UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

Case IPR2020-00712
Patent No. 8,738,148

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,738,148

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I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics" or "Petitioner") respectfully petitions for initiation of *inter partes* review of all claims 1 through 18 of U.S. Patent No. 8,738,148 ("the '148 Patent"), Ex. 1001, in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq*. ("Petition").

The '148 Patent generally relates to a system for charging the battery inside a medical device that is implanted beneath the skin of a patient. The '148 Patent describes such transcutaneous energy transfer system as having an external power source which includes a primary inductive coil, and an implanted medical device which includes a secondary inductive coil and an internal rechargeable power source. Placing the external power source in proximity of the implanted medical device generates, via inductive coupling, a charging current in the internal power source. Ex. 1001, Abstract. The '148 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, 7:33-8:15. The purported novelty it claims relates to optimizing the battery charging process by automatically varying the power that is output by the external output source based on a value associated with the current passing through the internal battery. Ex. 1001, 21:58-22:18. As explained herein, however, the '148 Patent did not disclose anything new. Indeed, such systems for transcutaneous energy transfer, including those with the claimed automatic adjusting of the external power supplied to the implanted device, had been known, written about and in widespread use for decades prior to the filing date of the '148 Patent. The '148 Patent adds nothing to the art and its claims should be found unpatentable as anticipated and/or obvious.

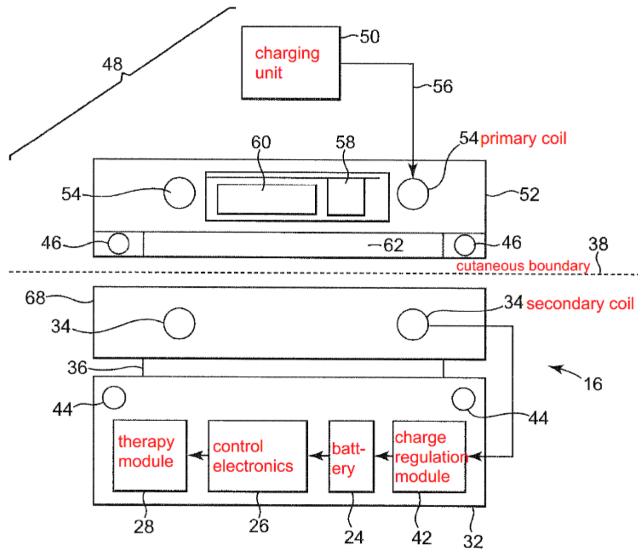
II. OVERVIEW OF THE '148 Patent

A. Background and Summary of the '148 Patent

The '148 Patent issued May 27, 2014, from Application No. 13/836,527, filed March 15, 2013. The '148 Patent is a final patent issued in a family of related patents, claiming earliest priority date of April 29, 2005. The '148 Patent is therefore subject to the *pre*-America Invents Act ("AIA") provisions of 35 U.S.C. §§ 102 and 103.

The '148 Patent relates generally to a system for charging the battery inside a medical device that is implanted beneath the skin of a patient. The '148 Patent describes such transcutaneous energy transfer system as having two main components: 1) an implantable device that includes a therapy module that stimulates tissue of the patient, electronics for driving the therapy module, and a rechargeable battery that powers the device; and 2) an external charging device that transcutaneously provides power to recharge the battery in the implantable device when placed in proximity of the implanted device.

FIG. 3 of the '148 Patent, an annotated version of which is reproduced herein, is a block diagram of the system showing an implantable medical device 16 positioned under cutaneous boundary 38, and an external charging device 48. Implantable medical device 16 includes "a rechargeable power source 24, such as a Lithium ion battery, that powers electronics 26 and therapy module 28 ***in a conventional manner***." Ex. 1001, 7:33-36 (emphasis added).[1] "Therapy module 28 is coupled to [the patient] ***also conventionally***." Ex. 1001, 7:36-38 (emphasis added). Similarly, "charging regulation [module 42] and therapy control [electronics 26 and therapy module 28] ***is conventional***." Ex. 1001, 7:62-64 (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, 7:46-47 (emphasis added). "Implantable medical device 16 also has "internal telemetry coil 44 configured ***in***



[1] Per the '148 Patent, "implantable medical device 16" of FIG. 3 "is similar to the embodiment illustrated in FIG. 2" except for breaking charging regulation module 42 off into a separate block form electronics 26. Ex. 1001, 7:59-62.

conventional manner to communicate through external telemetry coil 46 to [the charging unit 50] ***in a conventional manner*** in order to both program and control" implantable medical device 16 … ." Ex. 1001, 7:63-67 (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, 8:21-29.

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, 21:27-28. An excerpt of FIG. 19, related to the claims of the '148 Patent, is reproduced below:

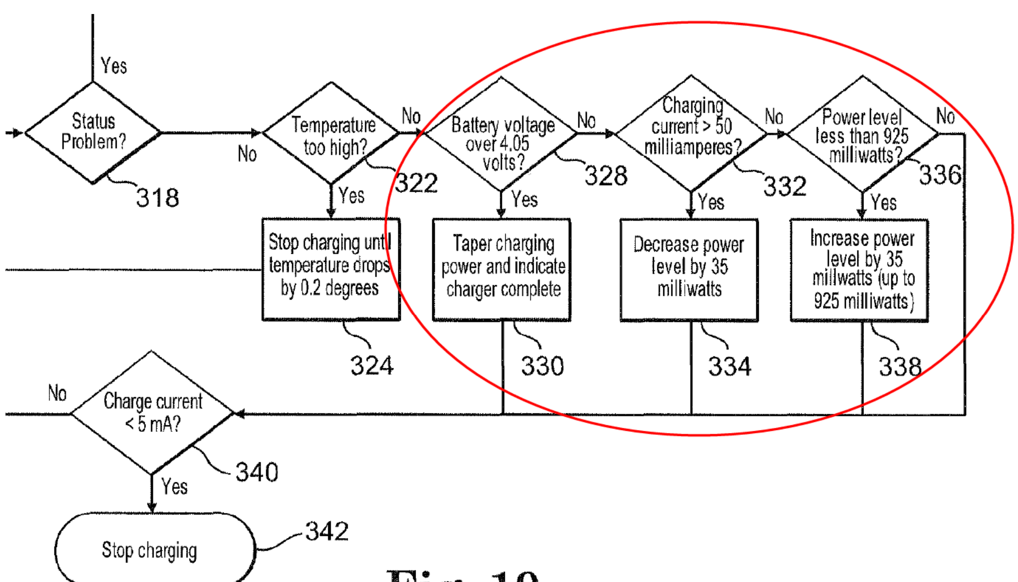


Fig. 19

FIG. 19 shows a method including several decision steps used to control the amount of power supplied by charging unit 50 to implantable medical device 16. 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, 21:58-61. 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, 21:61-63.

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, 21:64-22:1. 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, 22:1-2.

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, 22:4-6. 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, 22:6-9. 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, 22:11-14.

B. Prosecution History of the '148 Patent

The prosecution of the '148 Patent included one substantive Office Action. A copy of the file history can be found at Ex. 1002. The application that matured into the '148 Patent was filed with 18 claims, including 3 independent claims. In an Office Action, dated September 9, 2013, all pending claims were rejected based on nonstatutory double patenting over the claims of each of the other three patents already issued in the '148 family, specifically, U.S. Patent No. 8,457,758, U.S. Patent No. 8,024,047 and U.S. Patent No. 7,774,069. The Office Action further rejected claims 1, 6, 7, 12, 13 and 18 as being anticipated by U.S. Patent No. 4,665,896 to LaForge ("LaForge"), and found the remaining claims 2-5, 8-11, and 14-17 to be allowable subject to the filing of a terminal disclaimer.

In a response filed December 9, 2013, the Applicant submitted a terminal disclaimer to address the double patenting rejection. The Applicant amended claims 1, 7, and 13 to insert the additional phrase "measured in said implantable device" in order to distinguish LaForge. Specifically, arguing that LaForge "discloses that voltage regulation is based on what goes on in the primary, external coil, without regard to the internal medical device," the Applicant stated that

LaForge "does not show, disclose nor suggest measuring a value associated with the current passing through the internal battery in the implantable medical device." Ex. 1002, p. 52 of 166 (all emphasis in the original). In that response the Applicant further amended claims 2, 5, 8, 11, 14, and 17, rewriting them in independent form to include limitations the Examiner had found to be allowable. On January 1, 2014, the Examiner issued a Notice of Allowance finding all claims as amended allowable, and the patent issued on May 27, 2014.

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 PhD. in Electrical and Computer Engineering from the University of Wisconsin-Madison in 1991 and 1993, respectively. Dr. Panescu has over 25 years of direct technical experience in electrical medical device technology including systems with implantable medical devices like those in the claims at issue. Dr. Panescu is an inventor on over 170 issued U.S. patent and is the author of over 150 industry publications. Additional details regarding Dr. Panescu's background are provided in 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 18 of the '148 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 Article"), Ex. 1006.
- U.S. Patent No. 3,888,260, issued June 10, 1975 ("Fischell '260"), Ex. 1007.

Each of the listed references was published more than one year before the '148 Patent's priority date of April 29, 2005, and is therefore prior art under pre-AIA 35 U.S.C. §102(b). Schulman and Fischell Article were not before the examiner during prosecution of the '069 patent, and while Fischell '260 was disclosed by the Applicant, Fischell '260 was not substantively raised during prosecution.

As discussed in greater detail under Section II.A. above, the '148 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 '148 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, 7:33-8:15. The purported novelty it claims relates to optimizing the battery charging process by automatically varying the power that is output by the external output source based on a value associated with the current passing through the internal battery. Ex. 1001, 21:58-22:18.

The listed prior art references similarly address systems for transcutaneous energy transfer with optimized methods for recharging of batteries in implanted devices. Schulman is directed to a rechargeable implantable medical device with external charging controlled by telemetered information associated with internal battery charging current. Fischell Article discloses a system including a rechargeable implantable cardiac pacemaker that telemeters sensed battery charge current to an external charger, based on which power supplied to the implanted device is adjusted. Fischell '260 discloses an improved system for charging of rechargeable batteries of implanted medical devices by transcutaneous transmission of power from an external charging device. Petitioner therefore respectfully requests that the Board cancel the challenged claims of the '148 Patent based on the following grounds:

- Ground 1: All claims 1 through 18 are unpatentable as anticipated by Schulman.

- Ground 2: Claims 1-4, 7-10 and 13-16 are unpatentable as anticipated by Fischell Article.
- Ground 3: Claims 5, 6, 11, 12, 17 and 18 are unpatentable as obvious over Fischell Article in view of Fischell '260.

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

A. Ground 1: Claims 1 through 18 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 '148 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 at column 3, lines 42 to 50: "a rechargeable tissue stimulating system comprising a charging circuit 10 including a telemetry circuit 12 and a tissue stimulator 11 including a catheter 16, all designed for implantation into the body of a living patient. The system further includes a power source 13 with a transducer 14 in the form of a detector circuit for recharging and for verifying the charging condition of the implanted portions of the tissue stimulating system." Ex. 1005, 3:42-50.

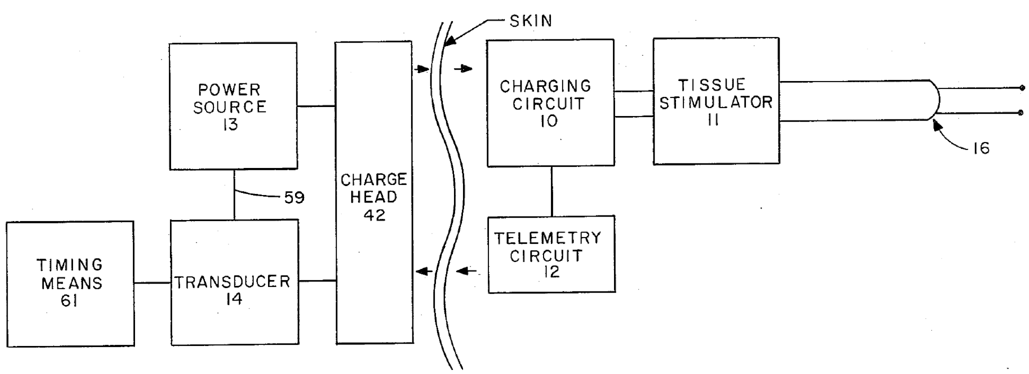


FIG. 1

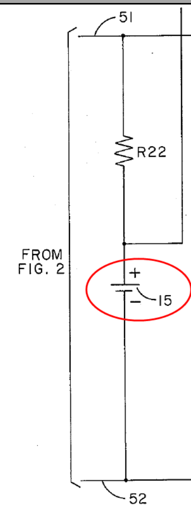
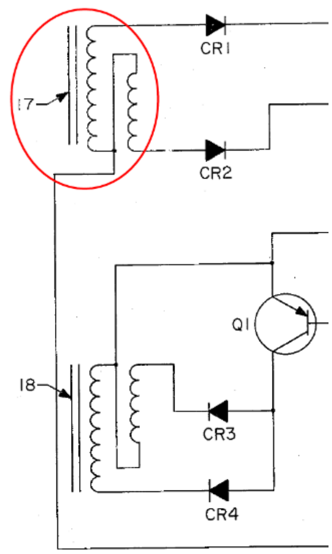
Schulman further teaches that the "external electrical charging power source [includes] an induction coil for positioning external to a living subject and proximate to the induction coil of the implantable charging circuit" and that the telemetry circuit in the implantable device detects "the magnitude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

