UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

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Case IPR2020-00680
Patent No. 8,457,758
Filing Date: August 16, 2011
Issue Date: June 4, 2013

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# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,457,758

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# I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics" or "Petitioner") respectfully petitions for initiation of *inter partes* review of claims 1 through 12 of U.S. Patent No. 8,457,758 ("the '758 Patent") in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq*. ("Petition").

The '758 Patent generally relates to a transcutaneous energy transfer system for charging the battery inside a medical device that is implanted beneath the skin of a patient. The '758 Patent describes such transcutaneous energy transfer system as having an external power source which includes a primary coil, and an implanted medical device which includes a secondary 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. Ex. 1001, Abstract. The '758 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, 7:31-8:12. The purported novelty '758 Patent claims relates to features for automatically varying (or terminating) a power output of the external primary coil based on a current "passing through [an] internal power source" of the medical device. *See* '758 Patent, claims 1-12. As explained herein, however, the '758 Patent did not disclose anything new. Indeed, such systems for transcutaneous

energy transfer, including those with the claimed features, had been known, written about, and in widespread use for decades prior to the filing date of the '758 Patent. The '758 Patent adds nothing to the art and its claims should be found unpatentable as anticipated and/or obvious.

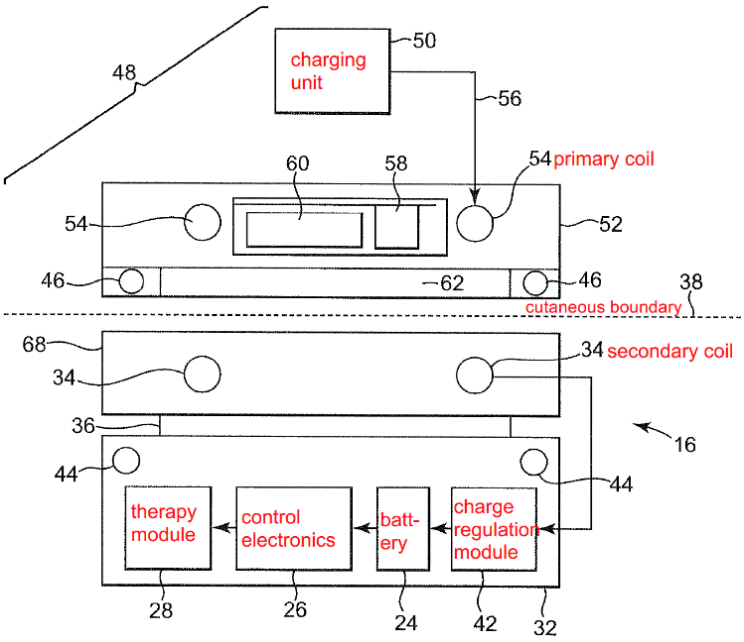
## II. OVERVIEW OF THE '758 PATENT

### A. Background and Summary of the '758 Patent

The '758 Patent issued June 4, 2013, from Application No. 13/210,852 filed August 16, 2011. The '758 Patent is a patent in a family of related patent, claiming earliest priority date of April 29, 2005. The '758 Patent is therefore subject to the *pre*-America Invents Act ("AIA") provisions of 35 U.S.C. §§ 102 and 103.

The '758 Patent relates generally to a system for charging the battery inside a medical device that is implanted beneath the skin of a patient. The '758 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, an annotated version of which is reproduced herein, shows 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, 7:31-34 (emphasis added). "Therapy module 28 is coupled to [the patient] ***also conventionally***." Ex. 1001, 7:34-35 (emphasis added). Similarly, "charging regulation [module 42] and therapy control [electronics 26 and therapy module 28] ***is conventional***." Ex. 1001, 7:60-61 (emphasis added). That is, "[e]lectronics 26 help provide control of the charging rate of rechargeable power source 24 ***in a conventional manner***." Ex. 1001, 7:44-45 (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 and to externally obtain information from implantable medical device 16." Ex. 1001, 7:61-67 (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, 8:19-27.

The operation of external charging unit 50 as it interacts with implantable medical device 16 is depicted as a flow diagram in FIG. 19. Ex. 1001, 21:24-25. An annotated excerpt of FIG. 19 is reproduced below:

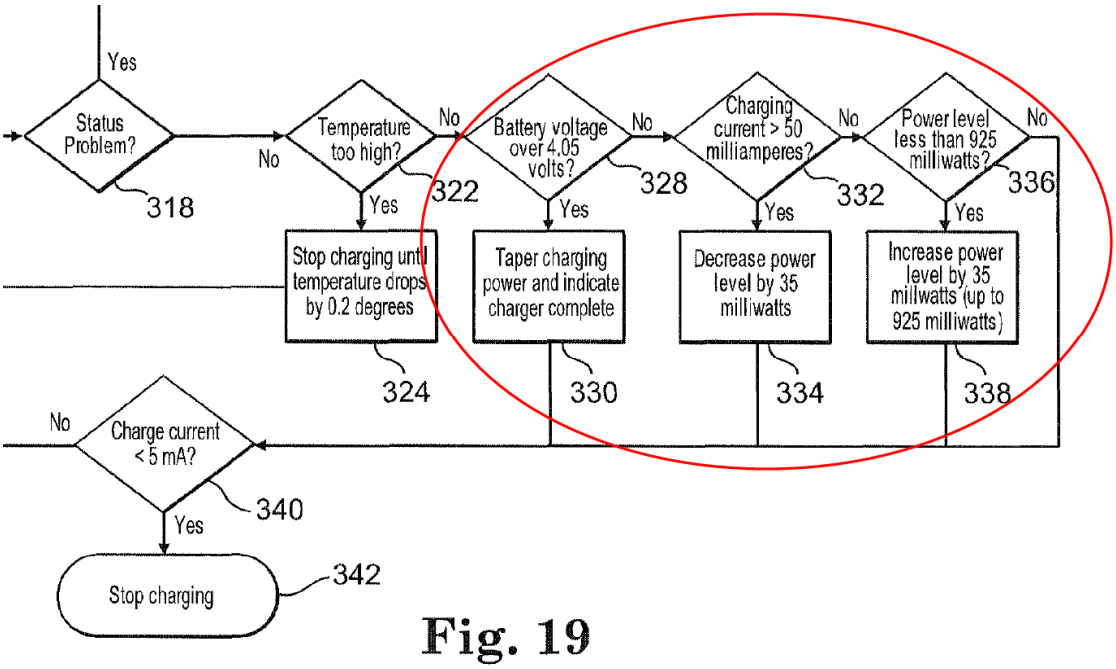



**Fig. 19**

FIG. 19 shows a method including several decision steps used to control the operation of the charging unit 50. After performing a number of other steps not relevant to the claims, the method proceeds to **step 328**, where the charging unit 50

determines "if the voltage across the rechargeable power source 24 is over a voltage at which the charging rate should begin to decrease, e.g., 4.05 volts." Ex. 1001, 21:49-58. If the voltage across the power source 24 is over 4.05 volts, the method proceeds to **step 330**, where the "charging unit 50 begins to taper charging power." Ex. 1001, 21:58-60.

If the voltage across rechargeable power source 24 is not over 4.05 volts, the method proceeds to **step 332**, where the charging unit 50 "determine[s] whether the charging current through rechargeable power source 24 is over a current rate that is not desirable, e.g., 50 milliamperes." Ex. 1001, 21:61-65. If the charging current is over 50 milliamperes, the method proceeds to **step 334**, where the charging power level is decreased "by an appropriate [amount], e.g., by 35 milliwatts." Ex. 1001, 21:65-67.

If the charging current is less than 50 milliamperes, the method proceeds to **step 336**, where the charging unit 50 "determine[s] if the charging power level is less than [an] appropriate amount, e.g., 925 milliwatts." Ex. 1001, 22:1-3. If the charging power level is less than 925 milliwatts, the method proceeds to **step 338**, where the charging power level is increased "by 35 milliwatts, up to a maximum of 925 milliwatts." Ex. 1001, 22:3-6. As illustrated by **steps 340 and 342**, the "charging unit 50 stops ... charging and indicates that charging is complete" when the charge current is below 5 milliamperes. Ex. 1001, 22:7-9.

### B. Prosecution History of the ’758 Patent

The ’758 Patent issued after two Office Actions. In the first Office Action, which was mailed on July 23, 2012, claims 5, 10 15, 20, 25, and 30 were indicated as allowable subject to the filing of a terminal disclaimer. In the final Office Action, which was mailed on December 19, 2012, previously identified claims 5, 10, 15, 20, 25, and 30 were again identified as allowable if rewritten in independent form, as were claims 7, 9, 17, 19, 27, and 29. In response to this final Office Action, Applicant merely rewrote each of these allowable claims in independent form to receive an allowance of the twelve independent claims that make up all the claims of the ’758 Patent.

## III. PROPOSED CLAIM CONSTRUCTION

Axonics submits 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.

## 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 Ph.D. 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 175 issued U.S. patents and is the author of over 200 industry publications. Additional details regarding Dr. Panescu's background are provided in Ex. 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 1 through 12 of the '758 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 '758 Patent's priority date of April 29, 2005, and is therefore prior art under pre-AIA 35 U.S.C. section 102(b). Schulman and Fischell were not before the examiner during prosecution of the '758 Patent. While Baumann was disclosed by the Applicant in an IDS, it was not substantively raised during prosecution.

As discussed in greater detail under section II.A, the '758 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 '758 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, 7:31-8:12. The purported novelty it claims relates to automatically varying or terminating a power output of the (external) primary coil based on a current "passing through [an] internal power source" of the medical device. *See* '758 Patent, claims 1-12.

The listed prior art references similarly address systems for transcutaneous energy transfer with methods for automatically varying (or terminating) a power output of an external charging (i.e., primary) coil based on a current passing through an internal battery of an implanted device.

Petitioner respectfully requests that the Board cancel the challenged claims of the '758 Patent based on the following grounds:

- Ground 1: Claims 1, 5, and 9 are unpatentable as anticipated by Schulman.
- Ground 2: Claims 1, 5, and 9 are unpatentable as anticipated by Fischell.

- Ground 3: Claims 1-12 are unpatentable as anticipated by Baumann.
- Ground 4: Claims 2-4, 6-8, and 10-12 are unpatentable as obvious over Schulman and Baumann.
- Ground 5: Claims 2-4, 6-8, and 10-12 are unpatentable as obvious over Fischell and Baumann.

### A. Ground 1: Claims 1, 5, and 9 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 '758 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 … 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.

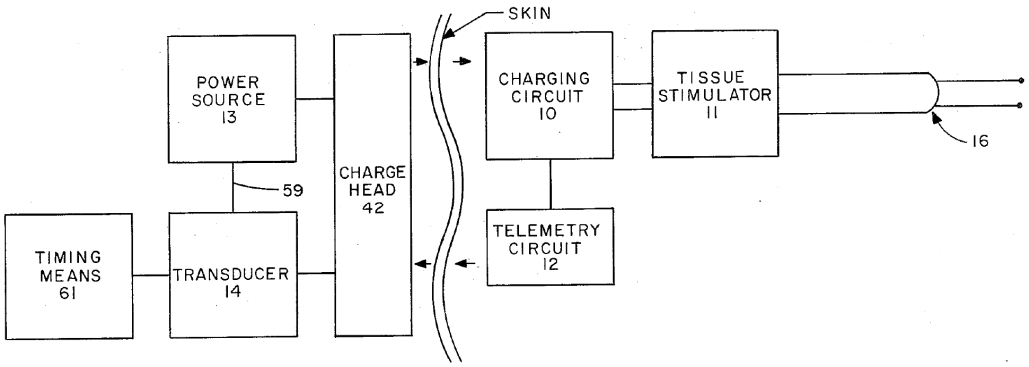


FIG. 1

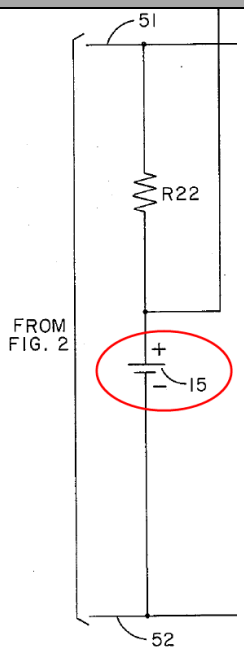
Schulman further teaches that the "external electrical charging power source [includes] an induction coil for positioning external to a living subject and proximate to the induction coil of the implantable charging circuit" and that the telemetry circuit in the implantable device detects "the magnitude of charging current received 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 automatically "adjust the strength of the magnetic field applied to said implantable charging circuit." Ex. 1005, 2:46-52.

