UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

IPR2020-00714
Patent No. 9,463,324

Title: INDUCTIVELY RECHARGEABLE EXTERNAL ENERGY SOURCE, CHARGER, SYSTEM AND METHOD FOR A TRANSCUTANEOUS INDUCTIVE CHARGER FOR AN IMPLANTABLE MEDICAL DEVICE

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 9,463,324

TABLE OF CONTENTS

Page

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent 9,463,324 (Patent at Issue)
1002	File History of U.S. Patent 9,463,324
1003	Declaration of Michael Colvin
1004	CV of Mike Colvin
1005	PCT Publication No. WO 01/83029 ("Torgerson")
1006	UL 544 (1998), Standard for Medical and Dental Equipment–Ed. 4.0 ("UL 544")
1007	U.S. Patent No. 5,702,431 ("Wang")
1008	U.S. Patent No. 4,082,097 ("Mann")
1009	U.S. Patent No. 5,733,313 ("Barreras")
1010	U.S. Patent No. 6,685,638 ("Taylor")
1011	BS EN 60601-1:1990, the British Standard (BS) for Medical electrical equipment—Part 1: General requirements for safety ("EN 60601")
1012	Declaration of Christine Ruther
1013	Proof of Service, Dkt. No. 26, *Medtronic, Inc. et al. v. Axonics Modulation Techs., Inc.*, No. 8:19-cv-02115-DOC-JDE (C.D. Cal.)

I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics" or "Petitioner") respectfully petitions for *inter partes* review of claims 1-24 of U.S. Patent No. 9,463,324 ("the '324 patent") in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 et seq. ("Petition").

The '324 patent is directed to a "mechanism for transferring energy from an external power source to an implantable medical device." Ex. 1001, Abstract. More specifically, the patent discloses a medical system that includes "an implantable medical device, an external device configured for transcutaneously coupling energy into the implantable medical device, a sensor configured for measuring a temperature generated by the external device during coupling of the energy into the implantable medical device, and a control circuit." *Id.* at 6:2-9. The control circuit is configured to compare the measured temperature to a limit stored within a memory of the external device, then control the temperature generated by the external device based on the comparison. *Id.* at 6:9-14.

The patent explains "heat build-up in tissue of [a] patient…beyond certain limits, is undesirable and should be limited as acceptable values" set by "current conditions and regulations." *Id*. at 15:55-16:13.

None of this was new as of the '324 patent's priority date as of October 2, 2003. The controlled recharging of implantable medical devices using external

devices was known as were safety standards mandating such devices could not exceed defined temperature limits. Thus, the ’324 patent claims should be found unpatentable as obvious.

II. OVERVIEW OF THE ’324 PATENT

A. Background and Summary of the ’324 patent

The ’324 patent discloses a medical system comprising “an implantable medical device” and “an external device configured for transcutaneously coupling energy into the implantable medical device.” Ex. 1001 at 6:2-7.

As the ’324 patent acknowledges, at the time of its filing, many “systems and methods ha[d] been used for transcutaneously inductively recharging a rechargeable used in an implantable medical device.” Ex. 1001 at 2:12-14. Such transcutaneous recharging systems were desirable because “[h]aving electrical wires which perforate the skin is disadvantageous due, in part, to the risk of infection” but “single cell batteries usually do not supply the lasting power required to perform new therapies in newer implantable medical devices.” *Id*. at 1:54-63. Known transcutaneous recharging systems allowed an expended or nearly expended battery to be recharged “from an external power source temporarily positioned on the surface of the skin.” *Id.* at 2:8-11.

These prior art systems “monitor[ed] the state of charge of the internal power source and control[led] the charging process by monitoring the amount of

energy used by the system, and hence the state of the charge of power source." *Id*. at 3:62-65. Such systems further included a "bidirectional telemetry link" that allowed the system to "inform the patient or clinician regarding the status of the system, including the state of the charge." *Id*. at 3:66-4:2.

The '324 patent explains that the prior art system disclosed in PCT Patent Publication No. WO 01/83029 A1 (Torgerson, Ex. 1005) included a "recharging module" comprising "a recharge measurement device monitoring at least one recharge parameter, and a recharge regulation control unit for regulating the recharge energy delivered to the power source in response to the recharge measurement device" wherein "[t]he recharge module adjusts the energy provided to the power source to ensure that the power source is being recharged under safe levels." Ex. 1001 at 4:33-47. Torgerson specifically taught that one "recharge parameter" to be monitored was "temperature." *See e.g.*, Ex. 1005, Claim 9.

Likewise, the '324 patent similarly discloses a system where "[a] sensor may be used to measure a parameter that correlates to a temperature of the system during recharge." Ex. 1001 at 5:51-52. And like the recharge regulation control unit of Torgerson, which regulates the energy delivered to the power source based on the measured parameter, the '324 patent teaches "using the output from temperature sensor" to "limit the energy transfer process." *Id.* at 20:23-26. Indeed, the '324 patent provides a block diagram (Figure 3) of the system that

shows only familiar components: implantable medical device 16 situated under cutaneous boundary 38 (i.e., the dashed line represents the patient's skin) above which is external charging device 48, which includes external antenna 52 . *See e.g.*, Ex. 1001 at 7:37-40; 9:20-22; 9:51-62.