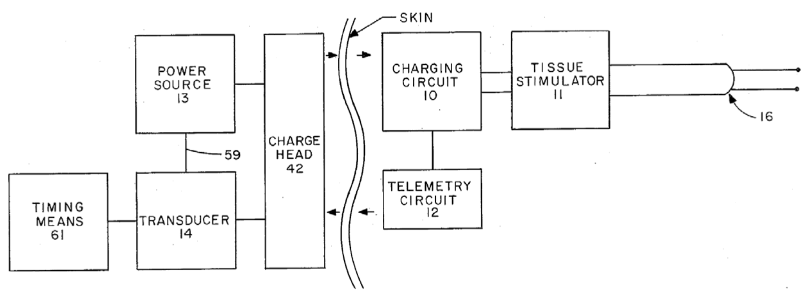
2. Applying Schulman to Claims 1 through 18

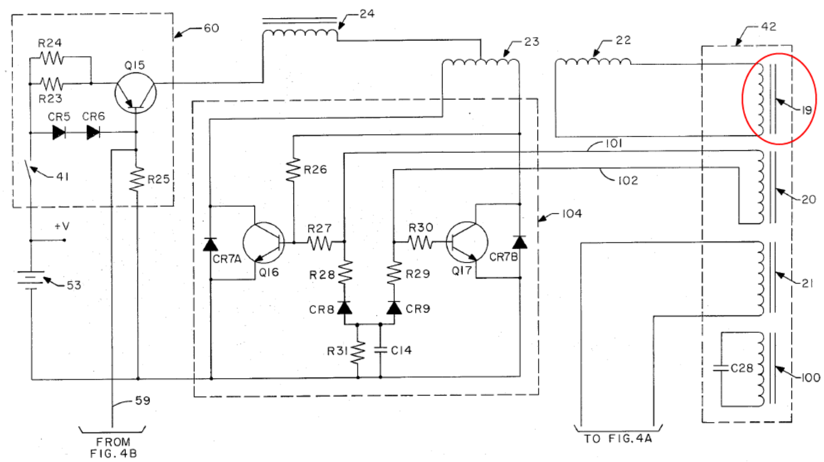
Schulman teaches every limitation of claims 1 through 18 of the '148 Patent, as set forth in greater detail in the following charts. The '148 Patent claims can be divided into three sets of claims with each set repeating identical language for most of the body of the claim except for slightly different "wherein" clauses. To avoid lengthy repetition of identical material, the identical portions of each set of claims are grouped together in one chart with any differing "wherein" clauses addressed in separate charts. Accordingly the charts below combine identical elements of independent claims 1, 3 and 6 into a single chart, identical elements of independent claims 7, 9 and 12 into a single chart, and identical elements of independent claim 13, 15 and 18 into a single chart. (See also Ex. 1003, ¶¶ 32-35, for a more detailed breakdown of the relationship between the three sets of claims.)

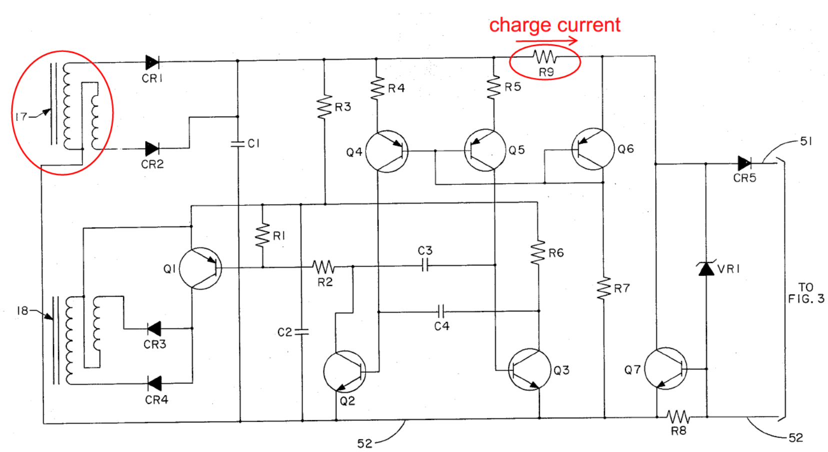
- **<u>Claims 1, 3 and 6: Identical Elements</u>**

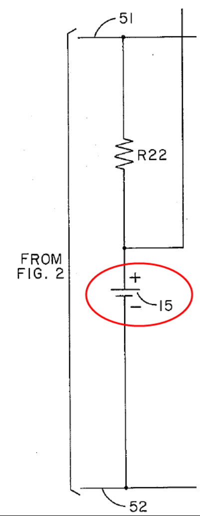
	Claims 1, 3, 6	Schulman
1.0 3.0 6.0	A system for transcutaneous energy transfer, comprising:	*Petitioner does not here advocate that the preamble limits the scope of the claim.* "This invention relates to a rechargeable tissue stimulating ***system for providing a charge to a voltage source implanted in a living being***, and for regulating recharging of the voltage source through the use of telemetry circuit." [Ex. 1005, 1:7-11, emphasis added]
1.1(a) 3.1(a) 6.1(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]

	Claims 1, 3, 6	Schulman
1.1(b) 3.1(b) 6.1(b)	said implantable medical device having an internal battery and a secondary coil operatively coupled to said internal battery,	"An implantable electrical tissue stimulator including a rechargeable d.c. voltage source" [Ex. 1005, 2:28-30]  *Partial view of FIG. 3 reproduced herein shows "rechargeable d.c. voltage" or "battery 15" ("internal battery").* "The charging circuit is illustrated in FIG. 2 and includes two induction coils 17 and 18. The output leads 51 and 52 from the induction coil 17 are rectified and are connected to the tissue stimulator of FIG. 3." [Ex. 1005, ¶¶ 59-62]  *Partial views of FIG. 2, reproduced herein shows "induction coil 17" ("secondary coil"). See Ex. 1003, ¶¶ 56-57 & 73-74.*

	Claims 1, 3, 6	Schulman
1.1(c) 3.1(c) 6.1(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) 3.2(a) 6.2(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]
1.2(b) 3.2(b) 6.2(b)	said external power source providing energy to said implantable medical device when said primary coil of said external	"[A]n external electrical charging power source including an induction coil for positioning external to a living subject and proximate to the induction coil of the implantable charging circuit" [Ex. 1005, 2:36-40] "Returning to the [external] power source illustrated in FIG. 4, a current control means 60 produces a constant current flow at its output into the induction coil 24. … " [Ex. 1005, 9:7-11] "This current flow is transformer coupled to the

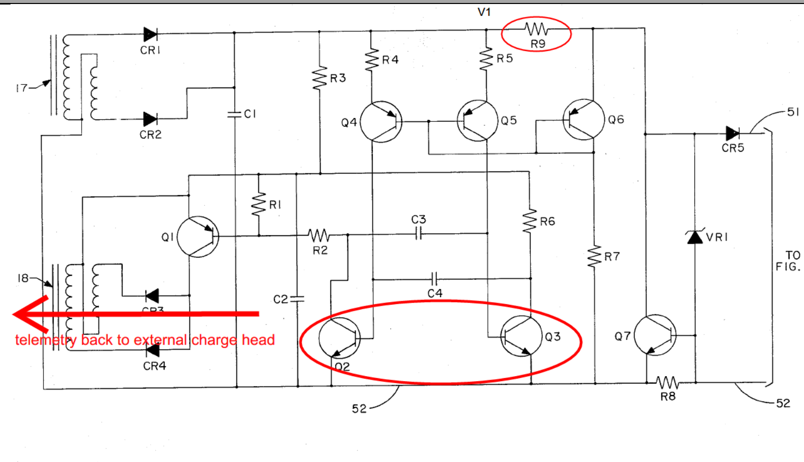
	Claims 1, 3, 6	Schulman
	power source is placed in proximity of said secondary coil of said implantable medical device and	secondary 22 and connected from there to the ***coil 19 on the charging head***.” [Ex. 1005, 7:46-48, emphasis added]  FIG. 4 “This lowered output current, through the use of induction coils 22, 23 and 24, results in a reduced ***magnetic field*** strength ***acting between the induction coils 19***, 20 and 21 of the power source ***and induction coils 17*** and 18 of the charging circuit.” [Ex. 1005, 7:29-33, emphasis added] *Schulman teaches external power source providing energy to the implanted device by creating a magnetic field when the induction coil 19 on the charging head of the external power source is placed in proximity of induction coil 17 of the implanted device. See Ex. 1003, ¶¶ 56-57 & 73-74.*

	Claims 1, 3, 6	Schulman
1.2(c) 3.2(c) 6.2(c)	thereby generating a current, having a value, passing through said internal battery;	"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 reproduced herein:*  "Charging current passes through the current sampling resistor R9 and through the diode CR5 to the tissue

	Claims 1, 3, 6	Schulman
		stimulator." [Ex. 1005, 4:11-13] "All current up to a maximum level will flow through the rectified output leads 51 and 52 to charge the battery 15." [Ex. 1005, 6:17-19] *Schulman teaches that the inductive coupling generates a "charging current," which has a value, that flows through the internal battery. See Ex. 1003, ¶¶ 56-57 & 73-74.* 

- **<u>Claim 1 (Cont.)</u>**

	Claim 1 (Cont.)	Schulman
1.3	wherein said external power source automatically varies its power output based on a value measured in said implantable medical device and associated with said current passing	"Charging current passes through the current sampling resistor R9." [Ex. 1005, 4:11-12] "[T]he 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]

	Claim 1 (Cont.)	Schulman
	through said internal battery.	 FIG. 2 "***[A]ny current less than this maximum passing through resistor R9*** is indicative of inadequate charging of the battery 15. It is ***the [internal] telemetry circuit 12*** [] ***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***." [Ex. 1005, 6:19-38, emphasis added] "***[R]esistor R8, which is connected in series with the rectified output leads 51 and 52*** […] can be selected for a regulation [of charging current] at a predetermined current. For example, if one wanted to maintain a charging current of 40 milliamperes

	Claim 1 (Cont.)	Schulman
		into the battery 15, and the base-emitter voltage drop required to initiate conductance in transistor Q7 is 0.4 volts, ***one would select a resistance value for resistor R8 such that 40 milliamperes would produce a 0.4 voltage differential*** between the base-emitter leads of transistor Q7. If the current began to increase beyond 40 milliamperes, transistor Q7 would conduct to an increasingly greater extent. Such an increasing load would alter the telemetry signal created by the transistor Q1." [5:2-35]. *The current passing through resistor R8 tracks the current through R9 and is equal to the current passing through battery 15. Transistor Q7 measures the current through (or voltage across) R8 and regulates the current passing through R9 to attain a predetermined charging current via the telemetry system. Schulman therefore teaches automatically (via telemetry feedback) varying the output of the external power source 13 based on a value measured in the implantable device associated with the current passing through internal battery 15. Given that Ohm's law defines voltage as current times resistance (V=I*R), both the current passing*

	Claim 1 (Cont.)	Schulman
		through resistor R8 and the voltage across it measure the same "value." See Ex. 1003, ¶¶ 75-88.

- **Claim 2**

	Claim 2	Schulman
	The system as in claim 1 wherein said current passing through said internal battery comprises a maximum amount of current for charging said internal battery.	"All ***current up to a maximum level*** will flow through the rectified output leads 51 and 52 to charge the battery 15." [Ex. 1005, 6:17-19, emphasis added] "[A]ny current less than this ***maximum*** passing through resistor R9 is indicative of inadequate charging of the battery 15." [Ex. 1005, 6:19-21, emphasis added] "[W]hen the current passing through resistor R9 in the charging circuit exceeds ***a maximum operating level***, the signal from circuit 59 will lower the output current from current control means 60." [Ex. 1005, 7:25-29, emphasis added]. *See Ex. 1003, ¶ 89.*

- **Claim 3 (cont.)**

	Claim 3 (Cont.)	Schulman
3.3	wherein said external power source automatically	*The only difference between the language of this "wherein" clause 3.3 and the wherein clause 1.3 of claim 1 is that claim element 3.3 deletes the words "measured in said implantable medical device and."*

	Claim 3 (Cont.)	Schulman
	varies its power output based on a value associated with said current passing through said internal battery; and	*Otherwise the two claim elements 1.3 and 3.3 are identical.* *As shown in detail under element 1.3 of claim 1, Schulman teaches automatically (via telemetry feedback) varying the power output of the external power source 13 based on a value (current or voltage across a resistor) associated with the charging current that passes through internal battery 15. See above element 1.3 and Ex. 1003, ¶¶ 75-88.*
3.4	wherein said external power source automatically varies its power output based on a signal proportional to said current passing through said internal battery.	*The only difference between this "wherein" clause and the one immediately preceding it (element 3.3) is the change from "*based on a value associated with*" to "*based on a signal proportional to.*" Schulman teaches automatically varying the power output of the external power source 13 based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the measured current through resistor R8 (1:1 proportion) or the measured voltage across R8 (proportional based on Ohm's law V=I*R). See above claim element 1.3 and Ex. 1003, ¶¶ 75-88.*

- **Claim 4**

	Claim 4	Schulman
	The system as in claim 3 wherein said external power source automatically varies its power output based on a current proportional to said current passing through said internal battery.	*Claim 4 further limits the term "a signal proportional to" of claim element 3.4 to "a current proportional to." Schulman teaches automatically varying the power output of the external power source 13 based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the measured current through resistor R8 which has a 1:1 proportion to the current passing through the internal battery 15. See above claim element 1.3 and Ex. 1003, ¶¶ 75-88.*

- **Claim 5**

	Claim 5	Schulman
	The system as in claim 3 wherein said external power source automatically varies its power output based on a voltage	*Claim 5 further limits "a signal proportional" of claim element 3.3 to "a voltage proportional." Schulman teaches automatically (via telemetry feedback) varying the power output of the external power source 13 based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the measured voltage across resistor R8 (proportional based on Ohm's law*