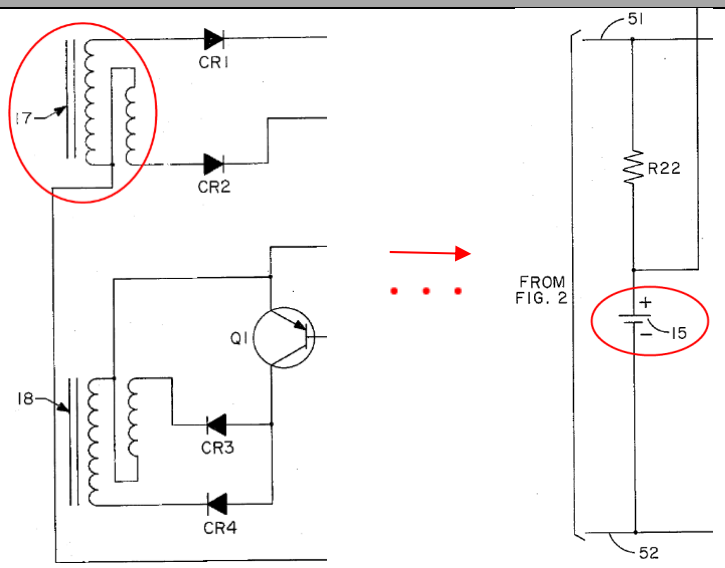
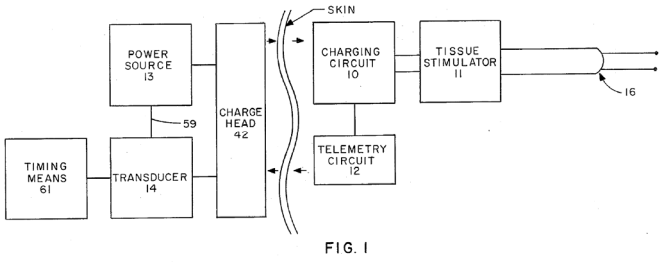
### 2. Applying Schulman to Claims 1, 5, and 9

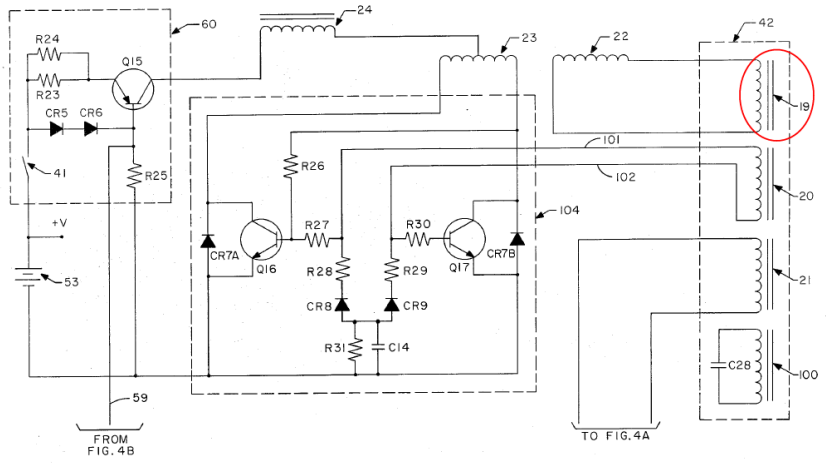
Schulman teaches every limitation of claims 1, 5, and 9 of the '758 Patent, as shown below.

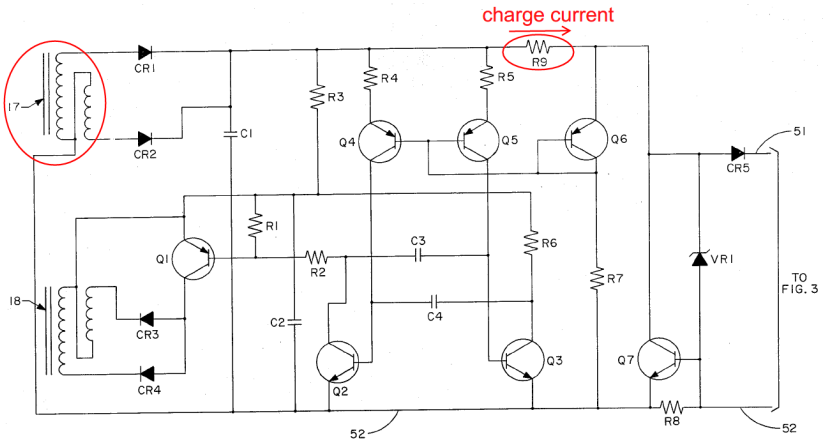
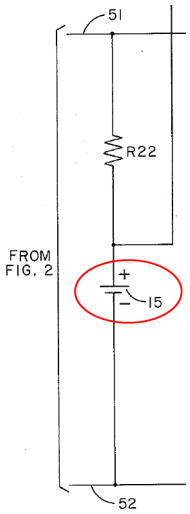
- **Claim 1**

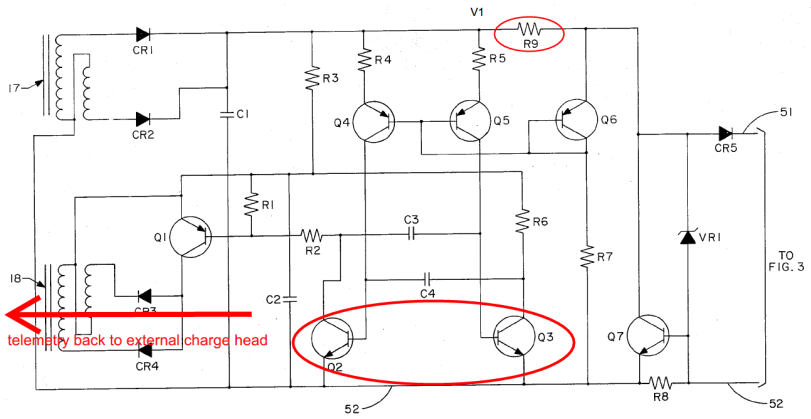
| | Claim 1 | Schulman |
|---|---|---|
| 1.0 | A system for transcutaneous energy transfer, comprising: | *Petitioner does not here advocate that the preamble is limiting.*<br>"This invention relates to a rechargeable tissue stimulating ***system for providing a charge to a voltage source implanted in a living being***, and for regulating recharging of the voltage source through the use of telemetry circuit." [Ex. 1005, 1:7-11, emphasis added] |
| 1.1(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 1 | Schulman |
|---|---|---|
| 1.1(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]<br><br>*Partial view of FIG. 3 reproduced at right shows "rechargeable d.c. voltage" or "battery 15" ("internal power source").*<br><br>  <br>"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]<br><br>*Partial views of FIGS. 2 and 3, reproduced below, show "induction coil 17" (secondary coil in the claim) supplying power to the battery 15.* |

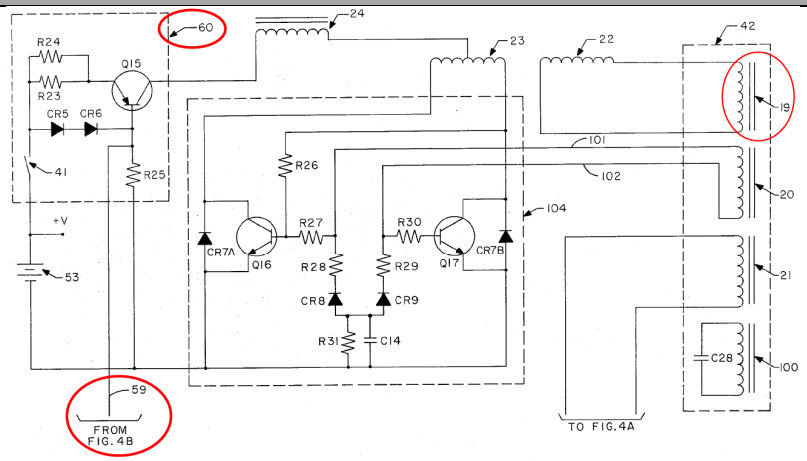
| | Claim 1 | Schulman |
|---|---|---|
| | |  FIG. 2 FIG. 3 |
| 1.1(c) | said implantable medical device adapted to be implanted in a patient; and | "Referring now to FIG. 1, there is illustrated a rechargeable tissue stimulating system comprising a charging circuit 10 including a telemetry circuit 12 and a 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 |
| 1.2(a) | an external power source having a primary coil, | "[A]n external electrical charging power source including an induction coil." [Ex. 1005, 2:36-38] |

| | Claim 1 | Schulman |
|---|---|---|
| 1.2(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 | "[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]<br>"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, 9:9-11]<br>  <br><br>FIG. 4<br>"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]<br>*Schulman teaches external power source providing energy to the implanted device when induction coil 19 on the charging head of the external power source is placed in proximity of induction coil 17 of the* |

| | Claim 1 | Schulman |
|---|---|---|
| | | *implanted device. See Ex. 1003, ¶¶ 62, 79.* |
| 1.2(c) | thereby generating a current, having a value, passing 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]. *See annotated FIG. 2:*<br>  <br>"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]<br>  <br>*Schulman teaches that the inductive coupling generates a "charging current" that flows through the internal battery. See Ex. 1003, ¶¶ 67, 76.* |
| 1.3 | wherein said | "Charging current passes through the current sampling |

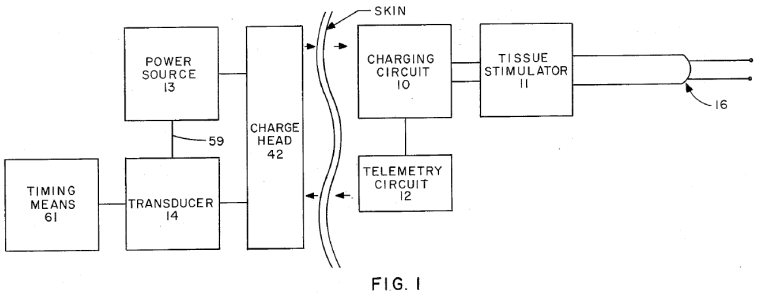
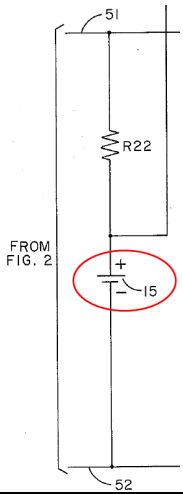
| | Claim 1 | Schulman |
|---|---|---|
| | external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | resistor R9." [Ex. 1005, 4:11-12]<br>"… the telemetry frequency is controlled by the transistors Q2 and Q3, which are in turn controlled by ***the current through the current sampling resistor R9***." [Ex. 1005, 4:63-66, emphasis added]<br>  <br><br>FIG. 2<br>*Schulman teaches using "sampling resistor R9" to provide a measure of the charging current that passes through the internal battery. The measured charging current through R9 controls the telemetry circuitry that communicates with the external power source. See Ex. 1003, ¶¶ 67-80.*<br>"… ***any 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 |

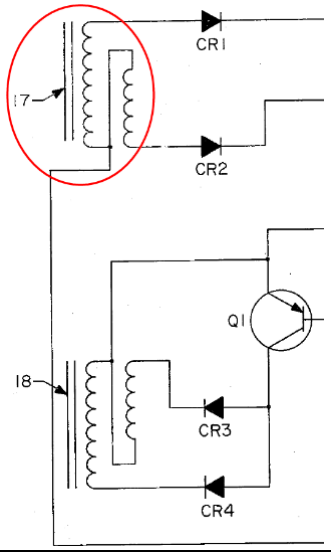
| | Claim 1 | Schulman |
|---|---|---|
| | | modulating the frequency of the amplitude peak fluctuation of the charging field … ***The electrical control signal generated in transducer 14 by the magnetic output signal from the telemetry circuit 12 will produce changes in the regulation of the power source 13***." [Ex. 1005, 6:19-38, emphasis added]<br><br>"Of course the electrical control signal on lead 59 from the transducer ***adjusts the current output from the current control means 60*** to the induction coil 24 in order ***to adjust the strength of the magnetic field*** applied to the implanted charging circuit. That is, ***when the current passing through resistor R9 in the charging circuit exceeds a maximum operating level, the signal from circuit 59 will lower the output current from current control means 60***. This lowered output current, through the use of induction coils 22, 23 and 24, ***results in a reduced magnetic field strength acting between the induction coils 19, 20 and 21 of the power source and induction coils 17 and 18 of the charging circuit***." [Ex. 1005, 7:20-33, emphasis added] |

| | Claim 1 | Schulman |
|---|---|---|
| | |  <br>FIG. 4<br><br>*Schulman thus teaches automatically (via telemetry feedback) regulating the output of the external power source 13 based on a measured current or value associated with the charging current that passes through internal battery 15. See Ex. 1003, ¶¶ 67-80.* |
| 1.4 | wherein said external power source automatically varies its power output based on a measured current associated with said current passing through said internal | *During prosecution this second wherein clause (1.4) was recited in then-pending dependent claim 5 which the Examiner had found allowable. Applicant simply appended the body of then-pending claim 1 in front of this second wherein clause to secure allowance. It is thus clear that the second wherein clause simply narrows the "value" of the first wherein clause to "measured current," and does not require a separate measurement. This is consistent with the specification, which does not describe two separate measurements.* |

| | Claim 1 | Schulman |
|---|---|---|
| | power source. | *Thus, see element 1.3 above.* |

- **Claim 5**

| | Claim 5 | Schulman |
|---|---|---|
| 5.0 | An external power source for use with an implantable medical device adapted to be implanted in a patient and having componentry for providing a therapeutic output, an internal power source and a secondary coil operatively coupled to said internal power source, | *Petitioner does not here advocate that the preamble is limiting.*<br>"[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]<br>  <br>FIG. 1<br>"A rechargeable tissue stimulating system comprising a charging circuit 10 including a telemetry circuit 12 and a tissue stimulator 11 … for implantation into the body of a living patient." [Ex. 1005, 3:42-46]<br>  <br>"In a broad aspect this invention is a rechargeable tissue stimulating system |

| | Claim 5 | Schulman |
|---|---|---|
| | comprising: | 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]<br><br>*Partial view of FIG. 3 reproduced above shows the “rechargeable d.c. voltage,” or “battery 15” (“internal power source”).*<br><br>“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]<br><br>*Partial views of FIG. 2, reproduced below shows*<br><br>  |