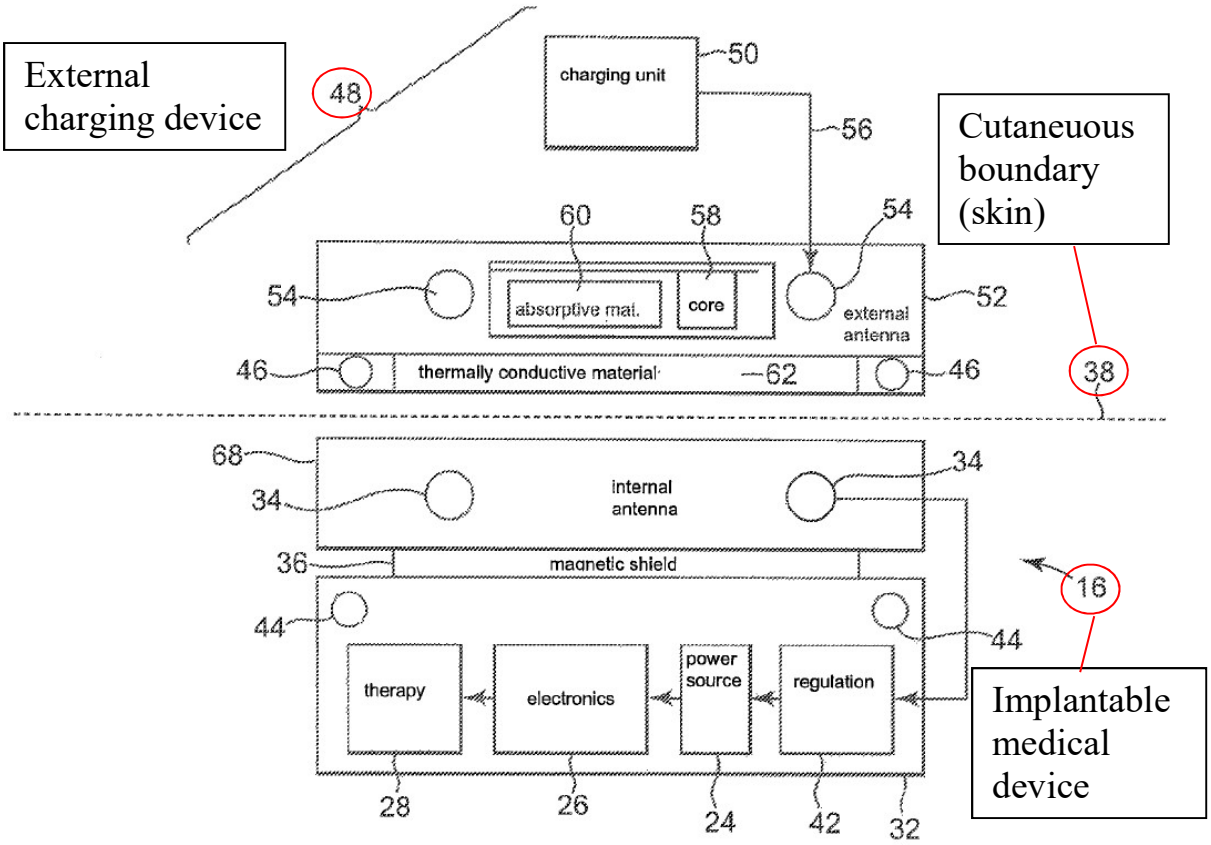


Fig. 3

B. Summary of Relevant Prosecution File History

The application that issued as the '324 patent was filed on July 20, 2015 with 10 original claims that were cancelled and replaced by claims 11-34 via preliminary amendment. Claims 11-34 underwent minimal prosecution. On February 24, 2016, the claims were rejected for obviousness-type double patenting

over U.S. Patent Nos. 9,108,063; 7,515,967; 7,225,032 and 7,650,192. The rejection based on U.S. Patent No. 7,650,192 was withdrawn and a terminal disclaimer was filed as to the other three patents on May 23, 2016. All claims were then allowed on June 15, 2016. The relevant portions of the file history can be found at Ex. 1002.

C. 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. *Gnosis S.p.A. v. South Alabama Med. Sci. Found.*, IPR2013-00116, Final Written Decision (Paper 68) at 9. Such a person is of ordinary creativity, and not an automaton, and is capable of making inferences and combining teachings in the prior art. See *id.* (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007)).

A POSITA at the time of the claimed invention would have a bachelor's degree in engineering as well as at least three years of experience in the industry working with active implantable medical devices; or with a bachelor's of science degree, a POSITA would have six years of experience designing, manufacturing, or overseeing active implantable medical systems. *See* Ex. 1003, ¶ 52.

III. PROPOSED CLAIM CONSTRUCTION

Axonics provides proposed constructions under *Phillips* v. *AWH Corp.,* 415 F.3d 1303 (Fed. Cir. 2005) (en banc)[1] for certain terms recited in claims 1, 5, 12 and 20 of the '324 patent. The remaining terms should be given their plain and ordinary meaning. Axonics demonstrates how the prior art discloses the limitations of the challenged claims under these interpretations.

A. "[a temperature sensor adapted to provide an output] indicative of a temperature of the side of the housing"

Independent claims 1 and 20 require "a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing." Independent claim 12 likewise requires "providing, via a temperature sensor of the external device, output indicative of a temperature of the side of the housing." Axonics submits that the phrase "indicative of a temperature of the side of the housing" should be interpreted as "accurately measuring a temperature of the

---

[1] Axonics addresses only the question of the correct construction of those terms relevant to this Petition. Axonics makes no admission as to the interpretation to be given any term in district court litigation. Axonics makes no admission that the claims conform to the requirements of 35 U.S.C. § 112 and preserves all such arguments.

external surface portion of housing that is placed against the patient during recharging."

Figure 3 of the '324 patent (shown below) is a block diagram illustrating implantable medical device 16 situated under cutaneous skin boundary 38. *See e.g.*, Ex. 1001 at 7:37-40; 9:20-22. Situated above the cutaneous boundary is external charging device 48, which includes external antenna 52 (green) containing charging unit 50. *Id.* at 9:51-62. "Thermally conductive material 62 [red] is positioned covering at least a portion of the surface of external antenna 52 which contacts cutaneous boundary 38 of patient 18." *Id.* at 10:10-13.