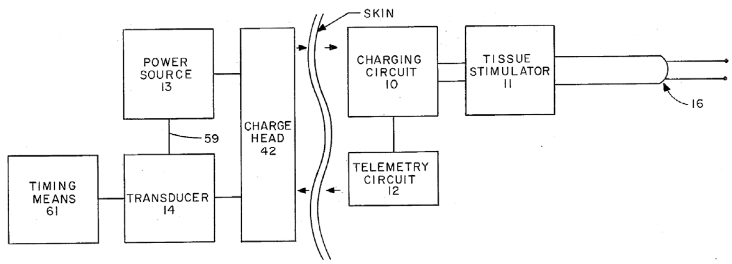
	Claim 5	Schulman
	proportional to said current passing through said internal battery.	*V=I*R). See above claim element 1.3 and Ex. 1003, ¶¶ 75-88.*

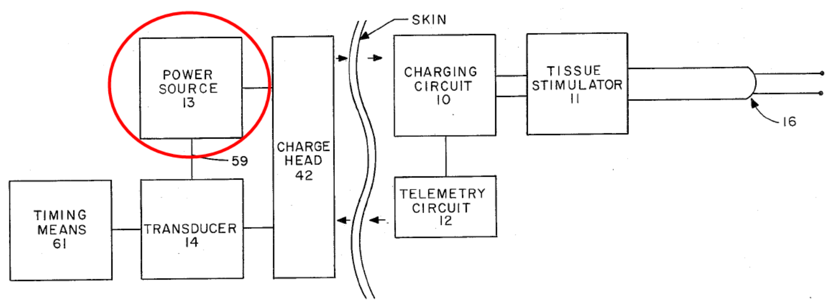
- **Claim 6 (Cont.)**

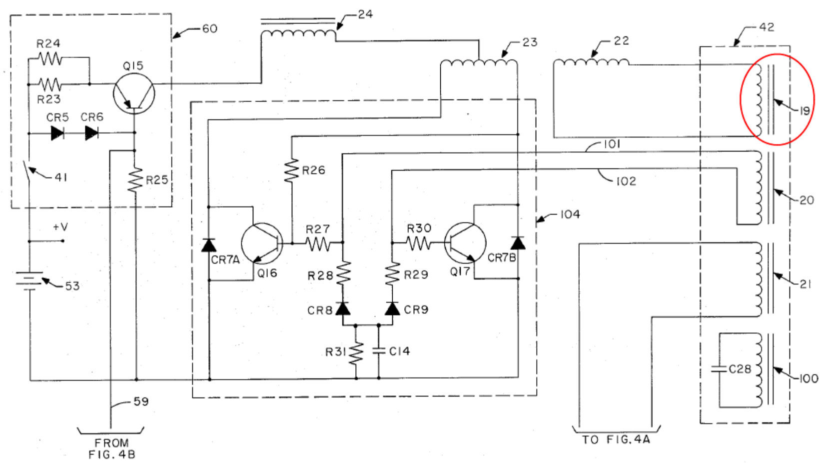
	Claim 6 (Cont.)	Schulman
6.3	wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal battery; and	*This claim limitation is identical to element 3.3 in claim 3. See above.*

	Claim 6 (Cont.)	Schulman
6.4	wherein said external power source automatically varies its power source output based on a measured voltage associated with said current passing through said internal battery.	*The only difference between this element of the claim and element 6.3 is that the term "value" in 6.3 is replaced with "measured voltage" in 6.4. As discussed in detail in connection with claim elements 1.3 and 3.3, Schulman teaches automatically varying the power output of the external power source 13 based on a measured voltage across resistor R8, which is associated with the charging current that passes through internal battery 15. See claim element 1.3 above and Ex. 1003, ¶¶ 75-88.*

- **<u>Claims 7, 9 and 12: Identical Elements</u>**

	Claims 7, 9 & 12	Schulman
7.0 9.0 12.0	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 battery and a secondary coil operatively coupled to said internal	*Petitioner does not here advocate that the preamble limits the scope of the claim.* *All terms recited in the preamble are duplicative of limitations recited in the body of the independent claim 1 (as well as being identical to those in claims 3 and 6). For detailed description of the following summary, see chart for claim 1 above:*  FIG. 1 "external power source" = *Schulman: "power source 13," "transducer 14," charge head 42," and "timing means 61" (FIG. 1)* "implantable medical device" = *Schulman: "an implantable electrical tissue stimulator" (FIG. 1)* "internal battery" = *Schulman: "rechargeable d.c. voltage source" 15 (FIG. 3)*

	Claims 7, 9 & 12	Schulman
	battery, comprising:	"secondary coil" = *Schulman: "induction coil 17" (FIG. 2)*
7.1 9.1 12.1	an external power unit; and	"The system further includes a power source 13" [3:47]  FIG. 1
7.2 9.2 12.2	a primary coil, operatively coupled to said external power unit;	"[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" [2:36-40, emphasis added] "Returning to the power source illustrated in FIG. 4, a current control means 60 produces a constant current flow at its output into the induction coil 24. … This current flow is transformer coupled to the secondary 22 and connected from there to the ***coil 19 on the***

	Claims 7, 9 & 12	Schulman
		charging head." [7:9-48, emphasis added]  FIG. 4 *As depicted in FIG. 4, Schulman teaches that the "power source 13"* ("external power unit"), *which comprises "current control means 60" and "power oscillator circuit 104," is coupled to inductive coil 19 ("primary coil") on the charging head. See Ex. 1003, ¶¶ 56-57 & 73-74.*
7.3(a) 9.3(a) 12.3(a)	said external power unit providing energy to said implantable medical device when said primary	*The language of this limitation is virtually identical to that recited in element 1.2(b) of claim 1. See element 1.2(b) of claim 1 above.*

	Claims 7, 9 & 12	Schulman
	coil is placed in proximity of said secondary coil of said implantable medical device and	
7.3(b) 9.3(b) 12.3(b)	thereby generating a current having a value passing through said internal battery;	*The language of this limitation is identical to that recited in element 1.2(c) of claim 1. See element 1.2(c) of claim 1 above.*

- **<u>Claim 7 (Cont.)</u>**

	Claim 7 (Cont.)	Schulman
7.4	wherein said external power source automatically varies its power	*The language of this limitation is identical to that recited in element 1.3 of claim 1. See element 1.3 of claim 1 above.*

	Claim 7 (Cont.)	Schulman
	output based on a value measured in said implantable medical device and associated with said current passing through said internal battery.	

- **Claim 8**

	Claim 8	Schulman
	The external power source as in claim 7 wherein said current passing through said internal battery comprises a maximum amount of current for charging said	*The language of this limitation is identical to that recited in claim 2 with the exception of the recitation of "internal power source" instead of "internal battery." This discrepancy appears to be an error since there is no antecedent basis for "internal power source" in claim 8 which instead recites "internal battery" as in claim 2. See claim 2 above.*

	Claim 8	Schulman
	internal power source.	

- **Claim 9 (Cont.)**

	Claim 9 (Cont.)	Schulman
9.4	wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal battery; and	*The language of this limitation is identical to that recited in element 3.3 of claim 3. See element 3.3 of claim 3 above.*
9.5	wherein said external power source automatically varies its power output based on a signal proportional to	*The language of this limitation is identical to that recited in element 3.4 of claim 3. See element 3.4 of claim 3 above.*

	Claim 9 (Cont.)	Schulman
	said current passing through said internal battery.	

- **Claim 10**

	Claim 10	Schulman
	The external power source as in claim 9 wherein said external power source automatically varies its power output based on a current proportional to said current passing through said internal battery.	*The language of this limitation is identical to that recited claim 4. See claim 4 above.*

- **Claim 11**

	Claim Language	Schulman
	The external power source as in claim 9 wherein said external power source automatically varies its power output based on a voltage proportional to said current passing through said internal battery.	*The language of this limitation is identical to that recited in claim 5. See claim 5 above.*

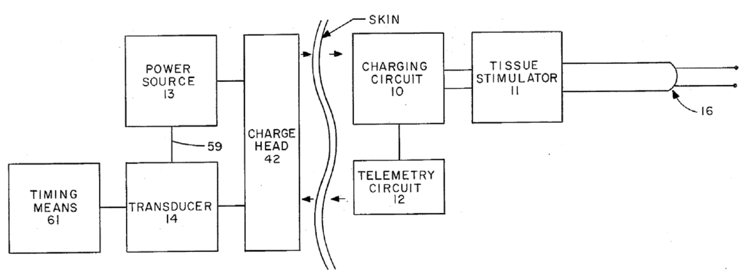
- **Claim 12 (Cont.)**

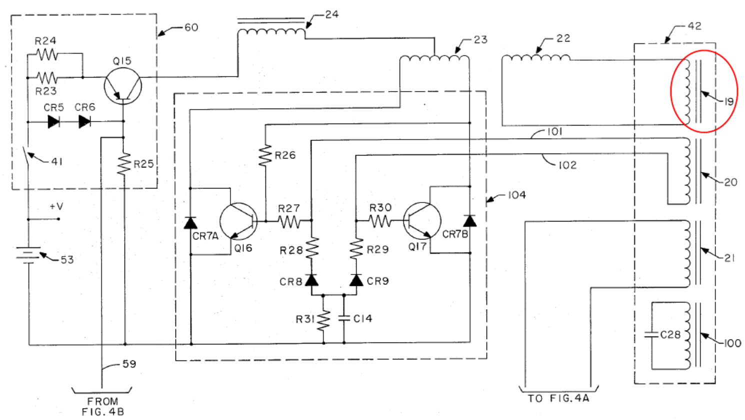
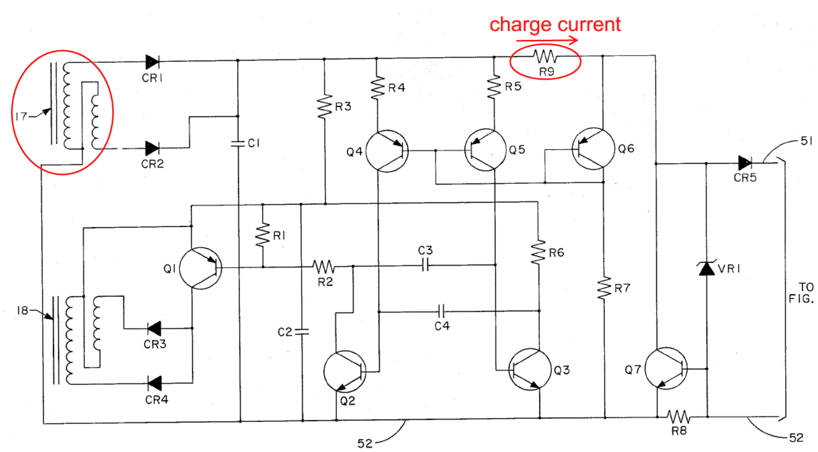
	Claim 12 (Cont.)	Schulman
12.4	wherein said external power source automatically varies its power output	*The language of this limitation is identical to that recited in element 6.3 of claim 6. See element 6.3 of claim 6 above.*

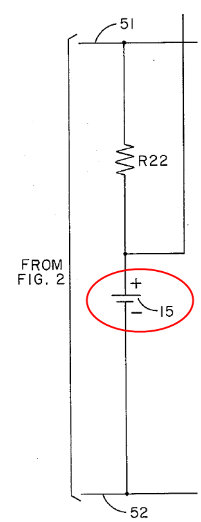
	Claim 12 (Cont.)	Schulman
	based on a value associated with said current passing through said internal battery; and	
12.5	wherein said external power source automatically varies its power output based on a measured voltage associated with said current passing through said internal battery.	*The language of this limitation is virtually identical to that recited in element 6.4 of claim 6. See element 6.4 of claim 6 above.*

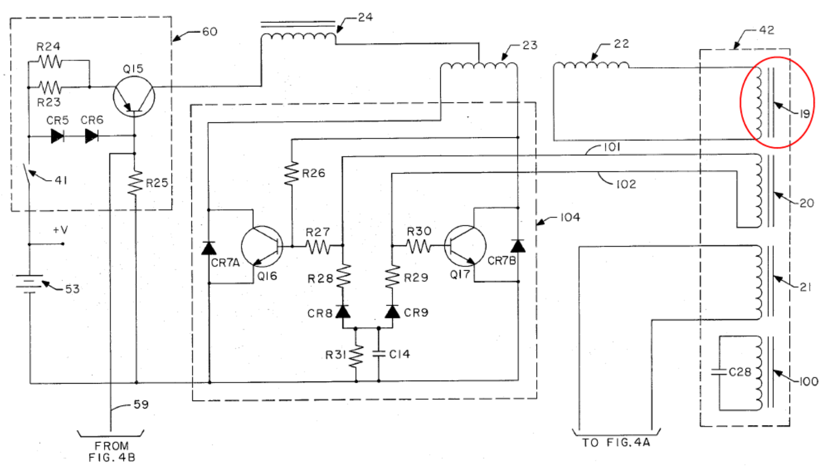
- **Claims 13, 15 & 18: Identical Elements**

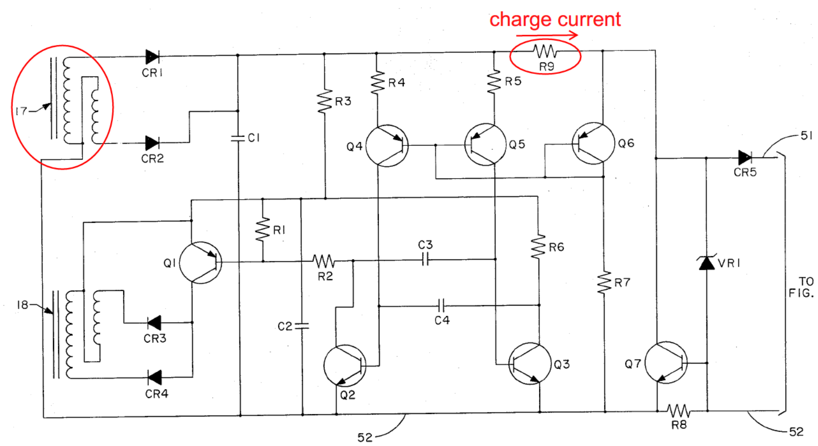
Claims 13 through 18 recast the language of prior claims in a method format. These method claims are similarly anticipated by Schulman as explained in the following charts.