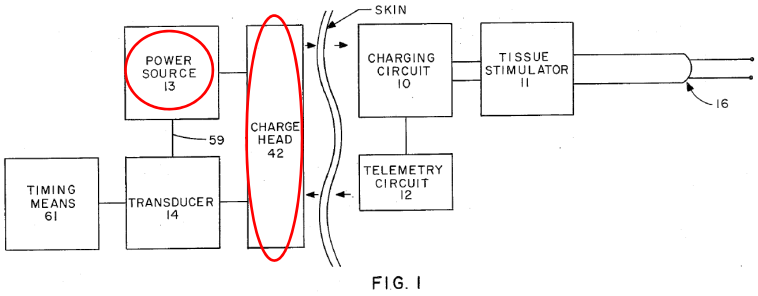
| | Claim 5 | Schulman |
|---|---|---|
| | | *"induction coil 17" (i.e., secondary coil in the claim).* |
| 5.1 | an external power unit; and | *See disclosures for Ground 1 [1.2(a)] above.* |
| 5.2 | a primary coil, operatively coupled to said external power unit; | *See disclosures for Ground 1 [1.2(a)] above.* |
| 5.3(a) | said external power unit providing energy to said implantable medical device when said primary coil is placed in proximity of said secondary coil of said implantable medical device and | *See disclosures for Ground 1 [1.2(b)] above.* |
| 5.3(b) | thereby generating a | *See disclosures for Ground 1 [1.2(c)] above.* |

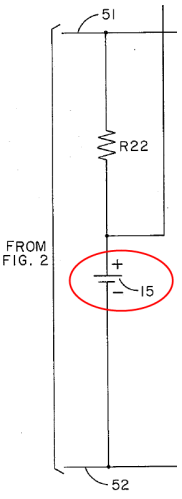
| | Claim 5 | Schulman |
|---|---|---|
| | current having a value passing through said internal power source; | |
| 5.4 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | *See disclosures for Ground 1 [1.3] above.* |
| 5.5 | wherein said external power source automatically varies its power output based on a measured current associated with | *Similar to claim 1, Applicant simply appended the body of then-pending claim 11 in front of this second wherein clause (from then-pending claim 15) to secure allowance.*<br>*Thus, see disclosures for Ground 1 [1.4] above.* |

| | Claim 5 | Schulman |
|---|---|---|
| | said current passing through said internal power source. | |

- **Claim 9**

| | Claim 9 | Schulman |
|---|---|---|
| 9.0(a) | A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted medical device, said external primary coil being operatively coupled to a charging unit, | *Petitioner does not here advocate that the preamble is limiting.*<br>*See disclosures for Ground 1 [1.0, 1.1(a), 1.1(b), 1.2(b), 1.1(c), 1.2(c)] above.* |

| | Claim 9 | Schulman |
|---|---|---|
| | said secondary coil supplying power to an internal power source of said implanted medical device, | |
| 9.0(b) | said internal power source having an internal impedance, comprising the steps of: | *It is an inherent property of batteries to have an internal resistance. See Ex. 1003, ¶ 109.* |
| 9.1 | driving said external primary coil with a charging signal from said charging unit generating a current passing through said internal power source; and |  <br>FIG. 1<br>"The power source 13 employs a power oscillator circuit 104 to generate a 21 kilohertz electric field which powers the charge head 42." [Ex. 1005, 3:51-53]<br>"A rechargeable tissue stimulating system with a |

| | Claim 9 | Schulman |
|---|---|---|
| | | telemetry controlled power source. 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, emphasis added]<br><br>"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]<br><br>*Schulman thus discloses a power source 13 that drives an external induction coil within a charge head 42 to induce a current flow in a charging circuit to charge the battery 15. See Ex. 1003, ¶¶ 61-63, 67.*<br><br>  |
| 9.2 | said charging unit automatically varying its power output based on a value associated with said current | *See disclosures for Ground 1 [1.3] above.* |

| | Claim 9 | Schulman |
|---|---|---|
| | passing through said internal power source; | |
| 9.3 | wherein said automatically varying step automatically varies its power output based on a measured current associated with said current passing through said internal power source. | *Similar to claim 1, Applicant simply appended the body of then-pending claim 21 in front of this second wherein clause (from then-pending claim 25) to secure allowance.*<br>*Thus, see disclosures for Ground 1 [1.4] above.* |

### B. Ground 2: Claims 1, 5, and 9 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"), Ex. 1006. Fischell was accessible to public at least as of April, 7, 1976, as evidenced by the declaration of Rachel J. Watters, Ex. 1008, 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 '758 Patent (April 29, 2005), Fischell qualifies as prior art under 35 U.S.C. 102(b).

Fischell is directed to rechargeable cardiac pacemakers utilizing "[a] new rechargeable cell specifically adapted for use at body temperature" that improves reliability of the pacemaker system. Ex. 1006 at 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 at 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"

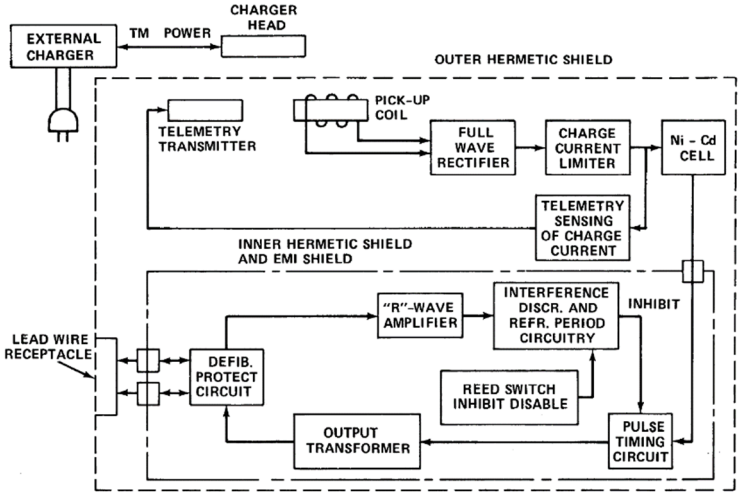



Fig. 8 Block diagram of rechargeable demand pacemaker

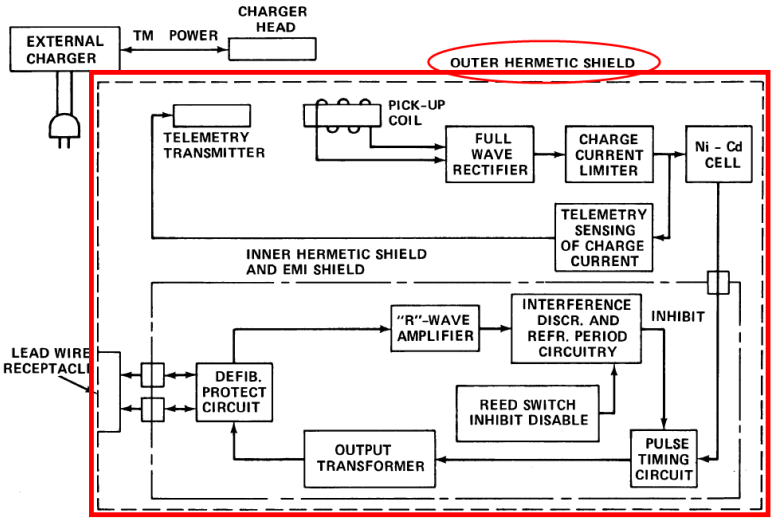
that interfaces with an induction coil in the "charger head" of the external device, circuitry to convert the magnetic energy to current for charging an internal rechargeable battery, a "Ni-Cd cell," a block titled "telemetry sensing of charge current" that is coupled between the battery and a "telemetry 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.

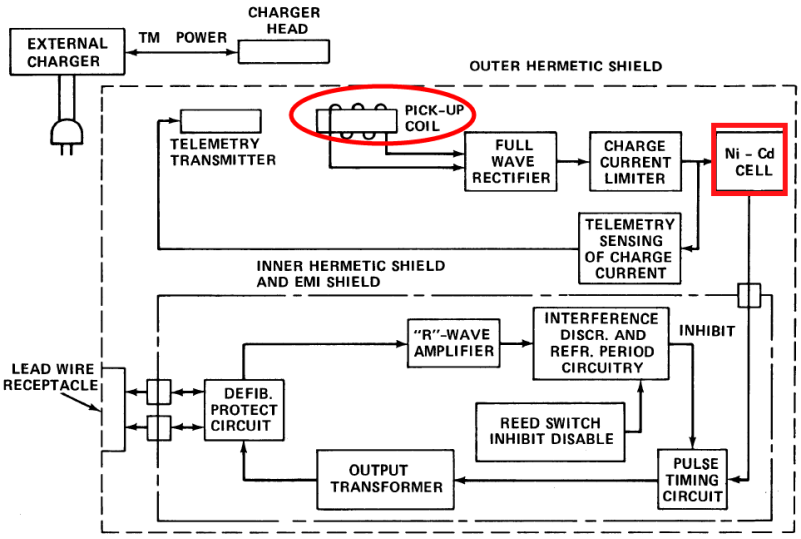
### 2. Applying Fischell to Claims 1, 5, and 9

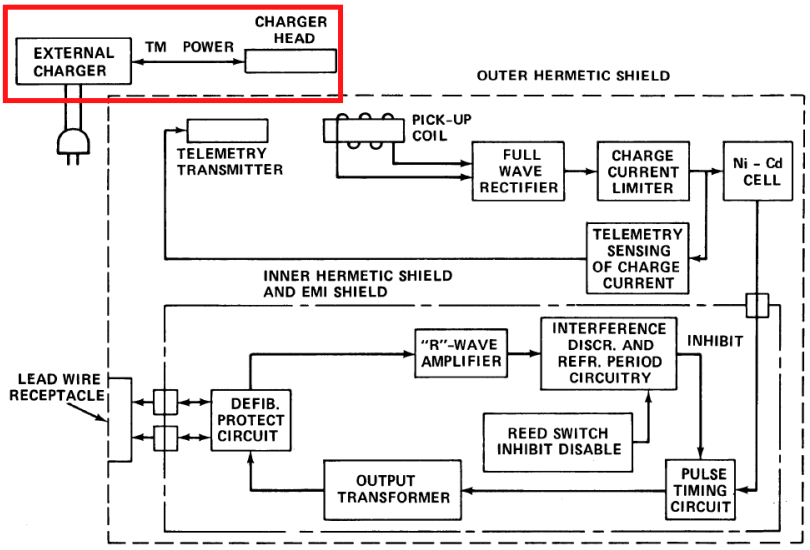
Fischell teaches every limitation of claims 1, 5, and 9 of the '758 Patent, as shown below.

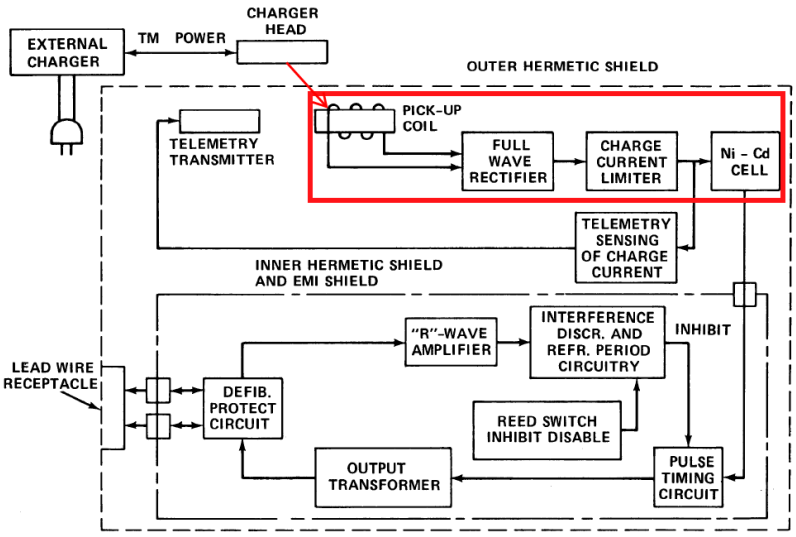
- **Claim 1**

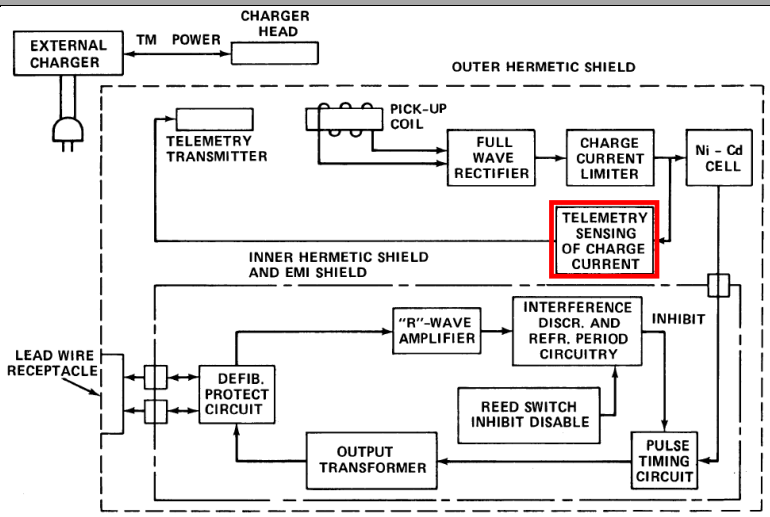
| | Claim 1 | Fischell |
|---|---|---|
| 1.0 | A system for transcutaneous energy transfer, comprising: | *Petitioner does not here advocate that the preamble is limiting.* |

| | Claim 1 | Fischell |
|---|---|---|
| 1.1(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 at 357, emphasis added]<br>*FIG. 8 of Fischell shows a "block diagram of rechargeable demand pacemaker" with a "Ni-Cd Cell" (battery).*<br>  <br><br>Fig. 8 Block diagram of rechargeable demand pacemaker |

| | Claim 1 | Fischell |
|---|---|---|
| 1.1(b) | said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br><br>"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 at. 372, emphasis added]<br><br>*FIG. 8 shows the "pick-up coil" (secondary coil) coupled to an Ni-Cd Cell (internal power source).* |
| 1.1(c) | said implantable medical device adapted to be implanted in a patient; and | "The concept of using a rechargeable cell for an implantable cardiac pacemaker is not new." [Ex. 1006 at 357] |
| 1.2(a) | an external power source having a primary coil, | |

| | Claim 1 | Fischell |
|---|---|---|
| | |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br><br>"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]<br><br>*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). See Ex. 1003, ¶¶ 84-85, 91; see also* Ex. 1006 at 368 (depicting *induction coil for "charger head" of the rechargeable pacemaker shown in Fig. 6).* |

| | Claim 1 | Fischell |
|---|---|---|
| 1.2(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, having a value, passing through said internal power source: |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br>"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]<br>*As depicted in Fig. 8, Fischell teaches the energy supplied by the external primary coil and picked up by the internal secondary "pick-up coil" is applied to a "full wave rectifier," the output of which goes through a "charge current limiter" that in turn applies charge current to the internal battery (Ni-Cd cell). See Ex. 1003, ¶ 85.* |