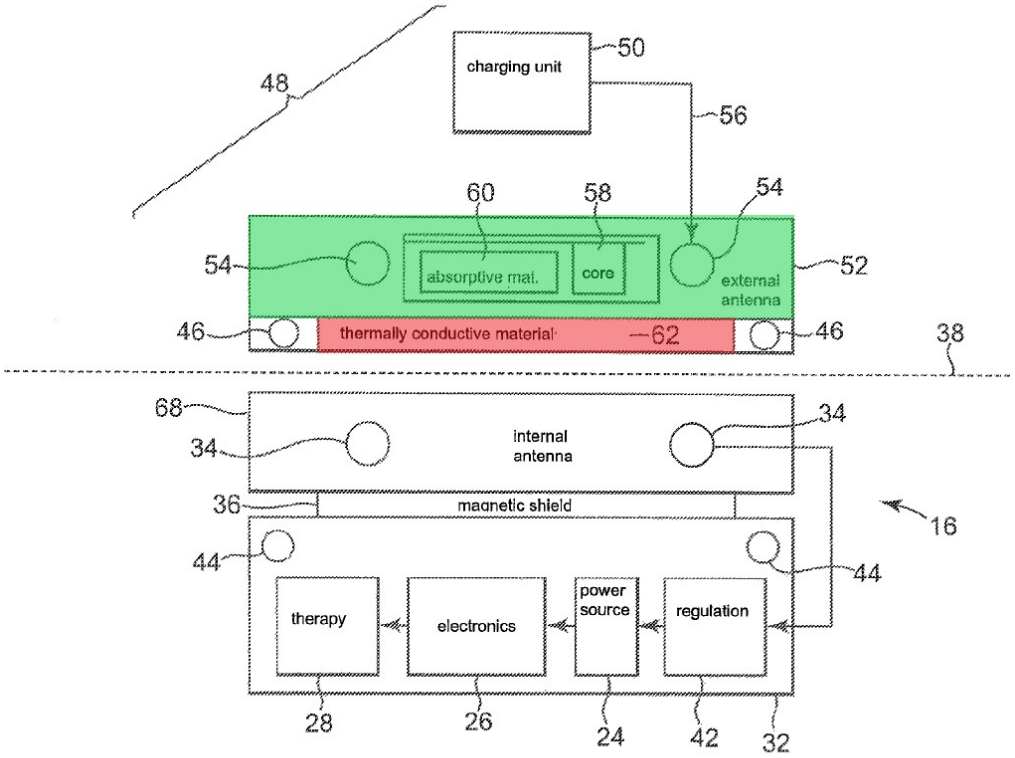


Fig. 3

The specification explains that inductive charging of an implantable medical device "has a tendency to heat surrounding components and tissue" and that "[t]he amount of heating of surrounding tissue, if excessive, can be deleterious." Ex. 1001 at 5:12-16. Thus, "external charging device 48 incorporates temperature sensor 87 in external antenna 52 and control circuitry in charging unit 50 which can ensure that external antenna 52 does not exceed acceptable temperatures, generally a maximum of thirty-eight degrees Centigrade (38° C.)." Ex. 1001 at 20:4-9. "Temperature sensor 87 can be positioned in close proximity to thermally conductive material 62 in order to obtain reasonably accurate information on the temperature of the external surface of external antenna 52 contacting patient 18." *Id*. at 20:11-15 (emphasis added). "Positioning temperature sensor 87 in the proximity or touching thermally conductive material 62 enables an accurate measurement of the contact temperature." *Id.* at 20:4-22 (emphasis added); *see also id.* at 20:34-21:15 (explaining the level of accuracy needed).

In view of the specification and the claim language, a POSITA would understand that the claims require a temperature sensor capable of providing an output "accurately measuring a temperature of the external surface portion of housing that is placed against the patient during recharging" in order to prevent the surface touching the patient from heating the patient's tissue to deleterious levels.

B. "Adjustable assembly adapted to adjust efficiency of energy transfer between the primary coil and the secondary coil"

Dependent claim 5 requires the external device to comprise an "adjustable assembly adapted to adjust efficiency of energy transfer between the primary coil and the secondary coil." This term should be interpreted to mean that "a component of the external device that is moveable relative another component of the external device to adjust efficiency of charging."

The '324 patent uses the term "adjustable" only one time outside of the claims. The final paragraph of the specification states "embodiments of the external power source for an implantable medical device having an adjustable magnetic core and system and method related thereto are disclosed." Ex. 1001 at 21:51-53 (emphasis added). The '324 patent explains that "[a]s magnetic core 58 is repositioned within primary coil 54, the focus of magnetic flux generated by primary coil 54 is also repositioned. As noted above, external antenna 52 is generally aligned with implanted medical device 16 using palpatory sensation. Moveable magnetic core 58 can then be used to provide a 'fine' adjustment to the lateral positioning of external antenna 52 with respect to secondary coil 34. After bracket 84 has been secured to patient 18, external antenna 52 is attached to bracket 84. Magnetic core 58 is then moved until the best lateral alignment with secondary coil 34." *Id.* at 12:62-13:5 (emphasis added). The '324 patent further explains that "[l]ower portion 122 of magnetic core 58 can be rotated to a plurality

of positions within primary coil 58 by rotating core cup assembly 92." *Id.* at 12:53-55.

Crucially, the adjustable/movable magnetic core 58 is moveable relative to other components of the external device. Further, the relative movement of the magnetic core based on rotating of the assembly is used to adjust efficiency of charging.

A POSITA would therefore understand that the term "adjustable assembly adapted to adjust efficiency of energy transfer between the primary coil and the secondary coil" means "a component of the external device that is moveable relative another component of the external device to adjust efficiency of charging."

IV. 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 1-24 of the '324 patent is invalid in light of the teachings of the following references:

- PCT Publication No. WO 01/83029 ("Torgerson"), published on November 8, 2001, Ex. 1005.
- UL 544 (1998), Standard for Medical and Dental Equipment–Ed. 4.0, published on December 30, 1998, Ex. 1006.