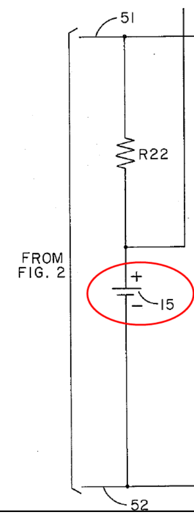
	Claims 13, 15 & 18	Schulman
13.0(a) 15.0(a) 18.0(a)	A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted medical device,	*Petitioner does not here advocate that the preamble limits the scope of the claim.* *All terms recited 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:*  FIG. 1 "external primary coil" = *Schulman: "induction coil 19" (FIG. 4) in "charge head 42" (FIG. 1)* "inductively coupled secondary coil" = *Schulman: "induction coil 17" (FIG. 2)* "implantable medical device" = *Schulman: "an implantable electrical tissue stimulator" (FIG. 1)*

	Claims 13, 15 & 18	Schulman
13.0(b) 15.0(b) 18.0(b)	said external primary coil being operatively coupled to a charging unit,	 FIG. 4 *Schulman teaches that an "external primary coil" 19 is coupled to a "charging unit" made up of current control means 60 and power oscillator circuit 10, as depicted in FIG. 4. See Ex. 1003, ¶¶ 56-57 & 73-74.*
13.0(c) 15.0(c) 18.0(c)	said secondary coil supplying power to an internal battery of said implanted medical device, said internal battery having an internal	*Annotated FIG. 2, showing internal charging circuit including "secondary coil" 17, is reproduced herein:*  "A 21 kilohertz charging signal is generated by the power source 13 for recharging the battery 15 of the

	Claims 13, 15 & 18	Schulman
	impedance, comprising the steps of:	tissue stimulating system. … The entire waveform of the current induced in the induction coil 17 is rectified by the diodes CR1 and CR2 to produce a d.c. output. … Charging current passes through the current sampling resistor R9 and through the diode CR5 to the tissue stimulator." [Ex. 1005, 3:68-4:13] "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]  *Schulman teaches that the inductive coupling between external primary coil and internal secondary coil generates a "charging current" that charges (i.e., supplies power) to the internal battery 15. See Ex. 1003, ¶¶ 56-57 & 73-74.* "A very suitable voltage source has been found to be a single cell nickel-cadmium battery" [1:30-32] *Internal impedance is an inherent property of batteries, including nickel-cadmium batteries. See Ex. 1003, ¶ 90.*

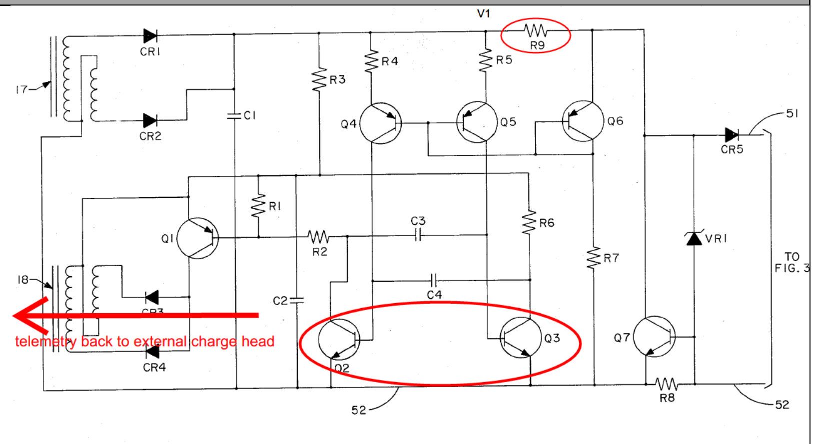
	Claims 13, 15 & 18	Schulman
13.1(a) 15.1(a) 18.1(a)	driving said external primary coil with a charging signal from said charging unit	"Returning to the [external] power source illustrated in FIG. 4, a current control means 60 produces a constant current flow at its output into the induction coil 24." [Ex. 1005, 9:7-11] "This current flow is transformer coupled to the secondary 22 and connected from there to the ***coil 19 on the charging head***." [Ex. 1005, 7:46-48, emphasis added]  FIG. 4 *Schulman teaches "current control means 60" (part of claimed "charging unit") generates a signal that drives external primary coil 19. See Ex. 1003, ¶ 86.*
13.1(b) 15.1(b) 18.1(b)	generating a current passing through said	"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.

	Claims 13, 15 & 18	Schulman
	internal battery; and	1005, 3:59-62]. *Annotated FIG. 2 depicting internal charging circuit 10 is reproduced herein:*  "A 21 kilohertz charging signal is generated by the power source 13 for recharging the battery 15 of the tissue stimulating system. … The entire waveform of the current induced in the induction coil 17 is rectified by the diodes CR1 and CR2 to produce a d.c. output. … Charging current passes through the current sampling resistor R9 and through the diode CR5 to the tissue

	Claims 13, 15 & 18	Schulman
		stimulator." [Ex. 1005, 3:68-4:13] "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] *Schulman teaches that the inductive coupling between external coil 19 and internal coil 17 generates a "charging current" that passes through the internal battery. See Ex. 1003, ¶¶ 56-57.* 

- **<u>Claim 13 (Cont.)</u>**

	Claim 13 (Cont.)	Schulman
13.2	said charging unit automatically varying its power output based on a value measured in said implantable medical device	"Charging current passes through the current sampling resistor R9." [Ex. 1005, 4:11-12] "[T]he 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]

	Claim 13 (Cont.)	Schulman
	and associated with said current passing through said internal battery.	 FIG. 2 "***[A]ny current less than this maximum passing through resistor R9*** is indicative of inadequate charging of the battery 15. It is ***the [internal] telemetry circuit 12*** [] ***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***." [Ex. 1005, 6:19-38, emphasis added] "***[R]esistor R8, which is connected in series with the rectified output leads 51 and 52*** […] can be selected for a regulation [of charging current] at a predetermined current. For example, if one wanted

	Claim 13 (Cont.)	Schulman
		to maintain a charging current of 40 milliamperes into the battery 15, and the base-emitter voltage drop required to initiate conductance in transistor Q7 is 0.4 volts, ***one would select a resistance value for resistor R8 such that 40 milliamperes would produce a 0.4 voltage differential*** between the base-emitter leads of transistor Q7. If the current began to increase beyond 40 milliamperes, transistor Q7 would conduct to an increasingly greater extent. Such an increasing load would alter the telemetry signal created by the transistor Q1." [5:2-35]. *The current passing through resistor R8 tracks the current through R9 and is equal to the current passing through battery 15. Transistor Q7 measures the current through R8 and regulates the current passing through R9 to attain a predetermined charging current via the telemetry system. Schulman therefore teaches automatically (via telemetry feedback) varying the output of the external power source 13 based on a value measured in the implantable device associated with the current passing through*

	Claim 13 (Cont.)	Schulman
		*internal battery 15. Given that Ohm's law defines voltage as current times resistance (V=I*R), both the current passing through resistor R8 and the voltage across it measure the same value. See Ex. 1003, ¶¶ 75-88.*

- **Claim 14**

	Claim 14	Schulman
	The method as in claim 13 wherein said current passing through said internal power source comprises a maximum amount of current for charging said internal battery.	*The language of this limitation is virtually identical to that recited in claim 2 with the exception of the recitation of "internal power source" instead of "internal battery." This discrepancy appears to be an error since there is no antecedent basis for "internal power source" in claim 14 which instead recites "internal battery" as in claim 2. See claim 2 above.*

- **Claim 15 (Cont.)**

	Claim 15 (Cont.)	Schulman
15.2	said charging unit automatically varying its power output based on a value associated	*This limitation replicates the language of element 13.2 of claim 13 except that it deletes the words* "measured in said implantable medical device" *from element 13.2 of claim 13, and is therefore broader in that respect. See element 13.2 of claim 13 above.*

	Claim 15 (Cont.)	Schulman
	with said current passing through said internal battery; and	
15.3	wherein said automatically varying step automatically varies its power output based on a signal proportional to said current passing through said internal battery.	*The only difference between this "wherein" clause (15.3) and the claim element immediately preceding it (element 15.2) is the change form "*based on a value associated with*" to "*based on a signal proportional to.*" Schulman teaches automatically varying the power output of the external charging unit based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the measured current through resistor R8 (1:1 proportion), or the measured voltage across R8 (proportional based on Ohm's law V=I*R). See Ex. 1003, ¶¶ 75-88.*

- **<u>Claim 16</u>**

	Claim 16	Schulman
	The method as in claim 15 wherein said	*Claim 16 further limits the term "*a signal proportional*" of claim element 15.3 to "*a current proportional.*" Schulman teaches*

	Claim 16	Schulman
	automatically varying step automatically varies its power output based on a current proportional to said current passing through said internal battery.	*automatically varying the power output of the external charging unit based on "*a signal proportional*" to the measured charging current that passes through the internal battery. The "*signal proportional*" is the measured current through resistor R8 which has a 1:1 proportion to the current passing through the battery. See element 13.2 of claim 13. See also, Ex. 1003, ¶¶ 75-88.*

- **<u>Claim 17</u>**

	Claim 17	Schulman
	The method as in claim 15 wherein said automatically varying step automatically varies its power output based on a voltage proportional to said current	*Claim 17 further limits the term* "a signal proportional to" *of claim element 15.3 to "*a voltage proportional to*." Schulman teaches automatically varying the power output of the external charging unit based on "*a signal proportional*" to the measured charging current that passes through the internal battery. The "*signal proportional*" is the measured voltage across resistor R8 (proportional based on Ohm's law V=I*R).*

	Claim 17	Schulman
	passing through said internal battery.	*See element 13.2 of claim 13. See also, Ex. 1003, ¶¶ 75-88.*

- **Claim 18 (Cont.)**

	Claim 18 (Cont.)	Schulman
18.2	said charging unit automatically varying its power output based on a value associated with said current passing through said internal battery; and	*This limitation replicates the language of element 15.2 of claim 15. See element 15.2 of claim 15.*
18.3	wherein said automatically varying step automatically varies its power output based on	*The only difference between this element 18.3 and the one immediately preceding it (18.2) is the replacing of the word "value" with "measured voltage." Schulman teaches automatically varying the power output of the external power source 13 based on a measured voltage across resistor R8,*

	Claim 18 (Cont.)	Schulman
	a measured voltage associated with said current passing through said internal battery.	*which is associated with the charging current that passes through internal battery 15. See claim element 13.2 above and Ex. 1003, ¶¶ 75-88.*

B. Ground 2: Claims 1-4, 7-10 and 13-16 are unpatentable as anticipated by Fischell Article

1. Fischell Article

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 Article"), Ex. 1006. Fischell Article 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 '069 patent (April 29, 2005), Fischell Article qualifies as prior art under 35 U.S.C. §102(b).

Fischell Article is directed at rechargeable cardiac pacemakers utilizing "[a] new rechargeable cell specifically adapted for use at body temperature" that improves reliability of the pacemaker system. Ex. 1006, p. 357. After a brief description of the history of development of implantable rechargeable cardiac pacemakers, dating as far back as 1958, Fischell Article 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, pp. 358-359.

FIG. 8 of Fischell Article, reproduced herein, is a block diagram of a rechargeable pacemaker system showing an "external charger" and a hermetically sealed rechargeable pacemaker that is implanted beneath the skin of the patient. The implantable device includes a "pick-up coil" that interfaces with an induction coil in the "charger head" of the external device, circuitry to convert the magnetic energy to current for charging an internal rechargeable battery, "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.

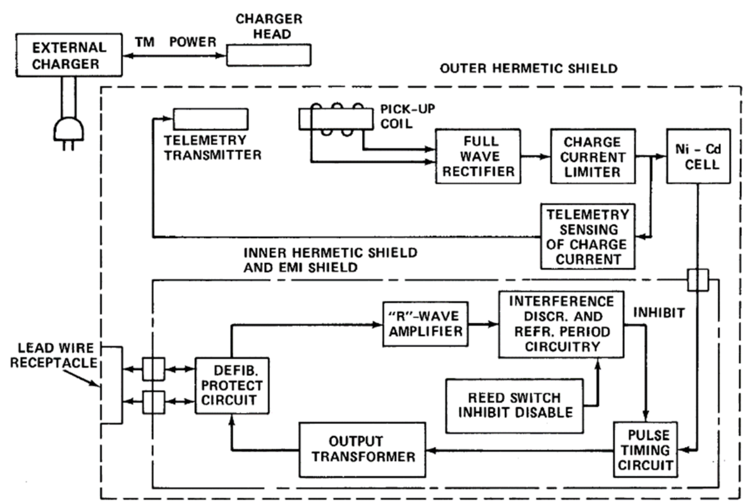


Fig. 8 Block diagram of rechargeable demand pacemaker

"When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil, a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery." Ex. 1006, pp. 372-373. 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, p. 373.

2. Applying Fischell Article to Claims 1-4, 7-10 and 13-16

Similar to the claim charts presented for Ground 1 under Section V.A., to avoid lengthy repetition of identical material, identical portions of each set of claims are group together in one chart with the differing "wherein" clauses addressed in separate charts. Accordingly the charts below combine identical elements of independent claims 1 and 3 into a single chart, identical elements of independent claims 7 and 9 into a single chart, and identical elements of independent claim 13 and 15 into a single chart.