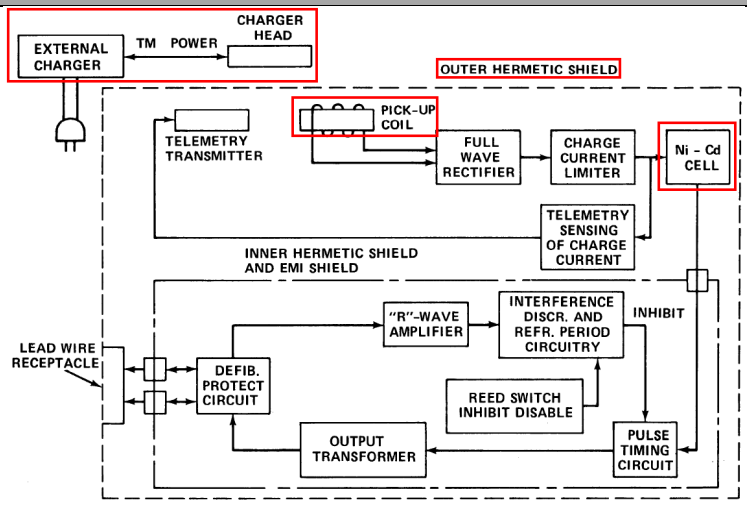
| | Claim 1 | Fischell |
|---|---|---|
| 1.3 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br>*FIG. 8 explicitly shows a 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. Table 3 of Fischell, partially reproduced below, identifies telemetry of battery charge current occurring by means of an FM output from the pulse generator. See Ex. 1003, ¶¶ 86-87.*<br>**Battery charge current telemetry** — **by pulse rate measurement and by means of FM output from pulse generator**<br>[Table 3, p. 370]<br>"Two types of telemetry systems that can provide the doctor and the patient with valuable information are available from the pacer, namely: ... b. ***telemetry*** by |

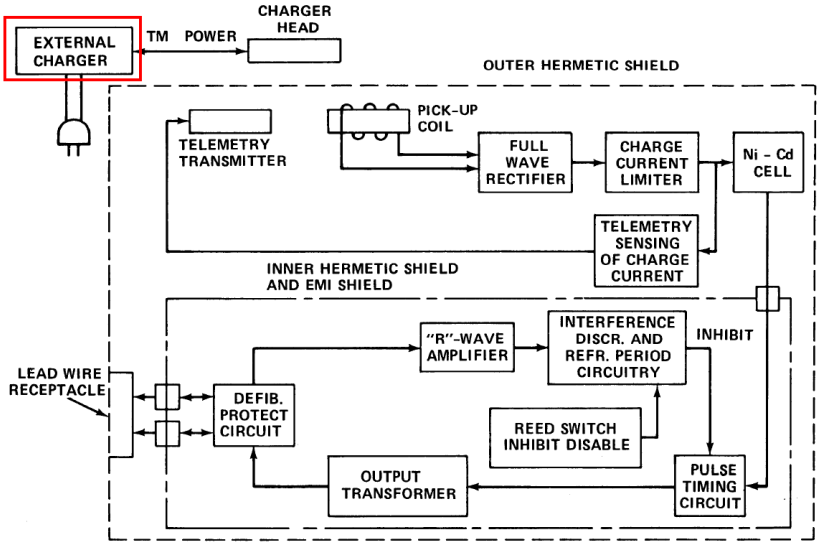
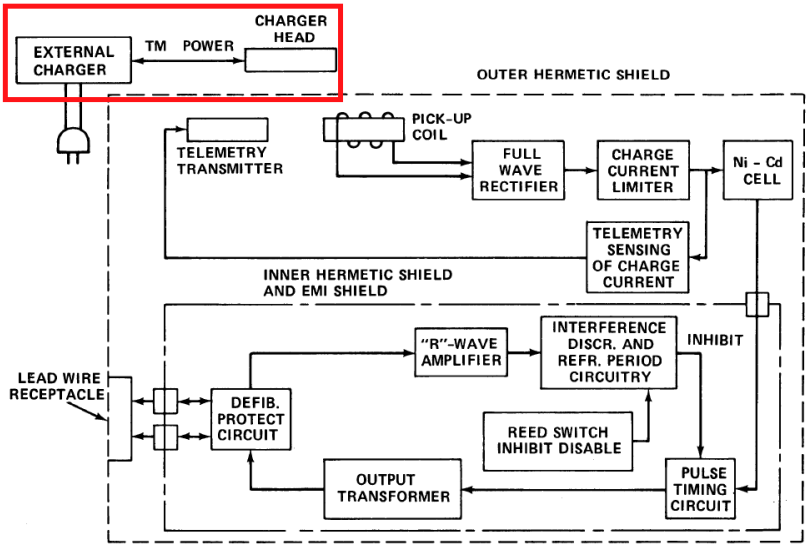
| | Claim 1 | Fischell |
|---|---|---|
| | | means of a frequency modulated signal from the pulse generator into the external charger to ***measure and control charge current into the battery***." [Ex. 1006 at 371-372, emphasis added]<br>"When the external charger applies an alternating magnetic field which is picked up … 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 … and ***closed-loop controls the battery charge current to a value of 40 mA***." [Ex. 1006 at 372-373, emphasis added]<br>"A feedback control system in the charger ***maintains the battery charge current at the proper 40 mA level***." [Ex. 1006 at 378, emphasis added]<br>*Fischell teaches a telemetry system that automatically adjusts the power of the external charger based on a value proportional to the charge current in the battery. See Ex. 1003, ¶¶ 86-91.* |
| 1.4 | wherein said external power source automatically varies its power | *During prosecution this second wherein clause (1.4) was recited in then-pending dependent claim 5 which the Examiner had found allowable. Applicant simply appended the body of claim 1 in front of this second wherein clause to secure allowance. It is thus clear* |

| | Claim 1 | Fischell |
|---|---|---|
| | output based on a measured current associated with said current passing through said internal power source. | *that the second wherein clause simply narrows the "value" of the first wherein clause to "measured current," and does not require a separate measurement. This is consistent with the specification, which does not describe two separate measurements.*<br>*Thus, see Ground 2 [1.3] above.* |

- **Claim 5**

| | Claim 5 | Fischell |
|---|---|---|
| 5.0 | An external power source for use with an implantable medical device adapted to be implanted in a patient and having componentry for providing a therapeutic output, an internal power | *Petitioner does not here advocate that the preamble is limiting.*<br>*All terms recited in the preamble are virtually identical to those recited in the body of the independent claim 1. For detailed description of the following summary, see chart for claim 1 above:* |

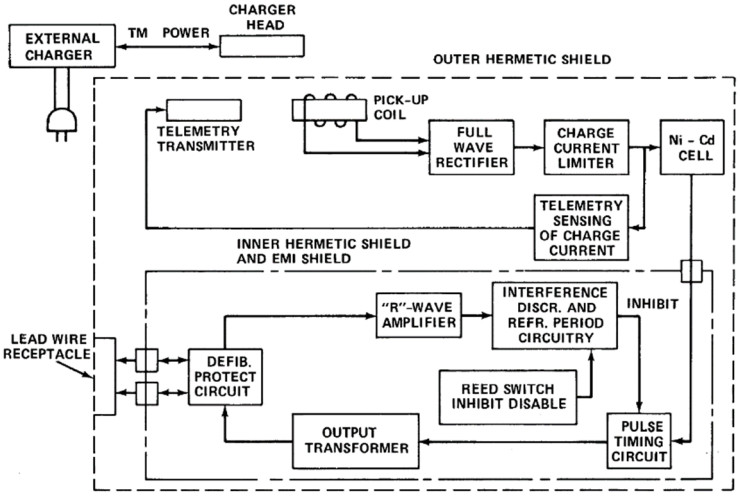
| | Claim 5 | Fischell |
|---|---|---|
| | source and a secondary coil operatively coupled to said internal power source, comprising: |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br>"external power source" = *Fischell: "external charger" and "charger head" (FIG. 8)*<br>"implantable medical device" = *Fischell: "implantable cardiac pacemaker" (defined by outline of "outer hermetic shield" in FIG. 8)*<br>"internal battery" = *Fischell: "Ni-Cd cell" (FIG. 8)*<br>"secondary coil" = *Fischell: "pick-up coil" (FIG. 8)* |
| 5.1 | an external power unit; and | *As shown in FIG. 8, the external power source includes an "external charger" block that corresponds to the claimed "external power unit."* |

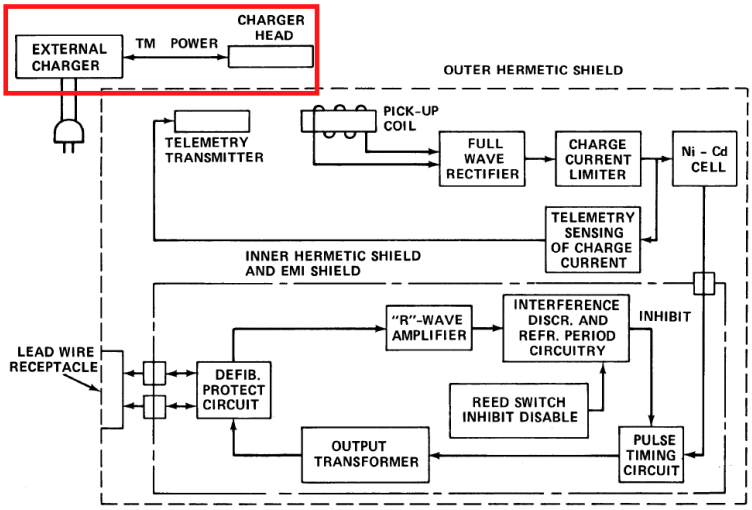
| | Claim 5 | Fischell |
|---|---|---|
| | |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker |
| 5.2 | a primary coil, operatively coupled to said external power unit; |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br><br>*Fischell teaches that the external charger includes a "charger head" that "applies an alternating magnetic field" which would be through an inductive coil* |

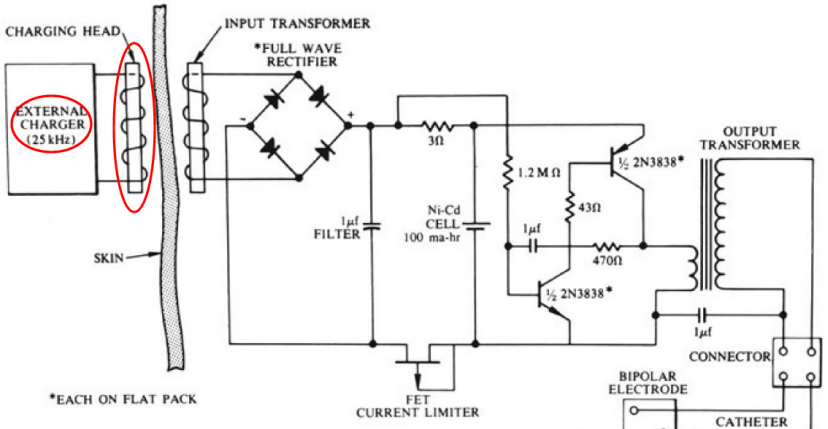
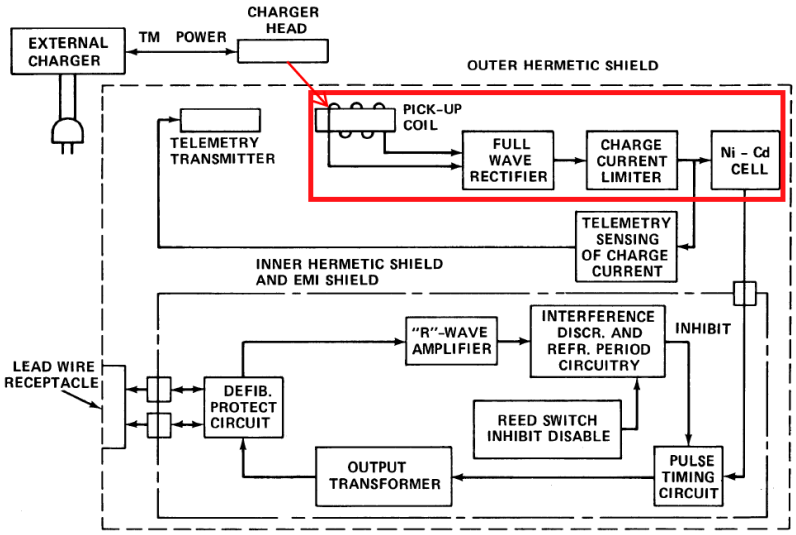
| | Claim 5 | Fischell |
|---|---|---|
| | | *("primary coil"). See also depiction of an induction coil for "charger head" of the rechargeable pacemaker shown in Fig. 6 of Fischell [p. 368]. See Ex. 1003, ¶¶ 84-85, 88.* |
| 5.3 | said external power unit providing energy to said implantable medical device when said primary coil is placed in proximity of said secondary coil of said implantable medical device and thereby generating a current having a value passing through said internal power | *See disclosures for Ground 2 [1.2(b)] above.* |

| | Claim 5 | Fischell |
|---|---|---|
| | source; | |
| 5.4 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | *See disclosures for Ground 2 [1.3] above.* |
| 5.5 | wherein said external power source automatically varies its power output based on a measured current associated with said current passing through said internal power source. | *Similar to claim 1, Applicant simply appended the body of then-pending claim 11 in front of this second wherein clause (from then-pending claim 15) to secure allowance.*<br>*Thus, see disclosures for Ground 2 [1.4] above.* |