- U.S. Patent No. 5,702,431 ("Wang"), issued on December 30, 1997, Ex. 1007.
- U.S. Patent No. 4,082,097 ("Mann"), issued on April 4, 1978, Ex. 1008.
- U.S. Patent No. 5,733,313 ("Barreras"), issued on March 31, 1998, Ex. 1009.
- U.S. Patent No. 6,685,638 ("Taylor"), filed on December 23, 2002, Ex. 1010.

Each of the listed references except Taylor was published more than one year before the '324 patent's priority date of October 2, 2003, and is therefore prior art under pre-AIA 35 U.S.C. section 102(b). Taylor is a patent application filed prior to the priority date of the '324 patent and is therefore prior art under pre-AIA section 102(e).

Each of Torgerson, Wang and Barreras were listed on Invention Disclosure Statements signed by the examiner—along with over 100 hundred other references initialed as reviewed on February 24, 2016. However, none of those references was ever 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 Applicant. *See, e.g.*, *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2018-01247, 2019 WL 214935, at *18 (PTAB Jan. 15, 2019) (granting institution on grounds

relying on prior art cited in Examiner's Notice of References Cited and presented to the Examiner in an Information Disclosure Statement when there was "no indication that the Examiner [] ever considered the combinations presented in the Petition"). Indeed, the examination of the '324 patent was solely on the basis of obviousness-type double patenting rather than any substantive evaluation of the prior art.

As discussed below, Petitioner respectfully requests that the Board cancel the challenged claims of the '324 patent based on the following grounds:

- Ground 1: Claims 1, 2, 4, 9, 11-12, 14-15, 18-20 are unpatentable as obvious over Torgerson in view of UL 544.
- Ground 2: Claims 3, 6-8, 13, 16, 17, and 21-24 are unpatentable as obvious over Torgerson in view of UL 544 further in view of Wang.
- Ground 3: Claims 5 and 10 are unpatentable as obvious over Torgerson in view of UL 544 further in view of Mann.
- Ground 4: Claims 1, 2, 4, 9, 11-12, 14-15, 18-20 are unpatentable as obvious over Barreras in view of Taylor.
- Ground 5: Claims 3, 6-8, 13, 16, 17, and 21-24 are unpatentable as obvious over Barreras in view of Taylor further in view of Wang.
- Ground 6: Claims 5 and 10 are unpatentable as obvious over Barreras in view of Taylor further in view of Mann.

A. Ground 1: Claims 1, 2, 4, 9, 11-12, 14-15, 18-20 are unpatentable as obvious over Torgerson in view of UL 544

1. Torgerson

PCT Patent Publication No. WO 01/83029 A1 ("Torgerson") discloses "a battery recharge management system for implantable medical devices." Ex. 1005 at 1:5-6. As an exemplar device, Torgerson describes an implantable neurostimulator (INS), which "delivers mild electrical impulses to neural tissue using an electrical lead." *Id.* at 1:21-22. Figure 1 shows INS medical device 14 (blue) in its general environment along with some of the other components of the neurostimulation system including an external physician programmer 30 (red), and an external patient programmer 35 (green). *Id.* at 5:1-11.

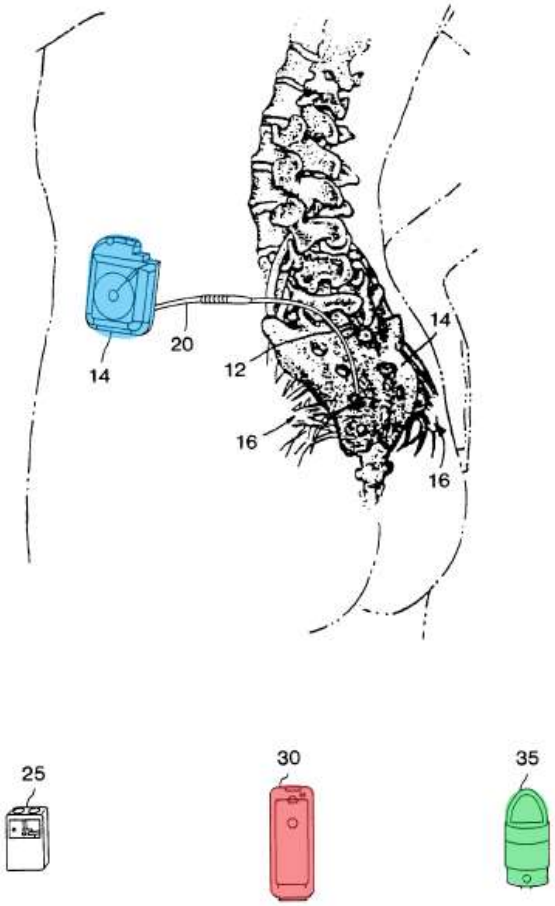


FIG. 1

"[T]he recharging process for the INS 14 begins with the patient or the physician, using an external patient programmer 35 or physician programmer 30, placing a telemetry head containing the recharge coil near the INS 14." *Id.* at 11:12-15. When the coil of the external charger and the coil of the INS are aligned

closely enough for transcutaneous charge coupling, the coil of the external charger "creates a magnetic field that a coil of the INS 14 receives." *Id*. at 11:15-18.

"[R]echarge module 310 serves to regulate the charging rate of the power source 315" within INS 14 and "also serves to maintain INS 14 temperature within acceptable limits so any temperature rise during recharge does not create an unsafe condition for the patient." *Id.* at 9:20-23. More specifically, recharge module 310 includes recharge measurement device 520 and recharge regulation control unit 525. *Id*. at 9:27-29. The recharge measurement device measures temperature of INS 14, including "the outer shield for the INS 14." "Based upon the recharge measurement, the recharge regulation control unit 525 can increase or decrease the energy reaching the power source 315." *Id*. at 10:19-23.