- **<u>Claims 1 and 3: Identical Elements</u>**

	Claims 1 & 3	Fischell Article
1.0 3.0	A system for transcutaneous energy transfer, comprising:	*Petitioner does not here advocate that the preamble limits the scope of the claim.*

<table>
<tr><th></th><th>Claims 1 & 3</th><th>Fischell Article</th></tr>
<tr><td>1.1(a)

3.1(a)</td><td>an implantable medical device having componentry for providing a therapeutic output,</td><td>“The concept of using a rechargeable cell for an implantable cardiac pacemaker is not new.” [Ex. 1006, p. 357, emphasis added]

FIG. 8 of Fischell Article, reproduced below, shows a “block diagram of rechargeable demand pacemaker” with a “Ni-Cd Cell” (battery).

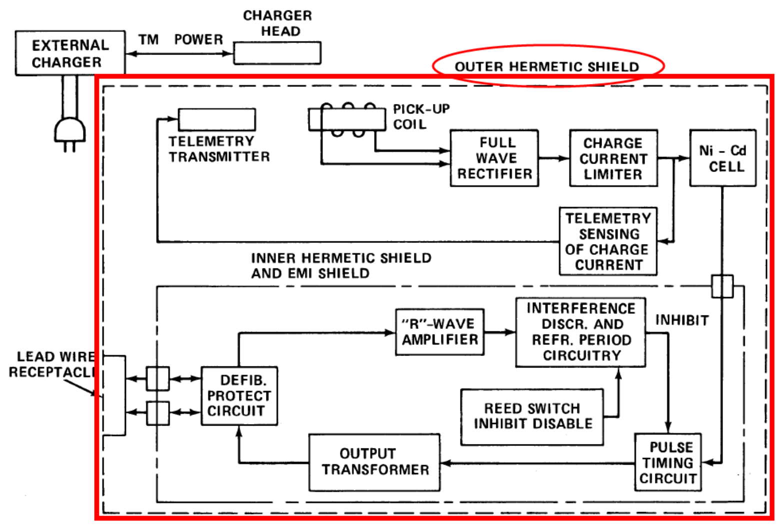


Fig. 8 Block diagram of rechargeable demand pacemaker</td></tr>
<tr><td>1.1(b)

3.1(b)</td><td>said implantable medical device having an internal battery and a secondary coil operatively coupled to said internal battery,</td><td>

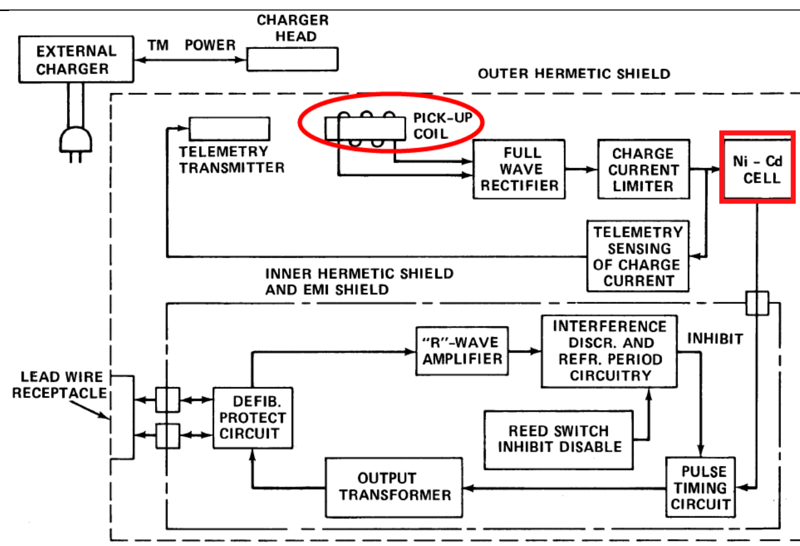
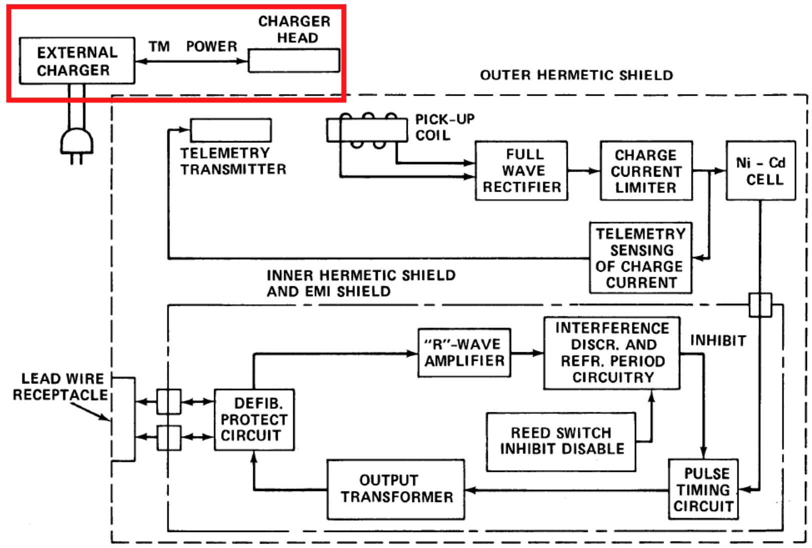


Fig. 8 Block diagram of rechargeable demand pacemaker</td></tr>
</table>

	Claims 1 & 3	Fischell Article
		"When the external charger applies an alternating magnetic field which is picked up through the intact skin by the ***pulse generator's pickup coil.***" [Ex. 1006, p. 372, emphasis added] "[O]ne can envision that the useful life of an implantable pacemaker would not be limited by cycle life if the ***nickel-cadmium cell*** is of the space type with hermetic sealing." [Ex. 1006, p. 364, emphasis added] *See highlighted components of FIG. 8, pick-up coil 9 ("secondary coil") and Ni-Cd Cell ("internal power source").*
1.1(c) 3.1(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, p. 357, emphasis added]

	Claims 1 & 3	Fischell Article
1.2(a) 3.2(a)	an external power source having a primary coil	 Fig. 8 Block diagram of rechargeable demand pacemaker "When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil, a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery." [Ex. 1006, pp. 372-373] *Fischell Article teaches that the external charger includes a "charger head" that "applies an alternating magnetic field" which would be through an inductive coil ("primary coil"). See also depiction of an induction coil for "charger head" of the rechargeable pacemaker shown in FIG. 6 of Fischell. [Ex. 1006, p. 368]; see Ex. 1003, ¶¶ 60-62.*

<table>
<tr><th></th><th>Claims 1 & 3</th><th>Fischell Article</th></tr>
<tr><td>1.2(b)

3.2(b)</td><td>said external power source providing energy to said implantable medical device when said primary coil of said external power source is placed in proximity of said secondary coil of said implantable medical device and thereby generating a current, having a value, passing through said internal battery;</td><td>

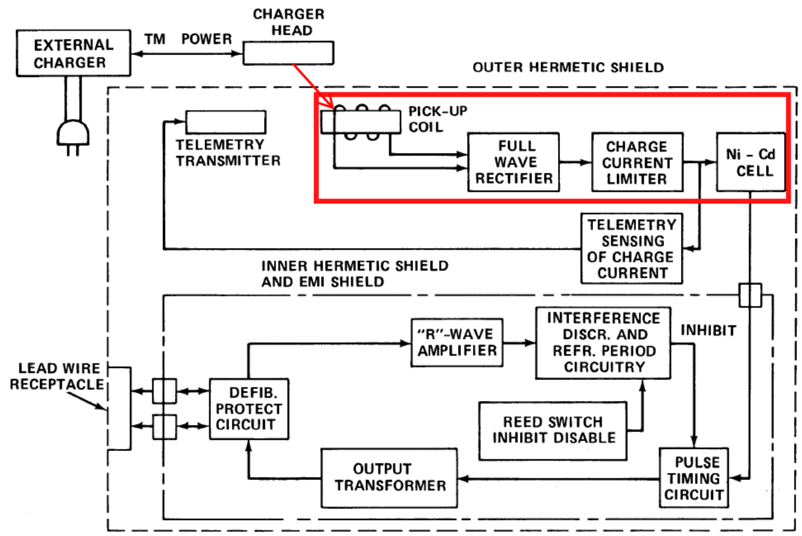


Fig. 8 Block diagram of rechargeable demand pacemaker

"When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil, a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery." [Ex. 1006, pp. 372-373]

As depicted in FIG. 8, Fischell Article teaches the energy supplied by the external primary coil and picked up by a proximally located internal secondary "pick-up coil" is applied to a "full wave rectifier" the output of which goes through a "charge current limiter" that in turn applies charge current to the internal battery (Ni-Cd cell). See Ex. 1003, ¶¶ 60-62 & 93-94.

</td></tr>
</table>

- **<u>Claim 1 (Cont.)</u>**

<table>
<tr><th></th><th>Claim 1 (Cont.)</th><th>Fischell Article</th></tr>
<tr><td>1.3</td><td>wherein said external power source automatically varies its power output based on a value measured in said implantable medical device and associated with said current passing through said internal battery.</td><td>

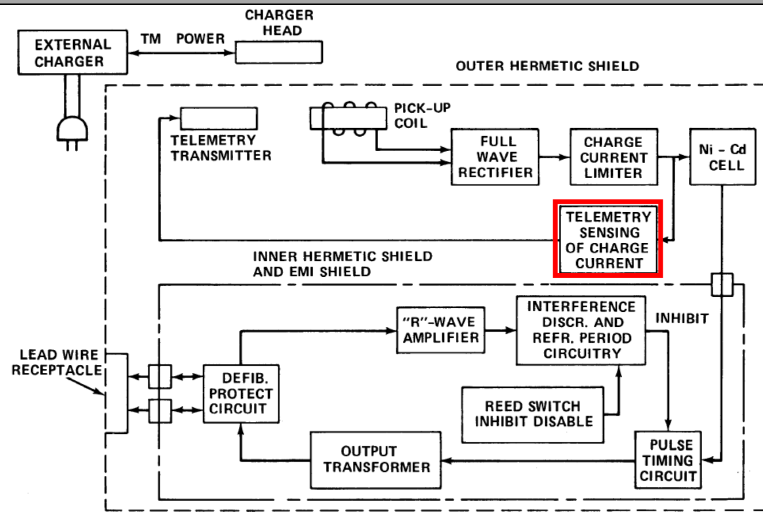


Fig. 8 Block diagram of rechargeable demand pacemaker

FIG. 8 explictly shows a block identified as the "telemetry sensing of charge current" whose input taps the node between the "charge current limiter" and the "Ni-Cd cell," and whose output is coupled to the "telemetry transmitter" block.

Fischell Article, at Table 3, partially reproduced below, identifies telemetry of battery charge current occurring by means of an FM output from the pulse generator.

<table>
<tr><td>Battery charge current telemetry</td><td>by pulse rate measurement and by means of FM output from pulse generator</td></tr>
</table>

[Table 3, p. 370]

"Two types of telemetry systems that can provide the doctor and the patient with valuable information are</td></tr>
</table>

	Claim 1 (Cont.)	Fischell Article
		availble from the pacer, namely: a. telemetry by means of pulse rate to measure battery voltage, and b. ***telemetry*** by means of a frequency modulated signal from the pusle generator into the external charger to ***measure and control charge current into the battery***." [Ex. 1006, pp. 371-372, emphasis added] "When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil, ***a telemetry system is powered whose output frequency*** from the pacer is ***proportional to the charge current*** in the battery. The external charger detects this frequency (which is picked up by the charger head) and closed-loop ***controls the battery charge current to a value of 40 mA***." [Ex. 1006, pp. 372-373, emphasis added] "A ***feedback control system*** in the charger ***maintains*** the battery ***charge current at the proper 40 mA level***, even though the charger head is varied considerably in its position relative to the implanted pulse generator." [Ex. 1006, p. 378, emphasis added] *Fischell Article teaches a feedback telemetry system that automatically varies the power of the external power source based on measuring the battery charge current in the pacemaker. See Ex. 1003, ¶¶ 95-98.*

- **Claim 2**

	Claim 2	Fischell Article
	The system as in claim 1 wherein said current passing through said internal battery comprises a maximum amount of current for charging said internal battery.	"The charging circuit for the rechargeable pacer ***limits the charge (and overcharge) current*** into the battery to 40 mA." [Ex. 1006, p. 367, emphasis added] "A feedback control system in the charger maintains the battery charge current at the proper 40 mA level." [Ex. 1006, p. 378]

- **Claim 3 (cont.)**

	Claim 3 (Cont.)	Fischell Article
3.3	wherein said external power source automatically varies its power output based on a value associated with said current	*The only difference between the language of this "wherein" clause 3.3 and the wherein clause 1.3 of claim 1 is that claim element 3.3 deletes the words "measured in said implantable medical device and." Otherwise the two claim elements 1.3 and 3.3 are identical.* *As shown in detail under element 1.3 of claim 1 under Ground 2, Fischell Article teaches a feedback*

	Claim 3 (Cont.)	Fischell Article
	passing through said internal battery; and	*telemetry system that automatically varies the power of the external power source based on the value of the current charging the battery. See Ground 2, claim element 1.3, and Ex. 1003, ¶95-98.*
3.4	wherein said external power source automatically varies its power output based on a signal proportional to said current passing through said internal battery.	*The only difference between this "wherein" clause and the one immediately preceding it (element 3.3) is the change form "*based on a value associated with*" to "*based on a signal proportional to.*" Fischell Article teaches automatically varying the power output of the external power source 13 based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the battery charging current as measured by the "telemetry sensing of charge current" block which passes through the internal battery (1:1 proportion). See Ground 2, claim element 1.3, and Ex. 1003, ¶ 95-98.*