- **Claim 9**

| | Claim 9 | Fischell |
|---|---|---|
| 9.0(a) | A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted medical device, said external primary coil being operatively coupled to a charging unit, said secondary coil supplying power to an internal power source of said | *Petitioner does not here advocate that the preamble is limiting.*<br>*All terms recited in the preamble of this method claim are structural features of the system claimed by the independent claims above including claim 1. For detailed description of the following summary, see chart for claim 1 above:*<br>  <br><br>Fig. 8 Block diagram of rechargeable demand pacemaker<br>"external primary coil" = *Fischell: "charger head" (Fig 8)*<br>"charging unit" = *Fischell: "external charger" (Fig. 8)*<br>"inductively coupled secondary coil" = *Fischell "pick-up coil" (Fig. 8)* |

| | Claim 9 | Fischell |
|---|---|---|
| | implanted medical device, | "internal power source" = *Fischell "Ni-Cd cell" (Fig. 8)*<br>"implantable medical device" = *Fischell: "an implantable electrical tissue stimulator" (FIG. 1), and "implanted portions of tissue stimulating system" (FIG. 10)* |
| 9.0(b) | said internal power source having an internal impedance, comprising the steps of: | *It is an inherent property of batteries to have an internal resistance. See Ex. 1003, ¶ 109.* |
| 9.1(a) | driving said external primary coil with a charging signal from said charging unit |  <br>Fig. 8 Block diagram of rechargeable demand pacemaker<br>*As shown by the highlighted portion in Fig. 8, the "external charger" drives the "charger head "with a* |

| | Claim 9 | Fischell |
|---|---|---|
| | | *signal labeled "POWER". A more detailed example of this is shown in Fig. 6 where the "external charger "drives the external coil with a "25 kHz" signal.*<br>  <br><br>Fig. 6 Circuit diagram for rechargeable fixed rate pacemaker |
| 9.1(b) | generating a current passing through said internal power source; and |  <br><br>Fig. 8 Block diagram of rechargeable demand pacemaker<br>*As depicted in Fig. 8, Fischell teaches the energy supplied by the external primary coil and picked up by the internal secondary "pick-up coil" is applied to a "full wave rectifier" the output of which goes through a "charge current limiter" that in turn applies charge* |

| | Claim 9 | Fischell |
|---|---|---|
| | | *current to the internal battery (Ni-Cd cell). See Ex. 1003, ¶¶ 84-85.* |
| 9.2 | said charging unit automatically varying its power output based on a value associated with said current passing through said internal power source; | *See disclosures for Ground 2 [1.3] above.* |
| 9.3 | wherein said automatically varying step automatically varies its power output based on a measured current associated with said current | *Similar to claim 1, Applicant simply appended the body of then-pending claim 21 in front of this second wherein clause (from then-pending claim 25) to secure allowance.*<br>*Thus, see disclosures for Ground 2 [1.4] above.* |

| | Claim 9 | Fischell |
|---|---|---|
| | passing through said internal power source. | |

### C. Ground 3: Claims 1-12 are unpatentable as anticipated by Baumann

#### 1. Baumann

U.S. Patent No. 6,227,204 to Joachim Baumann et al. ("Baumann"), Ex. 1007, titled "DEVICE AND PROCESS FOR CHARGING OF RECHARGEABLE BATTERIES OF IMPLANTS," issued on May 8, 2001, claims priority to parent application filed on August 21, 1998. With an issue date nearly four years before the earliest priority date of the '758 Patent (April 29, 2005), Baumann qualifies as prior art under 35 U.S.C. 102(b).

In an initial Information Disclosure Statement submitted on August 26, 2011, the '758 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 '758 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 on 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").

With respect to the substantive teachings of Baumann, with reference to the annotated FIG. 1 of Baumann 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.*

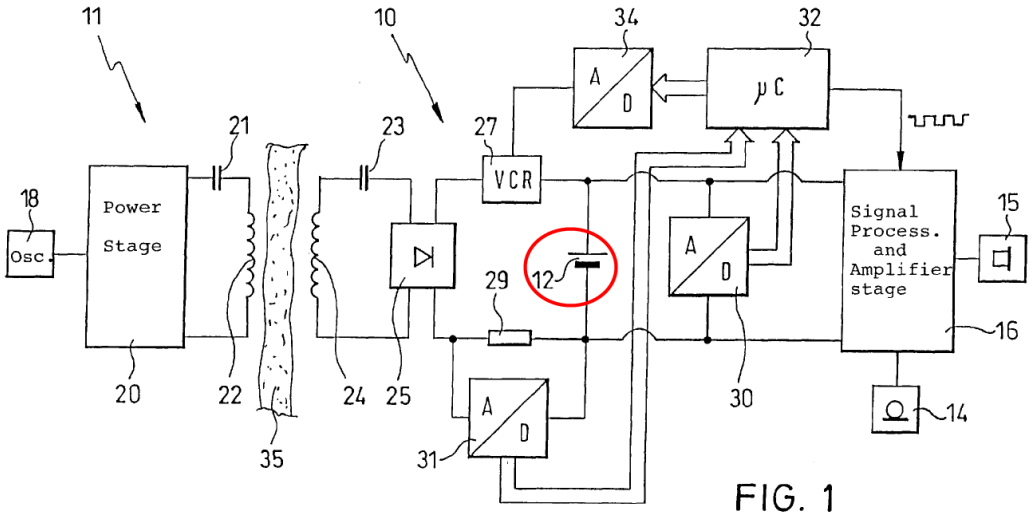



FIG. 1

As depicted in FIG. 3 of Baumann, "in a first charging phase (T1) [the charging current detector] allows a relatively high charging

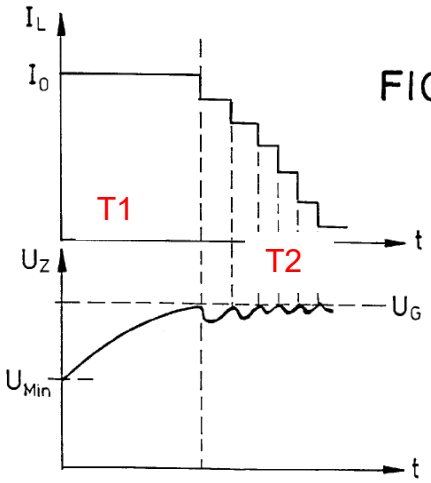



FIG. 3

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 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. Applying Baumann to Claims 1-12**

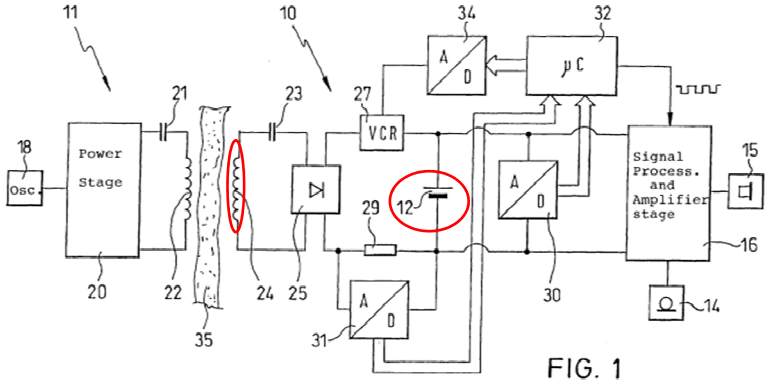
Baumann teaches every limitation of claims 1-12 of the '758 Patent, as shown below.

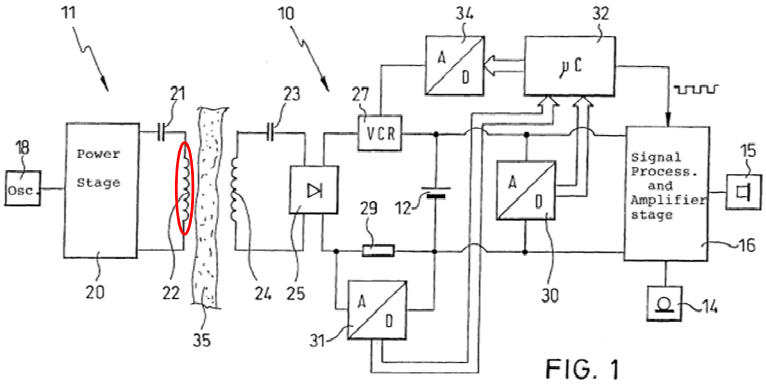
These claims can be grouped into three sets of claims, with the members of each set repeating identical language for most of the body of the claim except for different "wherein" clauses. The first set (claims 1-4) consists of ***system claims***;

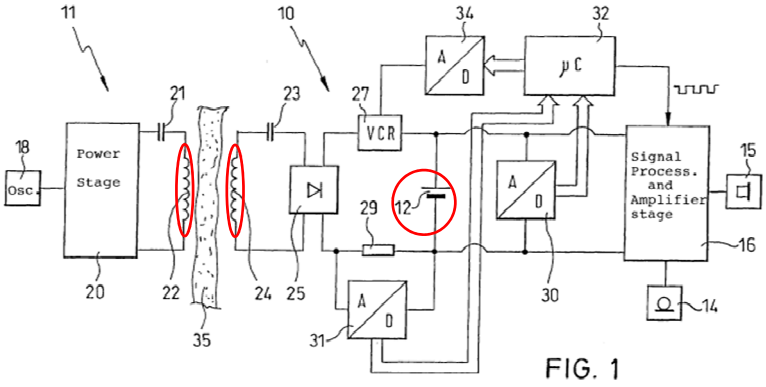
the second set (claims 5-8) consists of corresponding ***device claims***; and the third set (claims 9-12) consists of corresponding ***method claims***.

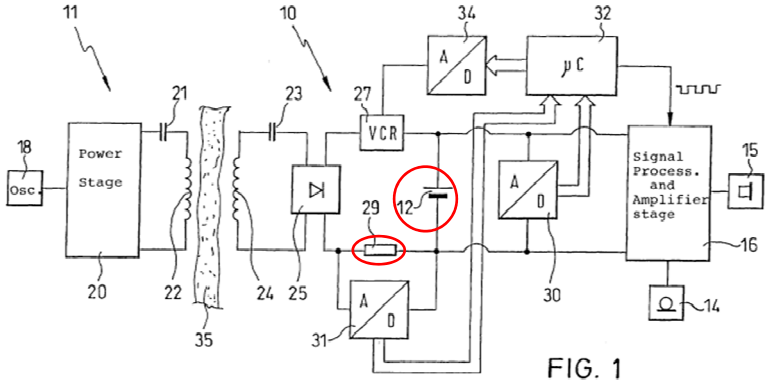
- **Claims 1-4: Identical Elements**

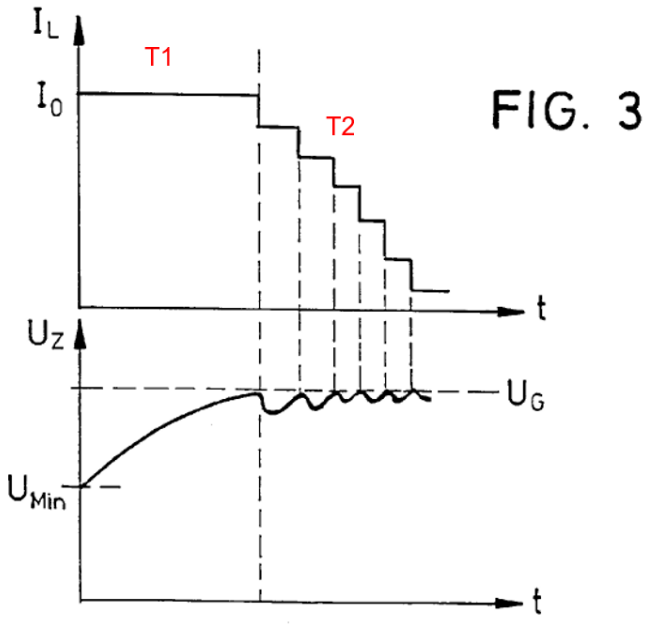
| | Claims 1-4 | Baumann |
|---|---|---|
| 1.0<br>2.0<br>3.0<br>4.0 | A system for transcutaneous energy transfer, comprising: | *Petitioner does not here advocate that the preamble is limiting.*<br>"The invention relates to a charging device for charging of rechargeable ... batteries of implants ... by transcutaneous transmission of electric power from an external power transmission part to a power receiving part which forms a part of the implant." [Ex. 1007, 1:7-13] |
| 1.1(a)<br>2.1(a)<br>3.1(a)<br>4.1(a) | an implantable medical device having componentry for providing a therapeutic output, | "The implant can be basically ***any implantable medical or biological device***. Thus, among others, it can be . . . a cardiac pacemaker, a defibrillator, . . . or the like." [Ex. 1007, 2:47-52, emphasis added] |