Thus, Torgerson discloses the transcutaneous coupling of implantable medical device (14) with a first coil, and external charging device (30, 35) with second coil, to transfer energy to implantable medical device, as well as a temperature sensor (520) and control circuitry adapted to control energy transfer to the implantable medical device based on output of the temperature sensor in order to ensure any temperature rise during recharge does not create an unsafe condition for the patient.

Torgerson further discloses an external sensor in an alternative embodiment "[o]ptionally, the neurostimulation system may include a sensor 25 to provide

closed-loop feedback control of the INS 14. For example, the INS 14 may receive feedback instructions from an external component, which processes a recorded signal from the sensor 25 and sends instruction to signal generator via antenna." *Id*. at 7:19-22.

Torgerson does not, however, explicitly disclose a temperature sensor located on the external charging device and measuring a temperature of the external housing of the external charging device (i.e., a surface touching a patient rather than one implanted within a patient).

2. UL 544

UL 544 (1998), Standard for Safety for Medical and Dental Equipment–Ed. 4.0, is a U.S. industry standard published by Underwriters Laboratories on December 30, 1998. *See* Ex. 1006. Thermal management of medical equipment and surfaces have to meet mandated technical standards for safety and performance concerns per regulatory body requirements. Ex. 1003, ¶¶ 47–48, 103-105. As of the October 2, 2003 priority date for the '324 patent, in particular, the temperature of an external surface of medical device parts contacted by the patient had to meet the UL 544 standard. *Id.* More specifically, UL 544 required that "the temperature on a part that is necessary to be applied to the patient so as to perform its intended function, but not intended to supply heat to patient, shall not exceed 41° C (106° F)." Ex. 1006 ¶ 36.2 at 62.

UL 544 further outlined requirements for testing the temperature of the surface of an applied part by use of a thermocouple attached to the surface to ensure the applied part meets applicable safety requirements. In particular, UL 544 taught that "[a] thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured. In most cases, adequate thermal contact will result from securely taping or cementing the thermocouple in place but, if a metal surface is involved, brazing or soldering the thermocouple to the metal may be necessary." Ex. 1006 ¶ 45.1.9 at 74.

3. The Combination of Torgerson in view of UL 544

A POSITA would have been motivated to combine Torgerson with UL 544 because it was effectively mandatory for the external charging devices (30, 35) of Torgerson to meet the requirements of UL 544—including the temperature testing requirements. Ex. 1003, ¶¶ 47–48, 103–107. Because the housing of the external charging device of Torgerson is applied to the skin of the patient, then, under UL 544, the temperature of the surface applied to the patient could not exceed predetermined temperature limit: 41°C. Ex. 1006 ¶ 36.2 at 62. If the external charging device exceeded this limit, it would not have been eligible for certification under UL 544 and would not have gained FDA pre-market approval for commercial marketing of the medical system to patients. Ex. 1003, ¶¶ 48, 107.

Thus, it would have been obvious, if not compulsory, for one of skill in the art in the medical device industry to include a thermocouple (e.g. temperature sensor) thermally connected to the surface applied to the patient in Torgerson's external programmers to monitor that temperature (as taught in UL 544), and to include control circuitry to ensure the external charging device does not exceed the mandated 41°C temperature limit so that the device meets the UL 544 standard. Ex. 1003, ¶¶ 107–107.

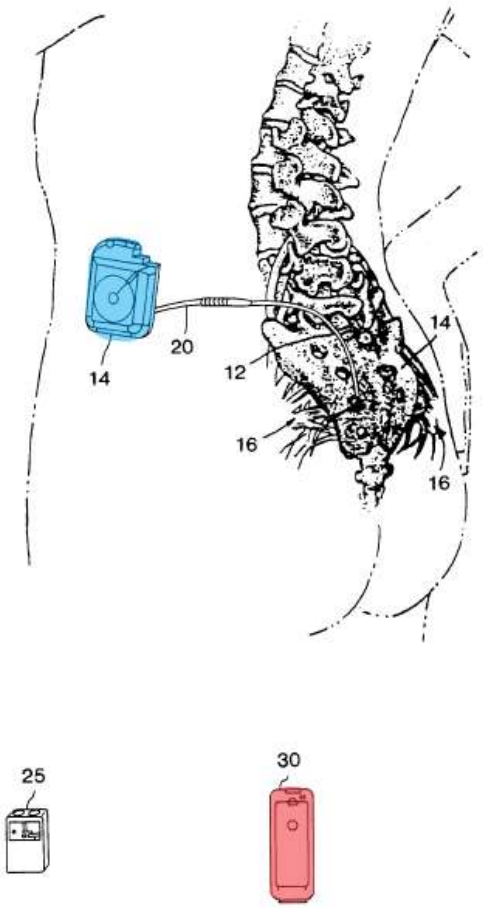
Torgerson already discloses the use of control circuitry to regulate energy transfer from the external charging devices (30, 35) to the implantable medical device (14) based on several temperature measurements. *See* e.g., Ex. 1005 at 10:19-23 ("temperature of specific areas of the INS 14 may be measured including, but not limited to, the recharge coil, recharge regulator 515, power source 315, and the outer shield for the INS 14. Based upon the recharge measurement, the recharge regulation control unit 525 can increase or decrease the energy reaching the power source 315."). Torgerson also contemplates the use of an external sensor to provide closed-loop feedback control to the INS 14. *See id*. at 7:19-22. Using the temperature of the external surface of the charging device that contacts the patient as another one of the temperature parameters to regulate energy transfer would have yielded the predictable result of ensuring that "temperature rise during

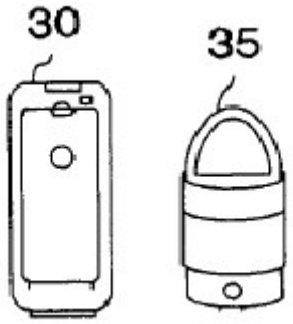
recharge does not create an unsafe condition for the patient"—a stated goal of Torgerson. *See id.* at 9:21-23.