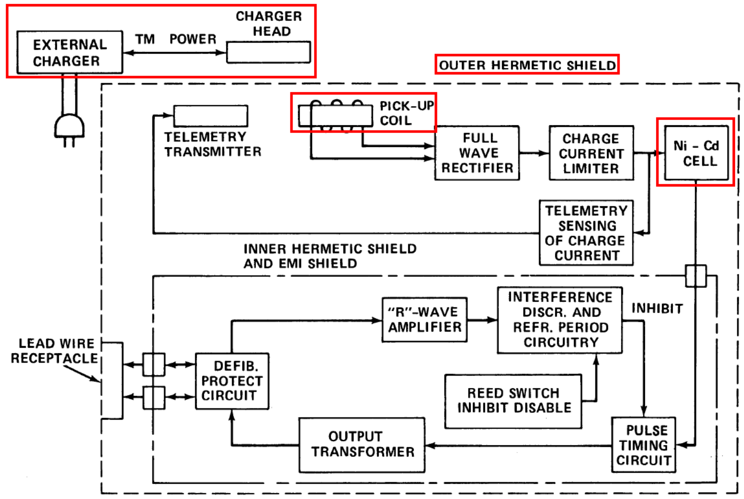
- **Claim 4**

	Claim 4	Schulman
	The system as in claim 3 wherein said external power source	*Claim 4 further limits the term "*a signal proportional to*" of claim element 3.4 to "*a current proportional to.*" Fischell Article teaches automatically varying the power output of the external power source 13 based on "a signal proportional" to the measured*

	Claim 4	Schulman
	automatically varies its power output based on a current proportional to said current passing through said internal battery.	*charging current that passes through the internal battery. The "signal proportional" is the battery charging current as measured by the "telemetry sensing of charge current" block which passes through the internal battery (1:1 proportion). See Ground 2, claim element 1.3, and Ex. 1003, ¶ 95-98.*

- **Claims 7 and 9: Identical Elements**

	Claims 7 & 9	Fischell Article
7.0 9.0	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,	*Petitioner does not here advocate that the preamble limits the scope of the claim.* *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 under Ground 1 above:*

	Claims 7 & 9	Fischell Article
	an internal battery and a secondary coil operatively coupled to said internal battery, comprising:	 Fig. 8 Block diagram of rechargeable demand pacemaker "external power source" = *Fischell Article: "external charger" and "charger head" (FIG. 8)* "implantable medical device" = *Fischell Article: "implantable cardiac pacemaker" (defined by outline of "outer hermetic shield" in FIG. 8)* "internal battery" = *Fischell Article: "Ni-Cd cell" (FIG. 8)* "secondary coil" = *Fischell Article: "pick-up coil" (FIG. 8)*
7.1 9.1	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."*

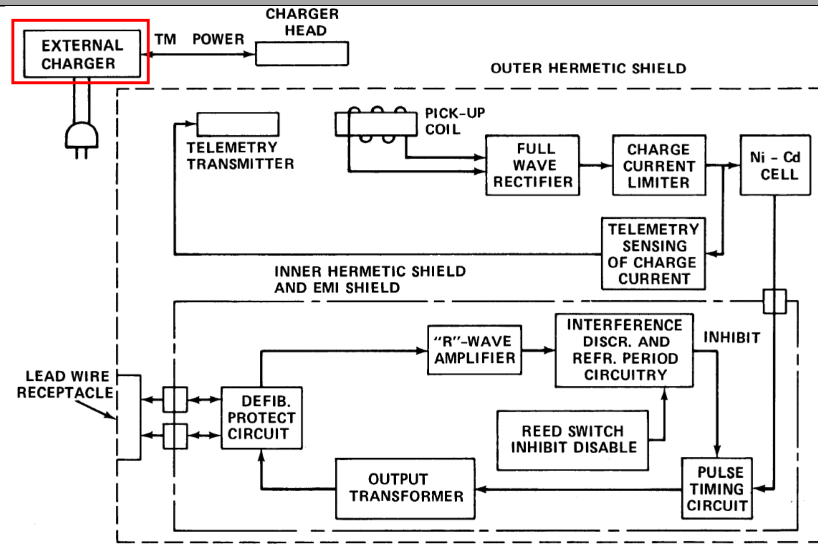
<table>
<tr><th></th><th>Claims 7 & 9</th><th>Fischell Article</th></tr>
<tr><td></td><td></td><td>


Fig. 8 Block diagram of rechargeable demand pacemaker
</td></tr>
<tr><td>7.2

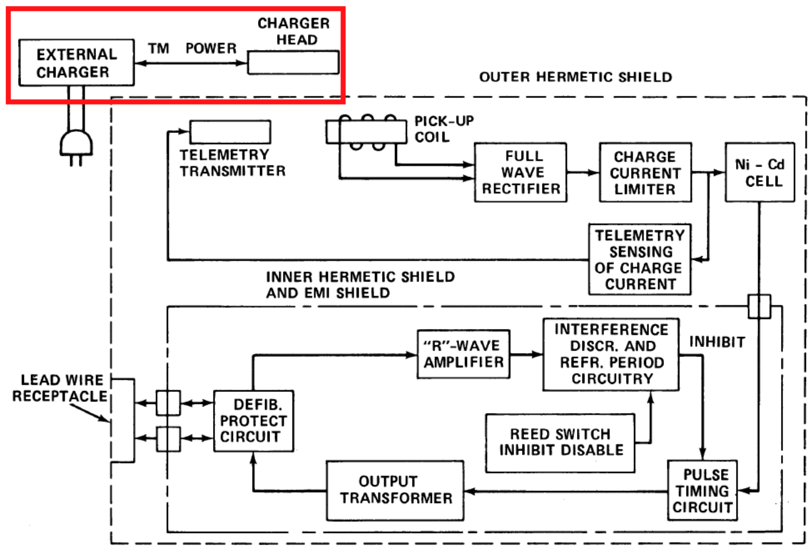
9.2</td><td>a primary coil, operatively coupled to said external power unit;</td><td>


Fig. 8 Block diagram of rechargeable demand pacemaker
“When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator’s pickup coil, a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery.” [Ex. 1006, pp. 372-373]
</td></tr>
</table>

	Claims 7 & 9	Fischell Article
		*Fischell Article teaches that the external charger includes a "charger head" that "applies an alternating magnetic field" which would be through an inductive coil ("primary coil"). See also depiction of an inductive coil for "charger head" of the rechargeable pacemaker shown in FIG. 6 of Fischell Article [*Ex. 1006, *p. 368];see Ex. 1003, ¶¶ 93-94.*
7.3(a) 9.3(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	*The language of this limitation is virtually identical to that recited in element 1.2(b) of claim 1. See Ground 2, element 1.2(b) of claim 1 above.*

	Claims 7 & 9	Fischell Article
7.3(b) 9.3(b)	thereby generating a current having a value passing through said internal battery;	*The language of this limitation is identical to that recited in element 1.2(c) of claim 1. See Ground 2, element 1.2(c) of claim 1 above.*

- **<u>Claim 7 (Cont.)</u>**

	Claim 7 (Cont.)	Fischell Article
7.4	wherein said external power source automatically varies its power output based on a value measured in said implantable medical device and associated with said current passing	*The language of this limitation is identical to that recited in element 1.3 of claim 1. See Ground 2, element 1.3 of claim 1 above.*

	Claim 7 (Cont.)	Fischell Article
	through said internal battery.	

- **Claim 8**

	Claim 8	Fischell Article
	The external power source as in claim 7 wherein said current passing through said internal battery comprises a maximum amount of current for charging said internal power source.	*The language of this limitation is identical to that recited in element 2 with the exception of the recitation of "internal power source" instead of "internal battery." This discrepancy appears to be an error since there is no antecedent basis for "internal power source" in claim 8 which instead recites "internal battery" as in claim 2. See Ground 2, claim 2 above.*

- **Claim 9 (Cont.)**

	Claim 9 (Cont.)	Fischell Article
9.4	wherein said external power source	*The language of this limitation is identical to that recited in element 3.3 of claim 3. See Ground 2, element 3.3 of claim 3 above.*

	Claim 9 (Cont.)	Fischell Article
	automatically varies its power output based on a value associated with said current passing through said internal battery; and	
9.5	wherein said external power source automatically varies its power output based on a signal proportional to said current passing through said internal battery.	*The language of this limitation is identical to that recited in element 3.4 of claim 3. See Ground 2, element 3.4 of claim 3 above.*

- **Claim 10**

	Claim 10	Fischell Article
	The external power source as in claim 9 wherein said external power source automatically varies its power output based on a current proportional to said current passing through said internal battery.	*The language of this limitation is identical to that recited claim 4. See Ground 2, claim 4 above.*

- **Claims 13 &15: Identical Element**

Claims 13 through 18 recast the language of prior claims in a method format. Claims 13 through 16 are similarly anticipated by Fischell Article as explained in the following charts.

	Claims 13, 15	Fischell Article
13.0(a)	A method of transcutaneous	*Petitioner does not here advocate that the preamble limits the scope of the claim.*

<table>
<tr><th></th><th>Claims 13, 15</th><th>Fischell Article</th></tr>
<tr><td>15.0(a)</td><td>energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted medical device,</td><td>

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 Ground 2, claim 1 above:

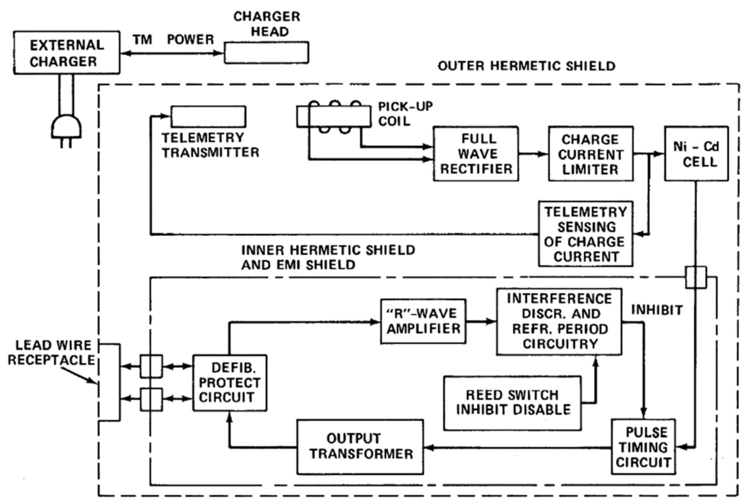


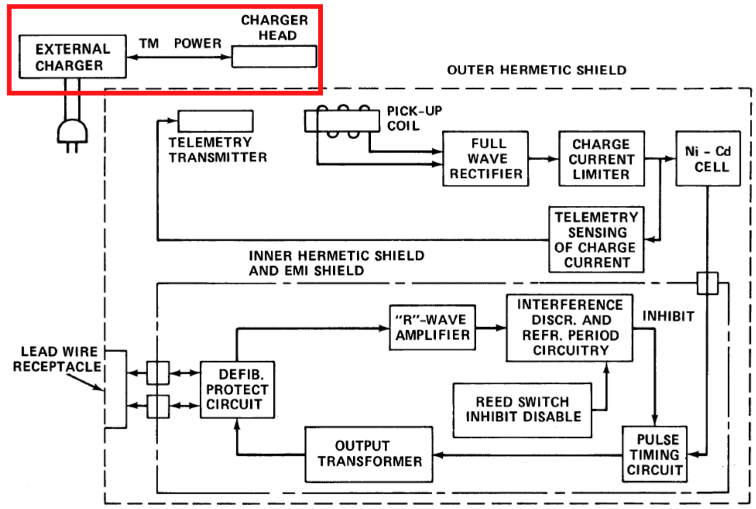
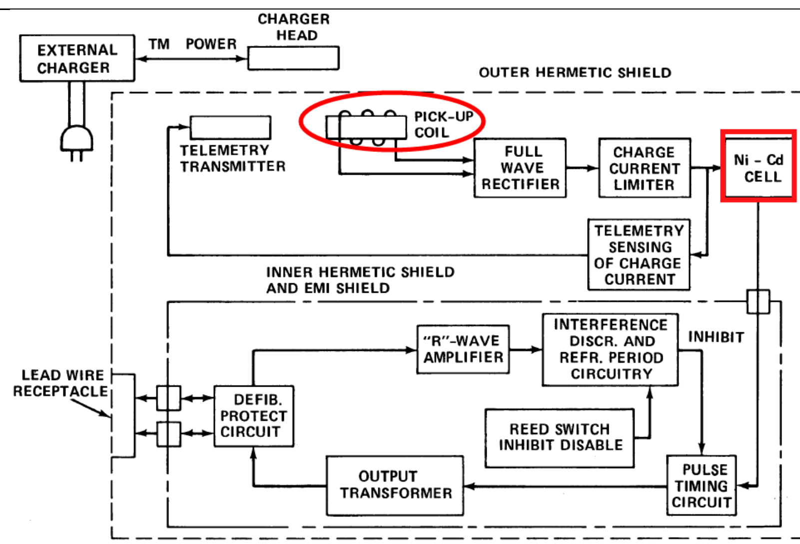
Fig. 8 Block diagram of rechargeable demand pacemaker

"external primary coil" = *Fischell: "charger head" (Fig 8)*

"inductively coupled secondary coil" = *Fischell "pick-up coil" (FIG. 8)*

"implantable medical device" = *Fischell: "an implantable electrical tissue stimulator" (FIG. 1), and "implanted portions of tissue stimulating system" (FIG. 10)*

</td></tr>
</table>

	Claims 13, 15	Fischell Article
13.0(b) 15.0(b)	said external primary coil being operatively coupled to a charging unit,	 Fig. 8 Block diagram of rechargeable demand pacemaker *As shown in FIG. 8, external coil in the "charger head" is coupled to an "external charger"* ("charging unit").
13.0(c) 15.0(c)	said secondary coil supplying power to an internal battery of said implanted medical device, said internal battery having an internal impedance,	 Fig. 8 Block diagram of rechargeable demand pacemaker "When the external charger applies an alternating magnetic field which is picked up through the intact skin by the ***pulse generator's pickup coil***" [Ex. 1006, p. 372, emphasis added]