| | Claims 1-4 | Baumann |
|---|---|---|
| 1.1(b)<br>2.1(b)<br>3.1(b)<br>4.1(b) | said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, |  <br>FIG. 1<br><br>"The charging device shown in FIG. 1 has an implantable power receiving part 10 and an external (outside the body) power transmission part 11. The charging device is used to charge a ***rechargeable battery 12*** which, for its part, in this embodiment, provides power to an active implantable electronic hearing aid." [Ex. 1007, 4:60-65, emphasis added]<br><br>"The power receiving part 10 includes a series resonant circuit with a capacitor 23 and ***an implant coil 24***. The series resonant circuit 23, 24 feed a rectifier stage 25, that is preferably in the form of a full bridge circuit. The ***battery 12*** is connected via a voltage controlled resistor (VCR) 27 to the output of the rectifier stage 25." [Ex. 1007, 4:15-20, emphasis added]<br><br>*FIG. 1 shows implant coil 24 (secondary coil) operatively coupled to battery 12 of implantable* |

| | Claims 1-4 | Baumann |
|---|---|---|
| | | *device. Ex. 1003, ¶ 94.* |
| 1.1(c)<br>2.1(c)<br>3.1(c)<br>4.1(c) | said implantable medical device adapted to be implanted in a patient; and | "The implant can be basically ***any implantable medical or biological device***. Thus, among others, it can be an active electronic hearing implant, a cardiac pacemaker, a defibrillator, a drug dispenser, a nerve or bone growth stimulator, a neurostimulator or retinal stimulator, a pain suppression device or the like." [Ex. 1007, 2:47-52, emphasis added] |
| 1.2(a)<br>2.2(a)<br>3.2(a)<br>4.2(a) | an external power source having a primary coil, | "The charging device shown in FIG. 1 has ... an external (outside the body) power transmission part 11." [Ex. 1007, 3:60-62]<br>  <br><br>FIG. 1<br>"The power transmission part 11 has an oscillator 18, an electronic power stage 20 and a series resonant circuit connected to the output side of the power electronic stage 20. The series resonant circuit is comprised of a capacitor 21 and ***an*** |

| | Claims 1-4 | Baumann |
|---|---|---|
| | | ***external field coil 22***." [Ex. 1007, 4:10-14, emphasis added] |
| 1.2(b)<br>2.2(b)<br>3.2(b)<br>4.2(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, having a value, passing through said internal power source; |  <br>FIG. 1<br><br>"***A charging process begins with the external field coil 22 being placed on the outside of the skin 35 of the implant wearer*** such that it is ***aligned at least approximately with the implant coil 24***. The electronic power stage 18, in interaction with the oscillator 18, ... an alternating current supplies to the field coil 22 which has a frequency in the range from 40 kHz to 50 MHz. ***The alternating electromagnetic field produced by the field coil 22 transcutaneously induces in the implant coil 24 an alternating current*** which is rectified in the rectifier stage 25. The ***battery 12 is charged with the rectified charging current $I_L$***." [Ex. 1007, 4:36-47, emphasis added] |

| | Claims 1-4 | Baumann |
|---|---|---|
| 1.3<br>2.3<br>3.3<br>4.3 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; |  <br>FIG. 1<br><br>"In the charging current circuit of the battery 12, between the rectifier stage 25 and the battery 12, is a ***current measuring resistor 29*** connected in parallel to the A/D converter 31." [Ex. 1007, 4:23-26, emphasis added]<br><br>"The size of ***the charging current $I_L$ is determined from the voltage drop on the current measuring resistor 29***, and a corresponding measured quantity travels to the microcontroller 32 via the A/D converter 31." [Ex. 1007, 4:52-55] – *Baumann discloses determining charging current by measuring a voltage drop across current measuring resistor 29. The voltage across current measuring resistor 29 is measured and is proportional to charging current $I_L$, as defined by Ohm's law (V=IR). This voltage is thus a value that is associated with the current passing through the battery. Ex. 1003, ¶ 96.* |

| | Claims 1-4 | Baumann |
|---|---|---|
| | | "It is also possible to ***control the charging current $I_L$***, during the high current charging phase ***using the measured current value*** acquired via the A/D converter 31 to a stipulated setpoint." [Ex. 1007, 5:9-12, emphasis added] – *Baumann teaches, during a first charging phase (T1) as illustrated in FIG. 3 below, controlling $I_L$ by maintaining it at a stipulated setpoint ($I_0$) based on the current value acquired from the A/D converter 31, which specifies current at the current measuring resistor 29, and which is associated with current passing through the battery 12. Ex. 1003, ¶¶ 96, 100.*<br>  <br><br>FIG. 3<br>*See also disclosures for Ground 3 [4.4] below – Baumann discloses that during the second charging phase (T2), when charging current ($I_L$) passing* |

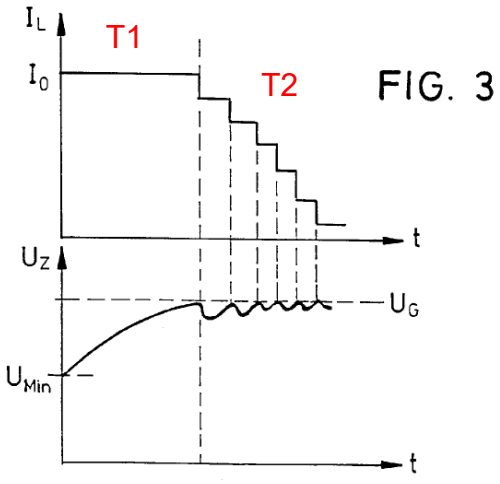
| | Claims 1-4 | Baumann |
|---|---|---|
| | | *through the battery is below a particular amount, the charging process is automatically ended. That is, the power output is automatically varied (such that it approaches zero) based on a value associated with the charging current $I_L$ passing through the battery.*<br><br>"The ***means necessary to set the charging current $I_L$***, in the described manner, depending on the cell voltage $U_Z$ of the battery 12 can, as shown in FIG. 1, be housed in an implantable power receiving part 10. Basically ***however[,] it can also be in the external power transmission part 11*** or distributed between both parts 10 and 11." [Ex. 1007, 5:59-64, emphasis added] – *Baumann is directed to the concept of varying of the charging current $I_L$ for optimizing charging of a rechargeable battery in an implanted device. In disclosing this concept, it focuses on various example embodiments using a controller in the implant. However, the above statement in Baumann makes it abundantly clear that the means for varying the charging current $I_L$ can also be in the external charging unit. Ex. 1003, ¶ 102.*<br><br>*Medtronic may allege that this embodiment is not enabling, since a telemetry system for* |

| | Claims 1-4 | Baumann |
|---|---|---|
| | | *communicating information from the internal circuitry to the external charging unit is not described. Enablement requires only that the disclosure of the patent be sufficient to enable a POSITA to make and use the claimed invention without undue experimentation.* In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). A POSITA would be able to readily implement a telemetry system to communicate from the internal circuitry to the external circuitry of the external charging unit so that the external circuitry can control a power output. Ex. 1003, ¶ 102. Schulman is an example of prior art showing such a telemetry system, as described below. Schulman issued in 1976, over 20 years before Baumann's earliest priority date. Thus, such a telemetry system was known for at least 20 years before Baumann, and would have been known to one of skill in the art at the time Baumann was filed. Ex. 1003, ¶ 102.* |

- **Claim 1 (Cont.)**

| | Claim 1 (Cont.) | Baumann |
|---|---|---|
| 1.4 | wherein said external power source automatically varies its power output based on a measured current associated with said current passing through said internal power source. | *See disclosures for Ground 1 [1.4] and Ground 3 [1.3] above.* |

- **Claim 2 (Cont.)**

| | Claim 2 (Cont.) | Baumann |
|---|---|---|
| 2.4 | wherein said current passing through said internal power source declines as said voltage of said internal power source |  FIG. 3 |

| | Claim 2 (Cont.) | Baumann |
|---|---|---|
| | increases during a charging cycle. | "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. 1007, 5:14-22]<br><br>**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 multiple other instances in the specification. See, e.g.,* [Ex. 1007, 5:22-25, emphasis added] ("In turn the ***limiting charging voltage $U_G$*** is selected such that the battery cannot be damaged. Preferably the ***limiting charging voltage $U_G$*** is less than $U_{Max}$ minus $\Delta U$). *Ex. 1003, ¶ 105 n.3.*<br><br>*The use of the term "as" in the claim, at first glance, suggests an inverse relationship between the change in battery voltage and battery current that is continuous in the course of the change. However, the only instance where it could be argued the '758 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*:<br><br>"If no over temperature condition exists, charging unit 50 checks (328) to determine if |

| | Claim 2 (Cont.) | Baumann |
|---|---|---|
| | | 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)***."<br><br>*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. Ex. 1003, ¶ 104.* |

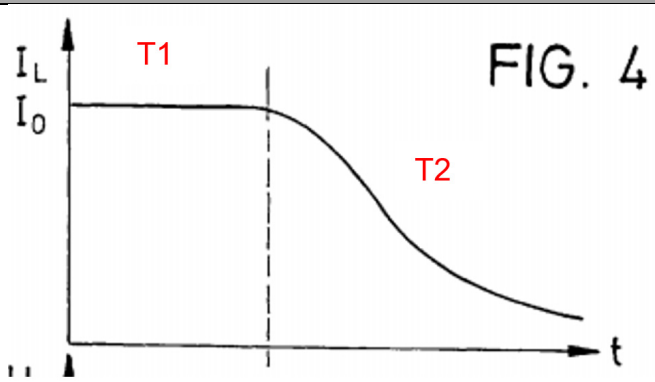
- **Claim 3 (Cont.)**

| | Claim 3 (Cont.) | Baumann |
|---|---|---|
| 3.4 | wherein said current passing through said internal power source comprises a maximum amount of current for charging said internal power source; | "… the charging device comprising a charging current detector having control means for producing a first charging phase in which a relatively high charging current flow is produced which is limited to a stipulated maximum value." [Ex. 1007, claim 1.]<br>*Baumann discloses that a maximum amount of charging current is produced during charging phase T1. Ex. 1003, ¶ 114.* |
| 3.5 | wherein said current passing through 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]<br>*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. Ex. 1003, ¶¶* |

| | Claim 3 (Cont.) | Baumann |
|---|---|---|
| | | *106-12.* |

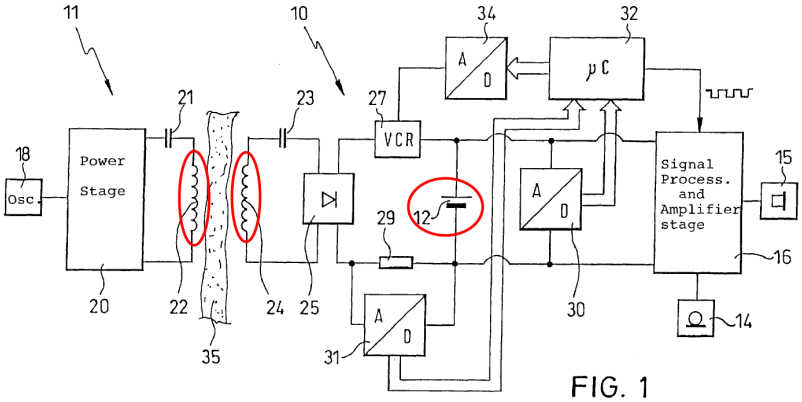
- **Claim 4 (Cont.)**

| | Claim 4 (Cont.) | Baumann |
|---|---|---|
| 4.4 | wherein said external power source terminates its power output if said current passing through said internal power source is below a minimum amount. | "Preferably, the arrangement is such that, by means of microcontroller 32, the time change of the charging current, i.e. the value $\Delta I_L/\Delta t$, is acquired during the second charging phase T2, and ***the second charging phase, and thus also the overall charging process, are ended when a predetermined slope of the charging current curve is not reached, in other words, when $\Delta I_L/\Delta t$ is less than a stipulated minimum value***. Determination of $\Delta I_L/\Delta t$ can then be performed directly by acquiring the voltage which drops on the current measuring resistor 29 via the A/D converter 31." [Ex. 1007, 5:36-45, emphasis added] – *Baumann discloses terminating charging based on $\Delta I_L/\Delta t$, which is the change in charging current $I_L$ over a period of time. $\Delta I_L/\Delta t$ corresponds to the slope of, for example, the portion of FIG. 4 showing a charging current graph, an annotated version of which is below:* |

| | Claim 4 (Cont.) | Baumann |
|---|---|---|
| | |  <br>*As shown in the charging current graph above, during the second charging phase T2, $\Delta I_L/\Delta t$ (i.e., the slope) declines as charging current $I_L$ declines.* ***When $I_L$ is below a particular (minimum) amount, "$\Delta I_L/\Delta t$ is less than a stipulated minimum value," at which point "the second charging phase, and thus also the overall charging process, are ended."*** *Ex. 1003, ¶ 116.*<br>"The means necessary to set the charging current $I_L$, in the described manner, depending on the cell voltage $U_Z$ of the battery 12 can, as shown in FIG. 1, be housed in an implantable power receiving part 10. ***Basically however[,] it can also be in the external power transmission part 11*** or distributed between both parts 10 and 11." [Ex. 1007, 5:59-64, emphasis added] – *As explained in the disclosure for Ground 3 [4.4] above, this statement makes it clear that the means for varying the charging* |

| | Claim 4 (Cont.) | Baumann |
|---|---|---|
| | | *current $I_L$ can also be in the external charging unit. Ex. 1003, ¶ 102.* |

