumann teaches the limitation in dependent claim 9.

	Claim 9	Schulman combined with Baumann
	The system as in claim 8 wherein said predetermined current in said internal power source declines over time as an internal impedance of said internal power source increases.	"In the device and process of the invention, the ***charging of the battery is regulated depending on the internal resistance of the battery***. It is ensured that the cell is charged only with as much energy as the electrochemical state allows, without excess gassing or heating of the cell occurring. Older cells with ***increasing internal resistance***, in this way, acquire ***less charge*** than new cells." [Ex. 1007, 2:34-40, emphasis added] *Baumann teaches that charging of batteries, as they age over time with increasing resistance, would be*

	Claim 9	Schulman combined with Baumann
		regulated by decreasing the amount of charge current being delivered to the battery. *See, Ex. 1003, ¶¶ 116-121.*

D. Ground 4: Claims 6, 7 and 9 are unpatentable as obvious over Fischell in view of Baumann

Fischell has been described herein under Section V.B.1 and Baumann has been described herein under Section V.C.1. The combination of Fischell and Baumann render claims 6, 7 and 9 obvious as presented below.

1. The Combination of Fischell in view of Baumann

Both Fischell and Bauman relate to the same field of rechargeable implanted medical devices, and both specifically address implantable tissue stimulators using nickel-cadmium type batteries. A POSITA would have been motivated to combine Fischell with Baumann for several reasons. Baumann discloses a charging protocol for rechargeable nickel-cadmium type batteries (among others) that maximizes charging speed while minimizing risk of harmful charging condition. Ex. 1007, 2:15-22. This is achieved via a two phase charging protocol. These two phases include a constant current phase to achieve "charging as fast as possible" (Ex. 1007, 4:65-5:5 and Figure 2), and a constant voltage phase with a limiting voltage "selected such that the battery cannot be damaged during charging" (Ex. 1007, 5:22-23 and Figure 3).

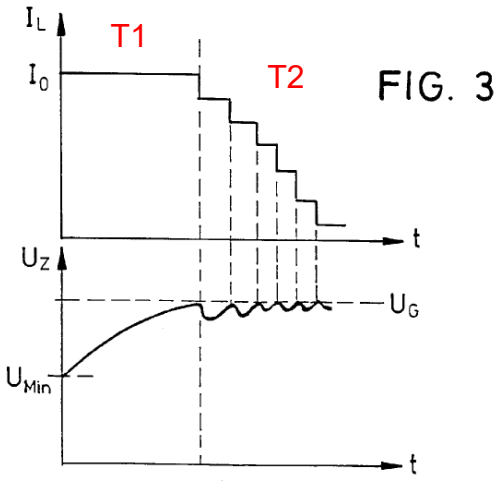
Same as Baumann, Fischell includes a rechargeable nickel-cadmium battery in the implanted device. Fischell similarly defines as its design goals charging and discharging of the internal battery that avoids damage to the battery. Ex 1006, pp. 358-359. A POSITA would have been motivated to incorporate the teachings of Baumann into Fischell to not only realize decreased charging time, but to also improve on the safety and reliability features of the system.

Further, Fischell and Baumann described Ni-Cd batteries as being a type suitable for implantable device because of their larger charge capacity and long service life. Ni-Cd batteries were known for their reduced internal resistance and larger output current capabilities. Baumann teaches charging batteries with significantly higher nominal capacity as compared to Fischell. A POSITA would have been motivated to incorporate the teachings of Baumann into Fischell in order to provide a charging process that charged batteries at an increased current, suitable for Ni-Cd batteries. A POSITA would have been able to make the necessary modifications to Fischell in order to incorporate the main technical principals taught by Baumann. See Ex. 1003, ¶ 127.

2. Applying combination of Fischell and Baumann to Claims 6, 7 and 9

With respect to dependent claim 6, as demonstrated above under section V.B.2, Fischell teaches all of the limitations of its base claim, independent claim 5.

Fischell arguably does not explicitly teach the relationship between the battery current and battery voltage as recited in claim 6. The combination of Fischell and Baumann, however, renders claim 6 obvious.

	Claim 6	Fischell combined with Baumann
	The system as in claim 5 wherein said predetermined current in said internal power source varies as a function of a voltage of said internal power source.	 FIG. 3 "When … the cell voltage has reached a limiting charging current* U_G, the microcontroller 32 … ***sets back the charging current I_L*** for a second charging phase T2 in appropriately chosen steps such that the cell voltage U_Z remains at least roughly constant for the further progression of the charging process, as depicted in FIG. 3." [Ex. 1005, 5:14-22] **It is unmistakable from the context and FIG. 3 that the use of "current" in this instance is a typographical error; U_G is identified as "limiting charging **voltage**" in all other instances in the specification. Accordingly, Baumann teaches that battery current varies as a function of battery voltage.* *Further, the use of the term "as" in the claim suggests that the inverse relationship between the*