4. Applying Torgerson in view of UL 544 to the Claims

The combination of Torgerson and UL 544 teaches every limitation of claims 1, 2, 4, 9, 11-12, 14-15, 18-20 of the '324 patent, as set forth in greater detail in the following charts.

	Claim Language	Torgerson in view of UL 544
1.0	1. A system, comprising: an implantable medical device comprising a secondary coil; and an external device comprising:	Torgerson teaches a system comprising an implantable medical device with a secondary coil as well as an external device. *See e.g.*, Ex. 1005 at 3:16-23 ("the present invention is a recharge management system for an implantable medical device having…a recharge coil associated with the implantable device capable of receiving via telemetry magnetic recharge energy from an external device.") Figure 1 of Torgerson (reproduced below) shows an "INS 14…a physician programmer 30, and a patient programmer 35." *Id*. at 5:2-4. "[M]agnetic recharge energy may then be delivered from the external programmers 30 or 35 to the INS 14." *Id*. at 11:22-23.

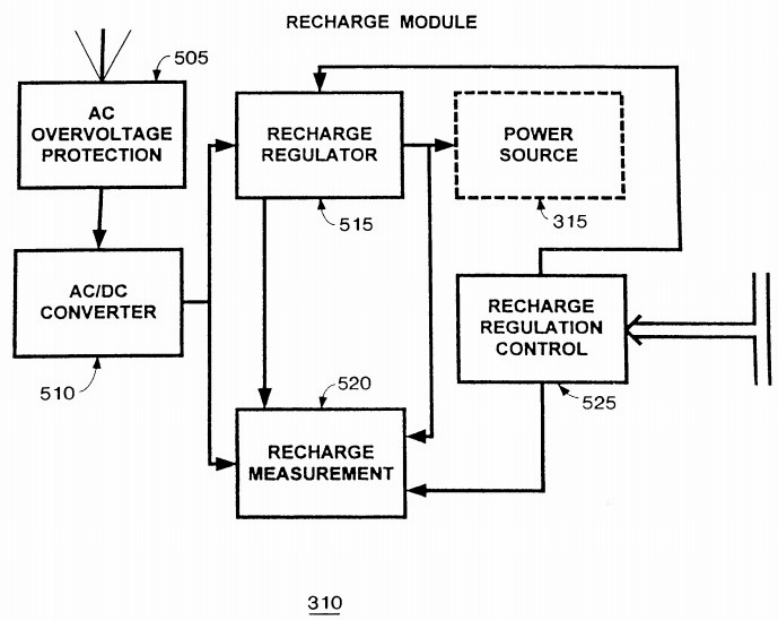
	Claim Language	Torgerson in view of UL 544
		 FIG. 1
1.1	a primary coil adapted to be transcutaneously coupled to the secondary coil to transfer energy to the implantable medical device;	Torgerson teaches that "the recharging process for the INS 14 begins with the patient or the physician, using an external patient programmer 35 or physician programmer 30, placing a telemetry head containing the recharge coil near the INS 14" and "when the telemetry head is aligned closely enough with the implanted INS 14 for adequate telemetry and charge coupling" a "coil … of the external component creates a magnetic field that a coil of the INS 14 receives." Ex. 1005 at 11:12-23; Fig. 6. Thus, Torgerson teaches an external device (30 or

	Claim Language	Torgerson in view of UL 544
		35)—which is outside of the patient—with a primary coil that is coupled to the secondary coil of the implantable medical device (14)—which is inside the patient—to transfer energy to the implantable medical device (14) through the patient's skin. Ex. 1003, ¶ 109.
1.2	a housing having a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously coupled to the secondary coil;	Portions of Figure 1 of Torgerson, depict external (e.g., patient and physician) programmers 30 and 35, which illustrate a housing:  Torgerson teaches "[b]oth the patient and physician programmers 30 and 35 have an antenna or coil locator that indicates when the telemetry head is aligned closely enough with the implanted INS 14 for adequate telemetry and charge coupling." Ex. 1005 at 11:12-23; Fig. 6. Thus, Torgerson teaches placing the programmer in proximity (i.e., near) the INS during recharging. Ex. 1003, ¶ 109. During coupling one side of the housing of the programmer would be positioned near the secondary

	Claim Language	Torgerson in view of UL 544
		coil. *Id.*
1.3	a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing; and	Torgerson teaches that the INS 14 includes a recharge module 310, which includes recharge measurement device 520. Ex. 1005 at 9:26-29. The recharge measurement device measures, inter alia, temperatures of INS 14, including "the outer shield for the INS 14." *Id*. at 10:19-23. "Based upon the recharge measurement, the recharge regulation control unit 525 can increase or decrease the energy reaching the power source 315." *Id*. Thus, Torgerson teaches use of a temperature sensor adapted to provide an output (used by control unit 525) indicative of a temperature of the side of the housing of the implantable medical device—rather than the external device. Ex. 1003, ¶ 110. UL 544 teaches medical equipment and surfaces have to meet mandated technical standards for safety and performance concerns per regulatory body requirements. In particular, because the housing of the external device would contact the patient's skin during recharging, a POSITA would have known that the device would have only passed the tests for UL 544 certification if the housing of the external device did not exceed a predetermined temperature limit. *See* Ex. 1006 ¶ 36.2 at 62 ("the temperature on a part that is necessary to be applied to the patient so as to perform its intended