	Claims 13, 15	Fischell Article
	comprising the steps of:	"one can envision that the useful life of an implantable pacemaker would not be limited by cycle life if the ***nickel-cadmium cell*** is of the space type with hermetic sealing." [Ex. 1006, p. 364, emphasis added] *As depicted in FIG. 8, Fischell Article teaches the energy supplied by the external primary coil and picked up by the internal secondary "pick-up coil" is applied to a "full wave rectifier" the output of which goes through a "charge current limiter" that in turn applies charge current to the internal battery (Ni-Cd cell). See Ex. 1003, ¶93-94. Further, internal impedance is an inherent property of batteries, including nickel-cadmium batteries. See Ex. 1003, ¶ 90. Fischell Article explicitly refers to* "low ***internal impedance*** of nickel-cadmium." [Ex. 1006, p. 379, item 12, emphasis added]

<table>
<tr><th></th><th>Claims 13, 15</th><th>Fischell Article</th></tr>
<tr><td>13.1(a)

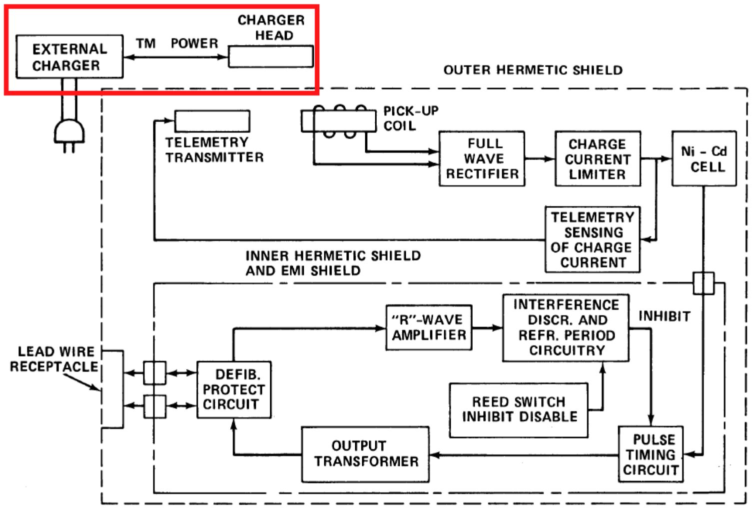
15.1(a)</td><td>driving said external primary coil with a charging signal from said charging unit</td><td>


Fig. 8 Block diagram of rechargeable demand pacemaker

As shown by the highlighted portion in FIG. 8, the "external charger" drives the "charger head "with a 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.

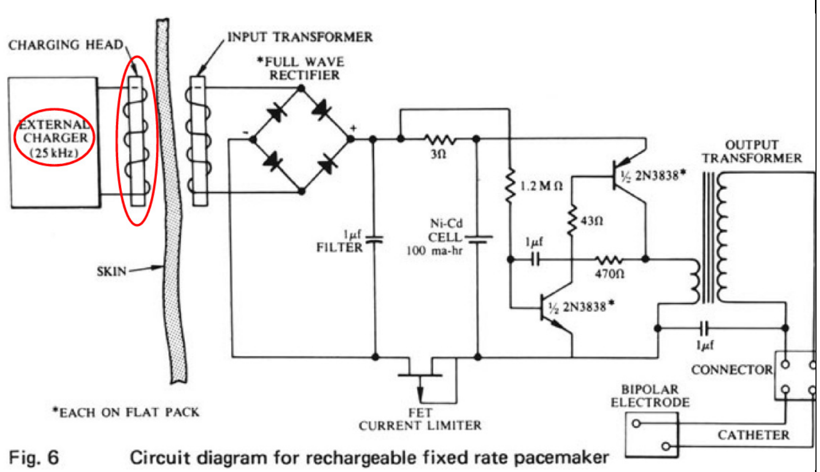
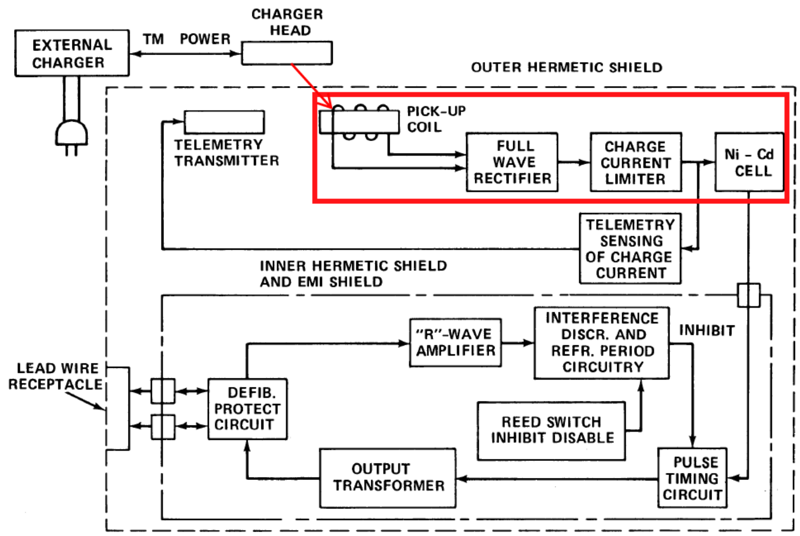


Fig. 6 Circuit diagram for rechargeable fixed rate pacemaker
</td></tr>
</table>

	Claims 13, 15	Fischell Article
13.1(b) 15.1(b)	generating a current passing through said internal battery; and	 Fig. 8 Block diagram of rechargeable demand pacemaker "When the external charger applies an alternating magnetic field which is picked up through the intact skin by the pulse generator's pickup coil, a telemetry system is powered whose output frequency from the pacer is proportional to the charge current in the battery." [Ex. 1006, pp. 372-373] *As depicted in FIG. 8, Fischell Article teaches the energy supplied by the external primary coil and picked up by the internal secondary "pick-up coil" is applied to a "full wave rectifier" the output of which goes through a "charge current limiter" that in turn applies charge current to the internal battery (Ni-Cd cell). See Ex. 1003, ¶ 93.*

- **Claim 13 (Cont.)**

	Claim 13 (Cont.)	Fischell Article
13.2	said charging unit automatically varying its power output based on a value measured in said implantable medical device and associated with said current passing through said internal battery.	*The only difference of note between the language of this claim element 13.2 and that of claim element 1.3 is the use of the term "charging unit" instead of "external power source." Fischell Article teaches a feedback telemetry system that automatically varies the power of the external power source based on measuring the battery charge current as explained in greater detail in the chart above under Ground 2, element 1.3 of claim 1.*

- **Claim 14**

	Claim 14	Fischell Article
	The method as in claim 13 wherein said current passing through said	*The language of this limitation is identical to that recited in element 2 with the exception of the recitation of "internal power source" instead of "internal battery." This discrepancy appears to be an error since*

	Claim 14	Fischell Article
	internal power source comprises a maximum amount of current for charging said internal battery.	*there is no antecedent basis for "internal power source" in claim 14 which instead recites "internal battery" as in claim 2. See claim 2 above under Ground 2.*

- **Claim 15 (Cont.)**

	Claim 15 (Cont.)	Fischell Article
15.2	said charging unit automatically varying its power output based on a value associated with said current passing through said internal battery; and	*This limitation replicates the language of element 13.2 of claim 13 except that it deletes the words "measured in said implantable medical device" from element 13.2 of claim 13, and is therefore broader in that respect. See element 13.2 of claim 13 under Ground 2.*
15.3	wherein said automatically varying step automatically varies its power output based on a signal proportional to said current passing through	*The only difference between this "wherein" clause (15.3) and the claim element immediately preceding it (element 15.2) is the change form "*based on a value associated with*" to "*based on a signal proportional to.*" Fischell Article teaches automatically varying the power output of the external power source 13 based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the battery charging current as measured by the "telemetry sensing of*

	Claim 15 (Cont.)	Fischell Article
	said internal battery.	*charge current" block which passes through the internal battery (1:1 proportion). See above claim element 3.4 under Ground 2, and Ex. 1003, ¶¶ 95-97.*

- **Claim 16**

	Claim 16	Fischell Article
	The method as in claim 15 wherein said automatically varying step automatically varies its power output based on a current proportional to said current passing through said internal battery.	*Claim 16 further limits the term "a signal proportional to" of claim element 15.3 to "a current proportional to." Fischell Article teaches automatically varying the power output of the external charging unit based on "a signal proportional" to the measured charging current that passes through the internal battery. The "signal proportional" is the battery charging current, as measured by the "telemetry sensing of charge current" block, which passes through the internal battery. See element 13.2 of claim 13 under Ground 2.*

C. Ground 3: Claims 5, 6, 11, 12, 17 and 18 are unpatentable as obvious over Fischell Article in view of Fischell ’260

1. Fischell ’260

U.S. Patent No. 3,888,260 to Robert E. Fischell (“Fischell ’260”), Ex. 1007, titled “RECHARGEABLE DEMAND INHIBITED CARDIAC PACER AND TISSUE STIMULATOR,” issued on June 10, 1975, claiming continuation-in-part priority to parent application filed on June 28, 1972. With an issue date decades before the earliest priority date of the ’148 Patent (April 29, 2005), Fischell ’260 qualifies as prior art under 35 U.S.C. §102(b).

In the parent application of the ’148 Patent, which matured into U.S. Patent 7,774,069, an Information Disclosure Statement was submitted on June 22, 2005, citing Fischell ’260 in a list that included 62 references. Fischell ’260, 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 ’148 Applicant. *See, e.g.*, *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2018-01247, 2019 WL 214935, at *18 (PTAB Jan. 15, 2019) (granting institution on grounds relying in prior art cited in Examiner’s Notice of References Cited and presented to the Examiner in an Information Disclosure Statement when there was “no indication that the Examiner [] ever considered the combinations presented in the Petition”). Moreover, the combination of Fischell Article and Fischell ’260 was not at any point before the Examiner. *See, e.g.*, *ZTE (USA) Inc., v. Bell N. Research, LLC*, IPR2019-013652020 WL 698725, at *3 (PTAB Feb. 11, 2020) ("Although the Examiner considered Irvin during prosecution, . . . Irvin *in combination with Mullymäki and/or Bodin* is not the same or substantially the same prior art previously presented to the Office. Moreover, even if Mullym*ä*ki and/or Bodin were deemed to disclose the same subject matter as a reference [] previously considered by the Examiner, we consider the error by the Examiner in considering Irvin . . . to outweigh the fact that the same or similar art was before the Examiner during prosecution.").

With respect to its substantive teachings, Fischell '260 provides in the Abstract:

> "An improved demand inhibited cardiac pacer or human tissue stimulator employs a rechargeable battery to furnish operating power to electronic pulse generating circuitry which generates output stimulating pulses. For the demand inhibited cardiac pacer these pulses are generated only when the patient's heart stops beating properly at its own intrinsic rhythm as monitored by other circuitry in the pacer unit. … The demand inhibited pacer or tissue stimulator has an improved circuit design and provides accurate telemetry indication as to when such recharging of the unit's battery is taking place."

As shown in FIG. 1a of Fischell ’260, reproduced below, Fischell ’260 teaches that the rechargeable cardiac pacer beneath the “PATIENT’S SKIN” includes a “POWER SUPPLY” block with “single cell rechargeable nickel-cadmium battery” 19 that receives recharge “energy inductively coupled through the patient’s skin” by means of external coil or “recharge head 20a” and internal coil 20. Recharging current available at the diagonals of a rectifier 30 is applied to battery 19 through a “current monitoring resistor 32.” Ex. 1006, 6:40-60.

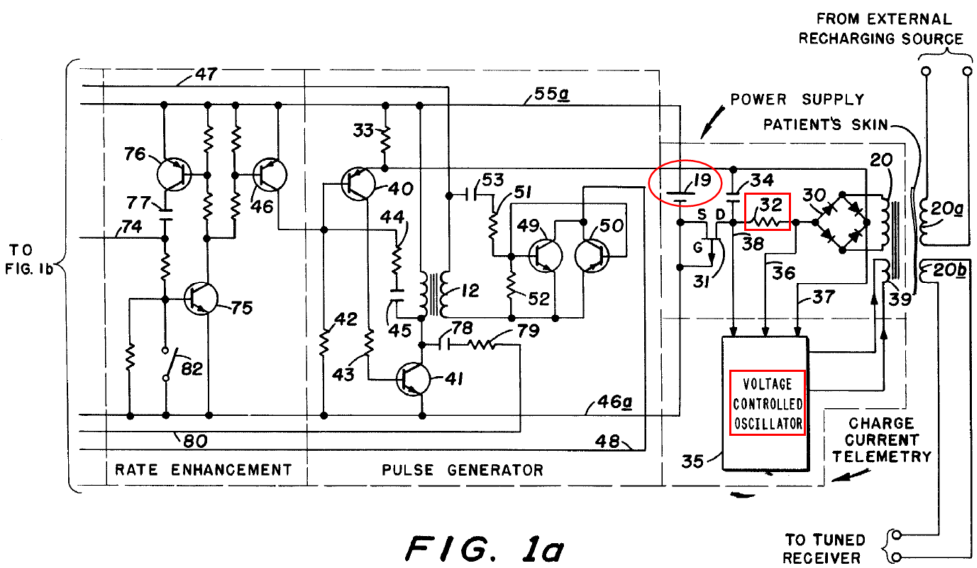


FIG. 1a

The implanted pacer further includes a “CHARGE CURRENT TELEMETRY” block that includes a voltage controlled oscillator 35 that receives “a control voltage signal developed across the current monitoring resistor 32.” The output frequency of the oscillator 35 that telemeters the state of the charge current is thus controlled “in accordance with the value of recharging current being supplied to the battery.” Ex. 1006, 6:66-7:6. The voltage controlled oscillator 35 generates a specific output frequency (10 kilohertz) at a predetermined maximum charge current ("a preselected saturation current of 40 milliamps"). This output frequency is telemetered to an external unit that detects the frequency indicating "both that charging is taking place and the precise value of the recharging current." Ex. 1006, 6:6-15.