- **Claims 5-9: Identical Elements**

| | Claims 5-9 | Baumann |
|---|---|---|
| 5.0<br>6.0<br>7.0<br>8.0 | An external power source for use with an implantable medical device adapted to be implanted in a patient and having componentry for providing a therapeutic output, an internal power source and a secondary coil operatively coupled to said internal power source, comprising: | *Petitioner does not here advocate that the preamble is limiting.*<br>*All terms recited in the preamble are virtually identical to those recited in the body of the independent claim 2. For detailed description of the following summary, see chart for claim 2 above:*<br>  <br><br>FIG. 1<br>"external power source" = *Baumann: "power transmission part 11"*<br>"implantable medical device" = *Baumann: "implantable power receiving part 10"*<br>"internal power source" = *Baumann: "rechargeable battery 12"* |

| | Claims 5-9 | Baumann |
|---|---|---|
| | | "secondary coil" = *Baumann: "implant coil 24"* |
| 5.1<br>6.1<br>7.1<br>8.1 | an external power unit; and | "The power transmission part 11 has an oscillator 18, ***an electronic power stage 20***…." [Ex. 1007, 4:10-11, emphasis added] |
| 5.2<br>6.2<br>7.2<br>8.2 | a primary coil, operatively coupled to said external power unit; | "The power transmission part 11 has an oscillator 18, an electronic power stage 20 and ***a series resonant circuit connected to the output side of the power electronic stage 20***. The series resonant circuit is comprised of a capacitor 21 and ***an external field coil 22*** in the illustrated embodiment. [Ex. 1007, 4:10-14, emphasis added] |
| 5.3<br>6.3<br>7.3<br>8.3 | said external power unit providing energy to said implantable medical device when said primary coil is placed in proximity of said secondary coil of said implantable medical | *See disclosures for Ground 3 [2.2(b)] above.* |

| | Claims 5-9 | Baumann |
|---|---|---|
| | device and thereby generating a current having a value passing through said internal power source; | |
| 5.4<br>6.4<br>7.5<br>8.4 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | *See disclosures for Ground 3 [2.3] above.* |

- **Claim 5 (Cont.)**

| | Claim 5 (Cont.) | Baumann |
|---|---|---|
| 5.5 | wherein said external power source automatically | *See disclosures for Ground 1 [5.5] and Ground 3 [1.4] above.* |

| | Claim 5 (Cont.) | Baumann |
|---|---|---|
| | varies its power output based on a measured current associated with said current passing through said internal power source. | |

- **Claim 6 (Cont.)**

| | Claim 6 (Cont.) | Baumann |
|---|---|---|
| 6.5 | wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *See disclosures for Ground 3 [2.4] above.* |

- **Claim 7 (Cont.)**

| | Claim 7 (Cont.) | Baumann |
|---|---|---|
| 7.4 | wherein said current passing through said internal power source comprises a maximum amount of current for charging said internal power source; | *See disclosures for Ground 3 [3.4] above.* |
| 7.6 | wherein said current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *See disclosures for Ground 3 [3.5] above.* |

- **Claim 8 (Cont.)**

| | Claim 8 (Cont.) | Baumann |
|---|---|---|
| 8.5 | wherein said external power source terminates its power output if said current passing through said internal power source is below a minimum amount. | *See disclosures for Ground 3 [4.4] above.* |

- **Claims 9-12: Identical Elements**

| | Claims 9-12 | Baumann |
|---|---|---|
| 9.0(a)<br>10.0(a)<br>11.0(a)<br>12.0(a) | A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted | *Petitioner does not here advocate that the preamble is limiting.*<br>*All terms recited in the preamble of this method claim are structural features of the "external power source" claimed by the independent claims above including claim 6.*<br>*See disclosures for Ground 3 [6.0, 6.1, 6.2] above.* |

| | Claims 9-12 | Baumann |
|---|---|---|
| | medical device, said external primary coil being operatively coupled to a charging unit, said secondary coil supplying power to an internal power source of said implanted medical device, | |
| 9.0(b)<br>10.0(b)<br>11.0(b)<br>12.0(b) | said internal power source having an internal impedance, comprising the steps of: | *It is an inherent property of batteries to have an internal resistance. See Ex. 1003, ¶ 109.* |
| 9.1<br>10.1<br>11.1<br>12.1 | driving said external primary coil with a charging signal from said charging unit | *See disclosures for Ground 3 [2.2(b)] above.* |

| | Claims 9-12 | Baumann |
|---|---|---|
| | generating a current passing through said internal power source; and | |
| 9.2<br>10.2<br>11.2<br>12.2 | said charging unit automatically varying its power output based on a value associated with said current passing through said internal power source; | *See disclosures for Ground 3 [2.3] above.* |

- **Claim 9 (Cont.)**

| | Claim 9 (Cont.) | Baumann |
|---|---|---|
| 9.3 | wherein said automatically varying step automatically varies its power output based on a measured current | *See disclosures for Ground 1 [9.3] and Ground 3 [1.4] above.* |

| | Claim 9 (Cont.) | Baumann |
|---|---|---|
| | associated with said current passing through said internal power source. | |

- **Claim 10 (Cont.)**

| | Claim 10 (Cont.) | Baumann |
|---|---|---|
| 10.3 | wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *See disclosures for Ground 3 [2.4] above.* |

- **Claim 11 (Cont.)**

| | Claim 11 (Cont.) | Baumann |
|---|---|---|
| 11.3 | wherein said current passing through said | *See disclosures for Ground 3 [3.4] above.* |

| | Claim 11 (Cont.) | Baumann |
|---|---|---|
| | internal power source comprises a maximum amount of current for charging said internal power source; | |
| 11.4 | wherein said current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *See disclosures for Ground 3 [3.5] above.* |

- **Claim 12 (Cont.)**

| | Claim 12 (Cont.) | Baumann |
|---|---|---|
| 12.3 | wherein said external power source terminates its power output if | *See disclosures for Ground 3 [4.4] above.* |

| | Claim 12 (Cont.) | Baumann |
|---|---|---|
| | said current passing through said internal power source is below a minimum amount. | |

### D. Ground 4: Claims 2-4, 6-8, and 10-12 are unpatentable as obvious over Schulman and Baumann

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

As discussed above with respect to Ground 3 (Section V.C.1), Baumann is not cumulative despite the fact that it was cited by Applicant in the initial Information Disclosure Statement. Furthermore, the combination of Schulman and Baumann is especially not cumulative, given that such combination 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.").

**1. 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 regarding cigarette lighters when both identified problem of making lighters safer). Both Schulman and Baumann 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 charging protocol that maximizes charging speed while minimizing the risk of harmful charging conditions. Ex. 1007, 2:15-22. This is achieved via a two-phase charging protocol. These two phases include a first high-current charging phase to achieve "charging as fast as possible" (Ex. 1007, 4:65-5:5 and FIG. 2), and a second phase with the battery voltage limited to 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 (e.g., a "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. Ex. 1003, ¶¶ 118-122.

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, ¶ 118-122.

### 2. Applying combination of Schulman and Baumann to Claims 2-4, 6-8, and 10-12

The combination of Schulman and Baumann renders claims 2-4, 6-8, and 10-12 of the '758 Patent obvious, as shown below.

Similar to Ground 3, the claims here can be grouped into three sets, with the members of each set repeating identical language for most of the body of the claim except for different "wherein" clauses. The first set (claims 2-4) consists of ***system claims***; the second set (claims 6-8) consists of corresponding ***device claims***; and the third set (claims 10-12) consists of corresponding ***method claims***.

- **Claims 2-4: Identical Elements**

| | Claim 2 | Schulman combined with Baumann |
|---|---|---|
| 2.0<br>3.0<br>4.0 | A system for transcutaneous energy transfer, comprising: | *Schulman*<br>*See disclosures for Ground 1 [1.0] above.* |
| 2.1(a)<br>3.1(a)<br>4.1(a) | an implantable medical device having componentry for providing a | *Schulman*<br>*See disclosures for Ground 1 [1.1(a)] above.* |

| | Claim 2 | Schulman combined with Baumann |
|---|---|---|
| | therapeutic output, | |
| 2.1(b)<br>3.1(b)<br>4.1(b) | said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, | <u>*Schulman*</u><br>*See disclosures for Ground 1 [1.1(b)] above.* |
| 2.1(c)<br>3.1(c)<br>4.1(c) | said implantable medical device adapted to be implanted in a patient; and | <u>*Schulman*</u><br>*See disclosures for Ground 1 [1.1(c)] above.* |
| 2.2(a)<br>3.2(a)<br>4.2(a) | an external power source having a primary coil, | <u>*Schulman*</u><br>*See disclosures for Ground 1 [1.2(a)] above.* |
| 2.2(b)<br>3.2(b)<br>4.2(b) | said external power source providing energy to said | <u>*Schulman*</u><br>*See disclosures for Ground 1 [1.2(b)] above.* |

| | Claim 2 | Schulman combined with Baumann |
|---|---|---|
| | 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 | |
| 2.2(c)<br>3.2(c)<br>4.2(c) | thereby generating a current, having a value, passing through said internal power sources; | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [1.2(c)] above.* |
| 2.3<br>3.3<br>4.3 | wherein said external power source automatically varies its power | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [1.3] above.* |

| | Claim 2 | Schulman combined with Baumann |
|---|---|---|
| | output based on a value associated with said current passing through said internal power source; | |

- **Claim 2 (Cont.)**

| | Claim 2 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 2.4 | wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *Baumann*<br><br>*See disclosures for Ground 3 [2.4] above.* |

- **Claim 3 (Cont.)**

| | Claim 3 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 3.4 | wherein said current passing | Schulman<br><br>"***All current up to a maximum level*** will flow |

| | Claim 3 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| | through said internal power source comprises a maximum amount of current for charging said internal power source; | through the rectified output leads 51 and 52 to charge the battery 15." [Ex. 1005, 6:17-19]<br><br>"***[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] – *Schulman teaches varying the charging current based on a measure of charging current (through current sampling resistor R9 and through shunt-network element R8)* ***to attain a maximum charging current****. See Ex. 1003, ¶ 127.*<br><br>"***[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. This lowered output current, through the |

| | Claim 3 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| | | 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] – *Schulman thus teaches ensuring that charging current is at a maximum value. See Ex. 1003, ¶ 127.* |
| 3.5 | wherein said current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *Baumann*<br>*See disclosures for Ground 3 [3.5] above* |

- **Claim 4 (Cont.)**

| | Claim 4 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 4.4 | wherein said external power source terminates its power output if | *Baumann*<br>*See disclosures for Ground 3 [4.4] above* |

| | Claim 4 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| | said current passing through said internal power source is below a minimum amount. | |

- **Claims 6-8: Identical Elements**

| | Claim 6 | Schulman combined with Baumann |
|---|---|---|
| 6.0<br>7.0<br>8.0 | An external power source for use with an implantable medical device adapted to be implanted in a patient and having componentry for providing a therapeutic output, an internal power source and a | *Petitioner does not here advocate that the preamble is limiting.*<br>*Schulman*<br>*See disclosures for Ground 1 [5.0] above.* |

| | Claim 6 | Schulman combined with Baumann |
|---|---|---|
| | secondary coil operatively coupled to said internal power source, comprising: | |
| 6.1<br>7.1<br>8.1 | an external power unit; and | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [5.1] above.* |
| 6.2<br>7.2<br>8.2 | a primary coil, operatively coupled to said external power unit; | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [5.2] above.* |
| 6.3(a)<br>7.3(a)<br>8.3(a) | said external power unit providing energy to said implantable medical device when said primary coil is placed in proximity of said | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [5.3(a)] above.* |

| | Claim 6 | Schulman combined with Baumann |
|---|---|---|
| | secondary coil of said implantable medical device and | |
| 6.3(b)<br>7.3(b)<br>8.3(b) | thereby generating a current having a value passing through said internal power source; | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [5.3(b)] above.* |
| 6.4<br>7.5<br>8.4 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [5.4] above.* |

- **Claim 6 (Cont.)**

| | Claim 6 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 6.5 | wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *Baumann*<br><br>*See disclosures for Ground 3 [2.4] above.* |