	Claim Language	Torgerson in view of UL 544
		function, but not intended to supply heat to patient, shall not exceed 41° C (106° F)"); *see also* Ex. 1003, ¶ 110. Here, the "part" applied to the patient would be the external surface that touches the patient during charging. Ex. 1003, ¶ 110. In order for a temperature sensor to provide an output indicative of a temperature of the side of surface (i.e., one "accurately measuring a temperature of the external surface portion of housing that is placed against the patient during recharging."), UL 544 also teaches that "[a] thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured." Ex. 1006 ¶ 45.1.9 at 74; *see also* Ex. 1003, ¶ 110. Thus, placing a temperature sensor on the external device to accurately measure a temperature of the side of housing contacting the patient would have been obvious to one of skill in the art in light of Torgerson and UL 544. *Id.* at ¶ 110.
1.4	control circuitry adapted to control the transfer of	Torgerson teaches "a recharge measurement device monitoring at least one recharge parameter, and a recharge regulation control unit for regulating the recharge energy delivered to the power source in

	Claim Language	Torgerson in view of UL 544
	energy to the implantable medical device based on the output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device.	response to the recharge measurement device." Ex. 1005 at 3:16-23; *see also id.* at Claim 36 (claiming a system with "a control unit for regulating the recharge energy delivered to the power source in response to the … temperature sensor.") Figure 5 (below) is a schematic block diagram of recharge module 310 in accordance with a preferred embodiment of Torgerson. Ex. 1005 at 9:17-26. ("The recharge module 310 provides a form of closed-loop feedback control to ensure proper and efficient charging of the battery with minimized risk of damage to the battery. The recharge module 310 serves to regulate charging rate of the power source 315 according to power source parameters. The recharge module 310 also serves to maintain INS 14 temperature within acceptable limits so any temperature rise during recharge does not create an unsafe condition for the patient.")

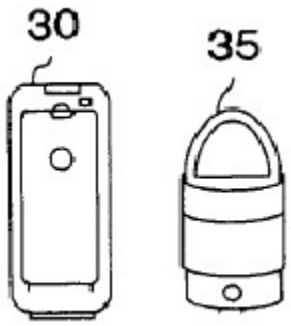
	Claim Language	Torgerson in view of UL 544
		 FIG. 5 More specifically, the "recharge measurement device 520…measures temperature of the INS 14. . . . Based upon the recharge measurement, the recharge regulation control unit 525 can increase or decrease the energy reaching the power source 315." Ex. 1005 at 10:15-23; *see also id.* at 13:6-14 ("the INS 14 will communicate to the charging device to lower the supplied energy if components in the INS 14 are heating up above safe limits for the pat[i]ent and/or device."); *see also* Ex. 1003, ¶¶ 111-112. Thus, Torgerson teaches control circuitry adapted to control the transfer of energy to the implantable medical device (e.g., by regulating the charging rate) based on the

	Claim Language	Torgerson in view of UL 544
		output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device (e.g., if a temperature exceeds safety limits, the recharging rate is lowered). Ex. 1003, ¶¶ 111-112. Further, Torgerson also teaches an alternative embodiment in which an external sensor provides "closed-loop feedback control" of INS 14 wherein external instructions are sent to INS 14 via an antenna. *See* Ex. 1005 at 7:19-22 ("the neurostimulation system may include a sensor 25 to provide closed-loop feedback control of the INS 14. For example, the INS 14 may receive feedback instructions from an external component, which processes a recorded signal from the sensor 25 and sends instruction to signal generator via antenna.") As noted in the disclosures for [1.3] above, Torgerson does not explicitly teach a temperature sensor coupled to the side of the housing of the external device. However, as per the disclosures for [1.3], the addition of such a temperature sensor would have been obvious in view of UL 544. Further, the control circuitry of Torgerson was disclosed as "increas[ing] or decreas[ing] the energy reaching the power source 315" based on various

	Claim Language	Torgerson in view of UL 544
		temperature measurements. *See* Ex. 1005 at 10:19-23. It would have been within the skill of a POSITA to modify the control circuitry of Torgerson to allow for energy transfer to be controlled based on this external temperature parameter of the combination. Ex. 1003, ¶¶ 111-112. Such modification is, in fact, taught by Torgerson, which discloses that control circuitry for implementing closed-loop feedback control of the INS 14 can be located on an external component, including external sensor, in the system. *Id.*
2.0	The system of claim 1, wherein the control circuitry is adapted to limit the transfer of energy between the external device and the secondary coil.	See disclosures for [1.4] above. Torgerson teaches that "the INS 14 will communicate to the charging device to lower the supplied energy if components in the INS 14 are heating up above safe limits for the pat[i]ent and/or device." Ex. 1005 at 13:6-14; *see also id.* at 10:19-23. It is inherent from this disclosure that the external device of Torgerson has control circuitry that is able to limit the transfer of energy to the secondary coil because it is lowering the supplied energy after receiving instructions from the INS. Ex. 1003, ¶ 115. Further, it would have been an obvious design choice to locate the control circuitry of Torgerson on the external device in order to reduce the size of the implantable medical device. *Id.*
4.0	The system of claim 1, wherein the external	UL 544 is a safety standard that prohibits medical devices that come in contact with patients from exceeding defined temperature limits. *See* Ex. 1006 ¶

	Claim Language	Torgerson in view of UL 544
	device is adapted to limit at least one of a temperature of the side and a temperature of a surface of the patient to no higher than a respective predetermined temperature.	36.2 at 62. As noted in the disclosures for [1.3] above, UL 544 teaches medical equipment and surfaces have to meet mandated technical standards for safety and performance concerns per regulatory body requirements. In particular, because the housing of the external device would contact the patient's skin during recharging, a POSITA would have known that the device would have only passed the tests for UL 544 certification if the housing of the external device did not exceed a predetermined temperature limit. *See* Ex. 1006 ¶ 36.2 at 62 ("the temperature on a part that is necessary to be applied to the patient so as to perform its intended function, but not intended to supply heat to patient, shall not exceed 41° C (106° F)"); *see also* Ex. 1003, ¶ 116.
9.0	The system of claim 1, wherein the external device further comprises a circuit adapted to monitor recharging of a rechargeable power source of	Torgerson teaches the use of a circuit adapted to monitor recharging of a rechargeable power source of the implantable medical device. *See* Ex. 1005 at 10:24-26 ("The regulated voltage and current is continually monitored during recharge."); *see also id.* at Claim 1 ("a recharge measurement device monitoring at least one recharge parameter"). While Torgerson does not require the circuit monitoring recharging to be within the external device, it would