	Claim 6	Fischell combined with Baumann
		*battery voltage and battery current is continuous in the course of the change. However, the only instance where it could be argued the '069 patent describes the relationship between the battery charging current and battery voltage with any specificity is, with reference to the flow diagram in FIG. 19, at column 21, lines 38 to 43: "*If no over temperature condition exists, charging unit 50 checks (328) 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. If the voltage across rechargeable power 24 is greater than 4.05 volts, then charging unit 50 begins to taper charging power (330).*" That is, charging current does not decrease in a continuous manner as the battery voltage increases during charging, and instead "begins to taper" only after it is determined that the increasing battery voltage has reached a level that "is greater than 4.05 volts." This is precisely how Baumann's "charging current detector" operates. Accordingly, Baumann teaches that the battery current declines as voltage of the battery increases. See Ex. 1003, ¶¶ 113-115.*

- **Claim 7**

	Claim 7	Fischell combined with Baumann
	The system as in claim 6 wherein said predetermined current in said internal power source declines as said voltage of said internal power source increases during a charging cycle.	*This limitation further recites that current decreasing as voltage increases. This is precisely what is taught by Baumann as demonstrated in the chart immediately above for claim 6. See above claim 6 under Ground 4.*

- **Claim 9**

Claim 9 is dependent on claim 8 which is dependent on claim 5. Both claims 5 and 8 have been shown, under Section V.B.2, to be anticipated by Fischell. Baumann teaches the limitation in dependent claim 9.

	Claim 9	Fischell combined with Baumann
	The system as in claim 8 wherein said predetermined	"In the device and process of the invention, the ***charging of the battery is regulated depending on the internal resistance of the battery***. It is ensured that the cell is charged only with as much energy as

	Claim 9	Fischell combined with Baumann
	current in said internal power source declines over time as an internal impedance of said internal power source increases.	the electrochemical state allows, without excess gassing or heating of the cell occurring. Older cells with ***increasing internal resistance***, in this way, acquire ***less charge*** than new cells." [Ex. 1007, 2:34-40, emphasis added] *Baumann teaches that charging of batteries, as they age over time with increasing resistance, would be regulated by decreasing the amount of charge current being delivered to the battery.* *See Ex. 1003, ¶¶ 116-121.*

VI. MANDATORY REQUIREMENTS

A. Grounds for Standing

Axonics certifies that the '069 Patent is available for IPR and Axonics is not barred or estopped from requesting an IPR of the challenged claims.. This petition is timely filed within one year of the service of Medtronic's complaint alleging infringement of the '069 Patent. Ex. 1009.

B. Mandatory Notices (37 C.F.R. § 42.8)

1. Real Parties in Interest

Axonics is the real party in interest for this Petition.

2. Related Matters

The '069 Patent is at issue in *Medtronic, Inc. v. Axonics Modulation Technols., Inc.*, No. 8:19-cv-02115-DOC-JDE (C.D. Cal.).

The '069 Patent is related to U.S. Patent Nos. 8,457,758 and 8,738,148, against which Axonics is filing separate petitions for IPR concurrently with this Petition.

3. Payment of Fees

This Petition requests review of five (5) claims of the '069 Patent and is accompanied by a payment of $30,500, which includes the $15,500 *inter partes* review request fee, and the $15,000 post-institution fee. *See* 37 C.F.R. § 42.15(a). Thus, this Petition meets the fee requirements under 35 U.S.C. § 312(a)(1). The

Board is hereby authorized to charge any additional fees required by this action to Deposit Account No. 20-1430.

4. Power of Attorney

Powers of attorney are filed herewith pursuant to 37 C.F.R. § 42.10(b).

5. Designation of Lead and Back-Up Counsel and Service Information

Axonics serves this Petition and all exhibits to the address of the correspondence address of record for the '069 Patent pursuant to 37 C.F.R. § 42.105(a) and the Certificate of Service. Axonics consents to be served via lead and back-up counsel identified below at the mailing and e-mail addresses below.

Respectfully submitted,

By: */s/ A. James Isbester*
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CERTIFICATE OF WORD COUNT

The undersigned certifies pursuant to 37 C.F.R. § 42.24(d) that the foregoing Petition for *Inter Partes* Review excluding any table of contents, table of authorities, certificates of service or word count, or appendix of exhibits or claim listing, contains 9,942 words according to the word-processing program used to prepare this paper (Microsoft Word). Petitioner certifies that this Petition for *Inter Partes* Review does not exceed the applicable type-volume limit of 37 C.F.R. § 42.24(a).

Dated: March 16, 2020

/s/ *A. James Isbester*
Lead Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Petition for *Inter Partes* Review of U.S. Patent No. 7,774,069, including its supporting Exhibits (1001-1009) has been served via USPS Priority Mail Express on March 16, 2020 upon Patent Owner's correspondence address of record for U.S. Patent No. 7,774,069:

David Cleveland
Brian Szymanski
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The Petition has also been served via email and USPS Priority Mail Express to lead trial counsel for litigation at the following address:

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For the additional litigation counsel of record, the Petition has been served via email to the following email addresses:

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Respectfully,

Dated: March 16, 2020

By: */s/ A. James Isbester*
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