- **Claim 7 (Cont.)**

| | Claim 7 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 7.4 | wherein said current passing through said internal power source comprises a maximum amount of current for charging said internal power | *Schulman*<br><br>*See disclosures for Ground 4 [3.4] above.* |

| | Claim 7 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| | source; | |
| 7.6 | wherein said current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *Baumann*<br><br>*See disclosures for Ground 3 [3.5] above.* |

- **Claim 8 (Cont.)**

| | Claim 8 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 8.5 | wherein said external power source terminates its power output if said current passing through said internal power source is below a minimum amount. | *Baumann*<br><br>*See disclosures for Ground 3 [4.4] above.* |

- **Claims 10-12: Identical Elements**

| | Claim 10 | Schulman combined with Baumann |
|---|---|---|
| 10.0(a)<br>11.0(a)<br>12.0(a) | A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of | *Petitioner does not here advocate that the preamble is limiting.*<br><br>*Schulman*<br><br>*See disclosures for Ground 1 [9.0(a)] above.* |

| | Claim 10 | Schulman combined with Baumann |
|---|---|---|
| | an implanted medical device, said external primary coil being operatively coupled to a charging unit, said secondary coil supplying power to an internal power source of said implanted medical device, | |
| 10.0(b)<br>11.0(b)<br>12.0(b) | said internal power source having an internal impedance, comprising the steps of: | *It is an inherent property of batteries to have an internal resistance. See Ex. 1003, ¶ 109.* |
| 10.1<br>11.1<br>12.1 | driving said external primary coil with a charging signal from said | <u>*Schulman*</u><br><br>*See disclosures for Ground 1 [9.1] above.* |

| | Claim 10 | Schulman combined with Baumann |
|---|---|---|
| | charging unit generating a current passing through said internal power source; and | |
| 10.2<br>11.2<br>12.2 | said charging unit automatically varying its power output based on a value associated with said current passing through said internal power source; | *Schulman*<br><br>*See disclosures for Ground 1 [1.3] above.* |

- **Claim 10 (Cont.)**

| | Claim 10 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 10.3 | wherein said current passing through said internal power source declines as said voltage of | *Baumann*<br><br>*See disclosures for Ground 3 [2.4] above.* |

| | Claim 10 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| | said internal power source increases during a charging cycle. | |

- **Claim 11 (Cont.)**

| | Claim 11 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 11.3 | wherein said current passing through said internal power source comprises a maximum amount of current for charging said internal power source; | *Schulman*<br><br>*See disclosures for Ground 4 [3.4] above.* |
| 11.4 | wherein said current passing through said internal power source declines over time as an internal | *Baumann*<br><br>*See disclosures for Ground 3 [3.5] above.* |

| | Claim 11 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| | impedance of said internal power source increases. | |

- **Claim 12 (Cont.)**

| | Claim 12 (Cont.) | Schulman combined with Baumann |
|---|---|---|
| 12.3 | wherein said external power source terminates its power output if said current passing through said internal power source is below a minimum amount. | *Baumann*<br><br>*See disclosures for Ground 3 [4.4] above.* |

### E. Ground 5: Claims 2-4, 6-8, and 10-12 are unpatentable as obvious over Fischell and 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 2-4, 6-8, and 10-12 obvious as presented below.

As discussed above with respect to Ground 4 (Section V.D), the combination of Fischell and Baumann is especially not cumulative, given that such combination was not at any point before the Examiner.

**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 first high-current phase to achieve "charging as fast as possible" (Ex. 1007, 4:65-5:5 and FIG. 2), and a second phase with the battery voltage limited to a limiting voltage "selected such that the battery cannot be damaged during charging" (Ex. 1007, 5:22-23 and FIG. 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 at 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 safety and reliability features of the system. Ex. 1003, ¶¶ 132-137.

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, ¶¶ 132-137.

**2. Applying combination of Fischell and Baumann to Claims 2-4, 6-8, and 10-12**

The combination of Fischell and Baumann renders claims 2, 4, 6, 8, 10 and 12 of the ’758 Patent obvious, as shown below.

Similar to Ground 4, the claims here can be grouped into three sets, with the members of each set repeating identical language for most of the body of the claim except for different “wherein” clauses. The first set (claims 2-4) consists of ***system***

***claims***; the second set (claims 6-8) consists of corresponding ***device claims***; and the third set (claims 10-12) consists of corresponding ***method claims***.

- **Claims 2-4: Identical Elements**

| | Claim 2 | Fischell combined with Baumann |
|---|---|---|
| 2.0<br>3.0<br>4.0 | A system for transcutaneous energy transfer, comprising: | *Fischell*<br><br>*See disclosures for Ground 2 [1.0] above.* |
| 2.1(a)<br>3.1(a)<br>4.1(a) | an implantable medical device having componentry for providing a therapeutic output, | *Fischell*<br><br>*See disclosures for Ground 2 [1.1(a)] above.* |
| 2.1(b)<br>3.1(b)<br>4.1(b) | said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, | *Fischell*<br><br>*See disclosures for Ground 2 [1.1(b)] above.* |

| | Claim 2 | Fischell combined with Baumann |
|---|---|---|
| 2.1(c)<br>3.1(c)<br>4.1(c) | said implantable medical device adapted to be implanted in a patient; and | <u>*Fischell*</u><br>*See disclosures for Ground 2 [1.1(c)] above.* |
| 2.2(a)<br>3.2(a)<br>4.2(a) | an external power source having a primary coil, | <u>*Fischell*</u><br>*See disclosures for Ground 2 [1.2(a)] above.* |
| 2.2(b)<br>3.2(b)<br>4.2(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 | <u>*Fischell*</u><br>*See disclosures for Ground 2 [1.2(b)] above.* |

| | Claim 2 | Fischell combined with Baumann |
|---|---|---|
| | generating a current, having a value, passing through said internal power sources; | |
| 2.3<br>3.3<br>4.3 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | *Fischell*<br><br>*See disclosures for Ground 2 [1.3] above.* |
| 2.4 | wherein said current passing through said internal power source declines as said voltage of said internal | *Baumann*<br><br>*See disclosures for Ground 3 [2.4] above.* |

| | Claim 2 | Fischell combined with Baumann |
|---|---|---|
| | power source increases during a charging cycle. | |

- **Claim 2 (Cont.)**

| | Claim 2 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 2.4 | wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *Baumann*<br><br>*See disclosures for Ground 3 [2.4] above.* |

- **Claim 3 (Cont.)**

| | Claim 3 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 3.4 | wherein said current passing through said internal power source comprises | *Fischell*<br><br>"The charging circuit for the rechargeable pacer ***limits the charge (and overcharge) current*** into the battery to 40 mA." [Ex. 1006 at 367, emphasis |

| | Claim 3 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| | a maximum amount of current for charging said internal power source; | added]<br>"A feedback control system in the charger maintains the battery charge current at the proper 40 mA level." [Ex. 1006 at 378] |
| 3.5 | wherein said current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *Baumann*<br>*See disclosures for Ground 3 [3.5] above.* |

- **Claim 4 (Cont.)**

| | Claim 4 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 4.4 | wherein said external power source terminates its power output if said current | *Baumann*<br>*See disclosures for Ground 3 [4.4] above* |

| | Claim 4 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| | passing through said internal power source is below a minimum amount. | |

- **Claims 6-8: Identical Elements**

| | Claim 6 | Fischell combined with Baumann |
|---|---|---|
| 6.0<br>7.0<br>8.0 | An external power source for use with an implantable medical device adapted to be implanted in a patient and having componentry for providing a therapeutic output, an internal power source and a secondary coil | *Petitioner does not here advocate that the preamble is limiting.*<br>*Fischell*<br>*See disclosures for Ground 2 [5.0] above.* |

| | Claim 6 | Fischell combined with Baumann |
|---|---|---|
| | operatively coupled to said internal power source, comprising: | |
| 6.1<br>7.1<br>8.1 | an external power unit; and | <u>*Fischell*</u><br>*See disclosures for Ground 2 [5.1] above.* |
| 6.2<br>7.2<br>8.2 | a primary coil, operatively coupled to said external power unit; | <u>*Fischell*</u><br>*See disclosures for Ground 2 [5.2] above.* |
| 6.3<br>7.3<br>8.3 | said external power unit providing energy to said implantable medical device when said primary coil is placed in proximity of said secondary coil of | <u>*Fischell*</u><br>*See disclosures for Ground 2 [1.2(b)] above.* |

| | Claim 6 | Fischell combined with Baumann |
|---|---|---|
| | said implantable medical device and thereby generating a current having a value passing through said internal power source; | |
| 6.4<br>7.5<br>8.4 | wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source; | *Fischell*<br><br>*See disclosures for Ground 2 [1.3] above.* |

- **Claim 6 (Cont.)**

| | Claim 6 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 6.5 | wherein said | *Baumann* |

| | Claim 6 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| | current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *See disclosures for Ground 3 [2.4] above.* |

- **Claim 7 (Cont.)**

| | Claim 7 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 7.4 | wherein said current passing through said internal power source comprises a maximum amount of current for charging said internal power source; | *Fischell*<br><br>*See disclosures for Ground 5 [3.4] above.* |
| 7.6 | wherein said | *Baumann* |

| | Claim 7 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| | current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *See disclosures for Ground 3 [3.5] above.* |

- **Claim 8 (Cont.)**

| | Claim 8 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 8.5 | wherein said external power source terminates its power output if said current passing through said internal power source is below a minimum amount. | *Baumann*<br><br>*See disclosures for Ground 3 [4.4] above.* |

- **Claims 10-12: Identical Elements**

| | Claim 10 | Fischell combined with Baumann |
|---|---|---|
| 10.0(a)<br>11.0(a)<br>12.0(a) | A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted medical device, said external primary coil being operatively coupled to a charging unit, said secondary coil supplying power to an internal power source of said implanted medical device, | *Petitioner does not here advocate that the preamble is limiting.*<br>*Fischell*<br>*See disclosures for Ground 2 [9.0(a)] above.* |
| 10.0(b) | said internal | *It is an inherent property of batteries to have an* |

| | Claim 10 | Fischell combined with Baumann |
|---|---|---|
| 11.0(b)<br>12.0(b) | power source having an internal impedance, comprising the steps of: | *internal resistance. See Ex. 1003, ¶ 109.* |
| 10.1<br>11.1<br>12.1 | driving said external primary coil with a charging signal from said charging unit generating a current passing through said internal power source; and | <u>*Fischell*</u><br><br>*See disclosures for Ground 1 [9.1] above.* |
| 10.2<br>11.2<br>12.2 | said charging unit automatically varying its power output based on a value associated with said current passing through said internal | <u>*Fischell*</u><br><br>*See disclosures for Ground 1 [1.3] above.* |

| | Claim 10 | Fischell combined with Baumann |
|---|---|---|
| | power source; | |

- **Claim 10 (Cont.)**

| | Claim 10 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 10.3 | wherein said current passing through said internal power source declines as said voltage of said internal power source increases during a charging cycle. | *Baumann*<br><br>*See disclosures for Ground 3 [2.4] above.* |

- **Claim 11 (Cont.)**

| | Claim 11 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 11.3 | wherein said current passing through said internal power source comprises a maximum amount of current | *Fischell*<br><br>*See disclosures for Ground 5 [3.4] above.* |

| | Claim 11 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| | for charging said internal power source; | |
| 11.4 | wherein said current passing through said internal power source declines over time as an internal impedance of said internal power source increases. | *Baumann*<br><br>*See disclosures for Ground 3 [3.5] above.* |

- **Claim 12 (Cont.)**

| | Claim 12 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| 12.3 | wherein said external power source terminates its power output if said current passing through said internal power source is | *Baumann*<br><br>*See disclosures for Ground 3 [4.4] above.* |

| | Claim 12 (Cont.) | Fischell combined with Baumann |
|---|---|---|
| | below a minimum amount. | |

# VI. MANDATORY REQUIREMENTS

## A. Grounds for Standing

Axonics certifies that the '758 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 '758 Patent. Ex. 1009.

## B. Mandatory Notices

### 1. Real Parties in Interest

Axonics is the real party in interest for this Petition.

### 2. Related Matters

The '758 Patent is at issue in *Medtronic, Inc. et al. v. Axonics Modulation Technologies, Inc.*, No. 8:19-cv-02115-DOC-JDE (C.D. Cal.).

The '758 Patent is related to U.S. Patent Nos. 7,774,069 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 twelve (12) claims of the '758 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 in accordance with 37 C.F.R. § 42.10(b).

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

Axonics serves this Petition and exhibits to the correspondence address of record for the '758 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*
A. James Isbester
Registration No. 36,315
Lead Counsel for Petitioner

| Lead Counsel | Back-Up Counsel |
|---|---|
| A. James Isbester<br>Registration No. 36,315<br>jisbester@kilpatricktownsend.com<br><br>Postal and Hand-Delivery Address:<br>Kilpatrick Townsend & Stockton LLP<br>Two Embarcadero Center, Suite 1900<br>San Francisco, CA 94111<br>Telephone: (415) 576-0200<br>Facsimile: (415) 576-0300 | Babak S. Sani<br>Registration No. 37,495<br>bssani@kilpatricktownsend.com<br><br>Postal and Hand-Delivery Address:<br>Kilpatrick Townsend & Stockton LLP<br>Two Embarcadero Center, Suite 1900<br>San Francisco, CA, 94111<br>Telephone: (415) 576-0200<br>Facsimile: (415) 576-0300 |

## 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 13,442 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*
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. 8,457,758, 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. 8,457,758:

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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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Respectfully,

Dated: March 16, 2020

By: */s/ A. James Isbester*
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Counsel for Petitioner

73056160V.1