2. The Combination of Fischell Article in view of Fischell '260

Both Fischell Article and Fischell '260 relate to the same field of rechargeable implanted medical devices. Indeed the remarkable similarity between the block diagram of FIG. 8 of Fischell Article and blocks identified in the circuitry depicted in FIGS. 1a and 1b of Fischell '260, suggests that the Fischell '260 circuit schematics provide a roadmap for the detailed implementation of FIG. 8 block diagram of Fischell Article. A POSITA would have been motivated to combine Fischell Article with Fischell '260 for several reasons. For example, while Fischell Article shows in FIG. 8, a block labeled "TELEMETRY SENSING OF CHARGE CURRENT," Fischell '260 teaches a detailed implementation for the "POWER SUPPLY" and "CHARGE CURRENT TELEMETRY" blocks in FIG. 1a that offer a "novel telemetry system which provides an accurate indication as to when the rechargeable battery contained in the unit is undergoing proper recharging." Ex. 1006, 2:39-46. The detailed telemetry implementation with the improved performance as disclosed by Fischell '260, includes a voltage controlled oscillator 35 that receives "a control voltage signal developed across the current monitoring resistor 32" indicating the charge current. A further improvement offered by Fischell '260 "involves the inclusion of transistorized switching circuitry which … functions to connect the output of the pulse generating circuitry to the catheter only when the pulse generating circuitry is outputting a heart stimulating pulse, so as to prevent the pulse generating circuitry from electrically loading the catheter and thereby prevent proper monitoring of the electrical wave generated by the patient's heart in response to each heart beat." Ex. 1006, 2:48-63. Accordingly, a POSITA would have been motivated to combine the teachings of Fischell '260 with Fischell Article to take advantage of the improvements offered by the detailed implementation of the rechargeable pacer offered by Fischell '260. See Ex. 1003, ¶¶ 101-103.

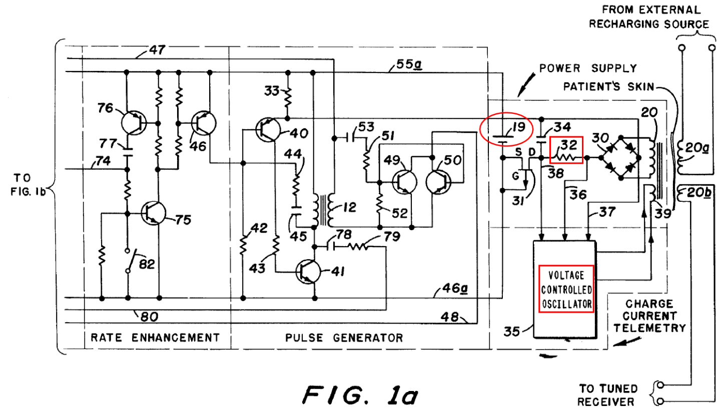
3. Applying combination of Fischell Article and Fischell '260 to Claims 5, 6, 11, 12, 17 and 18

As demonstrated above under Section V.B, Fischell Article anticipates claims 1-4, 7-10 and 13-16 of the '148 Patent. The remaining claims 5, 6, 11, 12, 17 and 18 of the '148 Patent are directed at varying the power supplied by the external power source based on "a voltage proportional to" or "a measured voltage associated with" the current passing through the internal battery. Fischell Article does teach "telemetry sensing of charge current" (i.e., the actual current passing through the battery) based on which the power supplied by the external power source is varied. Given that electrical current is commonly measured by measuring the voltage drop across a known resistor, according to Ohm's law, Fischell Article inherently also teaches varying the power supplied by the external power source based on a voltage associated with or proportional to the current passing through the internal battery. Thus, even if it is argued that Fischell Article does not inherently teach that limitation, it certainly suggests it.

To remove doubts or arguments as to the invalidity of these remaining claims 5, 6, 11, 12, 17 and 18, Fischell '260, which provides detailed circuit implementation for the rechargeable demand pacemaker, is discussed herein. The combination of Fischell Article and Fischell '260 renders these claims obvious as demonstrated by the charts below.

- **Claim 5**

	Claim 5	Fischell Article and Fischell '260
	The system as in claim 3 wherein said external power source automatically varies its power output based on a voltage	*Fischell Article teaches all elements of the base claim 3 as demonstrated above under Ground 2. In connection with FIG. 1a, Fischell '260 teaches:*

	Claim 5	Fischell Article and Fischell '260
	proportional to said current passing through said internal battery.	 FIG. 1a "The output ***recharging current*** available at the diagonals of the rectifier 30 is ***applied to the battery*** 19 through a series recharging circuit comprising a conventional field effect transistor current limiter 31, ***current monitoring resistor 32***, and a small (e.g., 3 ohm) voltage drop resistor 33." [Ex. 1006, 6:54-60, emphasis added] "[Voltage controlled] oscillator 35 is also connected, via wires 36 and 38, to receive a ***control voltage signal developed across the current monitoring resistor 32***. As a result, the output frequency generated by the oscillator 35 varies in accordance with the value of recharging current being supplied to the battery 19. For example, in one practical embodiment of the present invention, the voltage controlled oscillator 35 is designed to generate an output frequency of 10 kilohertz at a preselected saturation charge current of 40

	Claim 5	Fischell Article and Fischell '260
		milliamps. The ***output frequency telemetry signal*** from the oscillator 35, when detected by a suitable external receiving unit (not shown) via the winding 20b, thus ***provides*** accurate indications both that recharging is taking place and the ***precise value of the recharging current***." [Ex. 1006, 7:1-15, emphasis added] *While Fischell Article does not explicitly teach that the block "TELEMETRY SENSING OF CHARGE CURRENT" operates in response to a voltage proportional to the charging current, Fischell '260 teaches controlling the frequency output of the telemetry circuit based on a "**voltage signal** developed across the current monitoring resistor." This voltage is proportional to the current passing through the internal battery according to Ohm's Law: V = I*R. See Ex. 1003,* ¶¶ 104-107.

- **Claim 6**

Independent claim 6 repeats verbatim every limitation of independent claim 3 through the penultimate "wherein" clause. The only difference between the two claims is in the language of the final "wherein" clause. Instead of repeating identical material for identical limitations in the following chart, references are made to claim 3.

	Claim 6	Fischell Article and Fischell '260
6.0	A system for transcutaneous energy transfer, comprising:	*See element 3.0 of claim 3 above under Ground 2.*
6.1(a)	an implantable medical device having componentry for providing a therapeutic output,	*See element 3.1(a) of claim 3 above under Ground 2.*
6.1(b)	said implantable medical device having an internal battery and a secondary coil operatively coupled to said internal battery,	*See element 3.1(b) of claim 3 above under Ground 2.*
6.1(c)	said implantable medical device adapted to be implanted in a patient; and	*See element 3.1(c) of claim 3 above under Ground 2.*

	Claim 6	Fischell Article and Fischell '260
6.2(a)	an external power source having a primary coil,	*See element 3.2(a) of claim 3 above under Ground 2.*
6.2(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	*See element 3.2(b) of claim 3 above under Ground 2.*
6.2(c)	thereby generating a current, having a value, passing	*See element 3.2(c) of claim 3 above under Ground 2.*

	Claim 6	Fischell Article and Fischell ’260
	through said internal battery;	
6.3	wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal battery; and	*See element 3.3 of claim 3 above under Ground 2.*
6.4	wherein said external power source automatically varies its power source output based on a measured voltage associated with said current	*The only difference in the language of this claim element 6.4 and that of claim 5 is that element 6.4 replaces "a voltage proportional to" of claim 5 with "a measured voltage associated with." As explained under claim 5 above, Fischell ’260 teaches controlling the frequency output of the telemetry circuit based on measuring a "**<u>voltage signal</u>** developed across the current monitoring resistor." Since the "current monitoring resistor" monitors the battery charging current, the voltage measured across it is "associated with" the current*

	Claim 6	Fischell Article and Fischell '260
	passing through said internal battery.	*passing through the internal battery, according to Ohm's Law: V = I*R. See claim 5 under Ground 3, and Ex. 1003,* ¶¶ 104-107.

- **Claim 11**

	Claim 11	Fischell Article and Fischell '260
	The external power source as in claim 9 wherein said external power source automatically varies its power output based on a voltage proportional to said current passing through said internal battery.	*The limitation recited in claim 11 is identical to that recited in claim 5. See claim 5 above under Ground 3.*

- **Claim 12**

Independent claim 12 repeats verbatim every limitation of independent claim 9 through the penultimate "wherein" clause. The only difference between the two claims is in the language of the final "wherein" clause. Instead of repeating identical material for identical limitations in the following chart, references are made to claim 9.

	Claim 12	Fischell Article and Fischell '260
12.0	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 battery and a secondary coil operatively coupled to said internal battery, comprising:	*See element 9.0 of claim 9 above under Ground 2.*

	Claim 12	Fischell Article and Fischell '260
12.1	an external power unit; and	*See element 9.1 of claim 9 above under Ground 2.*
12.2	a primary coil, operatively coupled to said external power unit;	*See element 9.2 of claim 9 above under Ground 2.*
12.3(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 element 9.3(a) of claim 9 above under Ground 2.*

	Claim 12	Fischell Article and Fischell '260
12.3(b)	thereby generating a current having a value passing through said internal battery;	*See element 9.3(b) of claim 9 above under Ground 2.*
12.4	wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal battery; and	*See element 9.4 of claim 9 above under Section V.B*
12.5	wherein said external power source automatically varies its power output based on	*The language of this element 12.5 is virtually identical to that recited in the final "wherein" clause 6.4 of claim 6. See element 6.4 of claim 6 above under Ground 3.*

	Claim 12	Fischell Article and Fischell ’260
	a measured voltage associated with said current passing through said internal battery.	

- **<u>Claim 17</u>**

	Claim 17	Fischell Article and Fischell ’260
	The method as in claim 15 wherein said automatically varying step automatically varies its power output based on a voltage proportional to said current passing through said internal battery.	*The limitation recited in claim 17 is virtually identical to that recited in claim 5. See claim 5 above under Section V.C.*

- **Claim 18**

Independent claim 18 repeats verbatim every limitation of independent claim 13. The only difference between the two claims is the addition of the final "wherein" clause in claim 18. Instead of repeating identical material for identical limitations in the following chart, references are made to claim 13.

	Claim 18	Fischell Article and Fischell '260
18.0(a)	A method of transcutaneous energy transfer between an external primary coil and an inductively coupled secondary coil of an implanted medical device,	*See element 13.0(a) of claim 13 above under Ground 2.*

	Claim 18	Fischell Article and Fischell '260
18.0(b)	said external primary coil being operatively coupled to a charging unit,	*See element 13.0(b) of claim 13 above under Ground 2.*
18.0(c)	said secondary coil supplying power to an internal battery of said implanted medical device, said internal battery having an internal impedance, comprising the steps of:	*See element 13.0(c) of claim 13 above under Ground 2.*

	Claim 18	Fischell Article and Fischell '260
18.1	driving said external primary coil with a charging signal from said charging unit generating a current passing through said internal battery; and	*See element 13.1 of claim 13 above under Ground 2.*
18.2	said charging unit automatically varying its power output based on a value associated with said current passing through said internal battery; and	*See element 13.2 of claim 13 above under Ground 2.*

	Claim 18	Fischell Article and Fischell ’260
18.3	wherein said automatically varying step automatically varies its power output based on a measured voltage associated with said current passing through said internal battery.	*The only difference between this element 18.3 and the one immediately preceding it (18.2) is the replacing of the word "value" with "measured voltage." As explained under claim 5 above, Fischell ’260 teaches controlling the frequency output of the telemetry circuit based on measuring a "**voltage signal** developed across the current monitoring resistor." Since the "current monitoring resistor" monitors the battery charging current, the voltage measured across it is "associated with" the current passing through the internal battery, according to Ohm's Law: V = I*R. See Ex. 1003,* ¶¶ 104-107.

VI. MANDATORY REQUIREMENTS

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Axonics certifies that the ’148 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 ’148 Patent. Ex. 1009.

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

1. Real Parties in Interest

Axonics is the real party in interest for this Petition.

2. Related Matters

The ’148 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 ’148 Patent is related to U.S. Patent Nos. 7,774,069 and 8,457,758, against which Axonics is filing separate petitions for IPR concurrently with this Petition.

3. Payment of Fees

This Petition requests review of eighteen (18) claims of the ’148 Patent and is accompanied by a payment of $32,300, which includes the $15,500 *inter partes* review request fee, and the $16,800 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 all exhibits to the correspondence address of record for the '148 Patent. Axonics consents to be served via lead and back-up counsel identified below at the mailing and e-mail addresses below.

Respectfully submitted,

By: /s/ A. James Isbester
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Registration No. 36,315
Lead Counsel for Petitioner

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CERTIFICATE OF WORD COUNT

The undersigned certifies pursuant to 37 C.F.R. § 42.24(d) that the foregoing Petition for *Inter Partes* Review excluding any table of contents, table of authorities, certificates of service or word count, or appendix of exhibits or claim listing, contains 13,592 words according to the word-processing program used to prepare this paper (Microsoft Word). Including annotations in figures, Petitioner certifies that this Petition for *Inter Partes* Review does not exceed the applicable type-volume limit of 37 C.F.R. § 42.24(c).

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. 8,738,148, 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. 8,738,148:

IPLM GROUP, P.A.
685 Lindwood Avenue
St. Paul, MN 55105

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

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

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Respectfully,

Dated: March 16, 2020

By: */s/ A. James Isbester*

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