	Claim Language	Torgerson in view of UL 544
	the implantable medical device.	have been obvious to a POSITA to include it there in order to reduce the size of the INS. Ex. 1003, ¶ 118.
11.0	The system of claim 1, wherein at least a portion of the side is thermally conductive.	UL 544 teaches that the temperature sensor should be in "good thermal contact" with the surface being measured, thus, it would be obvious to include a "thermally conductive material" *(e.g.* thermally conductive cement, brazing, etc.) to thermally connect the temperature sensor to the contact surface to improve accuracy of the temperature measurement to ensure the required safety standard is being met. *See* Ex. 1006 ¶ 45.1.9 at 74 ("A thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured. In most cases, adequate thermal contact will result from securely taping or cementing the thermocouple in place but, if a metal surface is involved, brazing or soldering the thermocouple to the metal may be necessary.") (emphasis added); Ex. 1003, ¶ 119.
12.0	A method for transferring energy from an external device comprising a housing and a	See disclosures for [1.0] above. Figure 1 of Torgerson (reproduced below) shows an "INS 14…a physician programmer 30, and a patient programmer 35." Ex. 1005 at 5:2-4. "[M]agnetic recharge energy may then be delivered from the external

	Claim Language	Torgerson in view of UL 544
	primary coil to an implantable medical device, the method comprising:	programmers 30 or 35 to the INS 14." *Id*. at 11:22-23.
12.1	while a side of the housing is positioned in proximity to a secondary coil of the implantable medical device, transcutaneously coupling the primary coil to the secondary coil to transfer energy to the implantable medical device;	Portions of Figure 1 of Torgerson, depict external (e.g., patient and physician) programmers 30 and 35, which illustrate a housing:  Torgerson teaches "[b]oth the patient and physician programmers 30 and 35 have an antenna or coil locator that indicates when the telemetry head is aligned closely enough with the implanted INS 14 for adequate telemetry and charge coupling." Ex. 1005 at 11:12-23; Fig. 6. Torgerson further teaches that "the recharging process for the INS 14 begins with the patient or the physician, using an external patient programmer 35 or physician programmer 30, placing a telemetry head containing the

	Claim Language	Torgerson in view of UL 544
		recharge coil near the INS 14. Both the patient and physician programmers 30 and 35 have an antenna or coil locator that indicates when the telemetry head is aligned closely enough with the implanted INS 14 for adequate telemetry and charge coupling. A coil (not shown) of the external component creates a magnetic field that a coil of the INS 14 receives." Ex. 1005 at 11:12-23; Fig. 6. Thus, Torgerson teaches transcutaneously coupling the primary coil to the secondary coil to transfer energy to the implantable medical device while a side of the housing of the programmer is placed in proximity (i.e., near) the INS. Ex. 1003, ¶¶ 109, 113.
12.2	providing, via a temperature sensor of the external device, output indicative of a temperature of the side of the housing; and	See disclosures for [1.3] above.
12.3	controlling the transfer of energy from the	See disclosures for [1.4] above.

	Claim Language	Torgerson in view of UL 544
	primary coil to the secondary coil based on the output indicative of the temperature of the side of the housing to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device.	
14.0	The method of claim 12, further comprising limiting at least one of a temperature of the side and a temperature of a surface of the patient to no	*See* disclosures for [4.0] above.

	Claim Language	Torgerson in view of UL 544
	higher than a respective predetermined temperature.	
15.0	The method of claim 12, further comprising adjusting efficiency of energy transfer between the primary coil and the secondary coil based on the output of the temperature sensor.	Torgerson is directed to charging "at optimum efficiency and at a level that prevents the INS 14 from overheating yet charges the power source 315 efficiently." Ex. 1005 at 9:23-26. Thus, Torgerson teaches that "recharge regulation control unit 525 provides feedback as to…whether the recharge energy is too high or too low. . . . If the recharge energy is too low, it can be slowly increased to improve recharge efficiency. . . . Likewise, the INS 14 will communicate to the charging device to lower the supplied energy if components in the INS 14 are heating up above safe limits for the pat[i]ent and/or device. Similarly, if the temperature is safe and the current and voltage levels are below the charge rate capacity of the power source 315, the INS 14 will communicate to the charging device that the RF energy can be increased." *Id.* at 12:23-13:14. It would have been obvious for a POSITA to further utilize the output of the external temperature sensor of the Torgerson combination with UL 544 when adjusting efficiency of the energy transfer as taught in Torgerson. Ex. 1003, ¶ 120.
18.0	The method of	In view of UL 544's disclosure that the temperature of

	Claim Language	Torgerson in view of UL 544
	claim 12, further comprising limiting the temperature of the skin of the patient to thirty-nine degrees Centigrade (39º C.).	the portion of the external device's housing that contacts the patient during recharging should not exceed 41° C, the exercise of routine skill would have made it obvious to use a method of charging that limited the temperature of the patient's skin to 39º C. Ex. 1003, ¶ 121 (explaining that a POSITA would have selected a 39º C limit as a precautionary measure to prevent a safety hazard if the temperature rise from charging overshot the limit).
19.0	The method of claim 12, further comprising limiting the temperature of the side of the implantable medical device to not more than forty-one degrees Centigrade (41º C.).	In view of the UL 544 standard, it would be obvious, if not required to limit the temperature of the implantable medical device side that contacts the patient to ensure the temperature of the surface does not exceed the mandated safety standards. Ex. 1003, ¶ 122. Because UL 544 already set a 41º C limit for patient contacting portions of external devices a POSITA would have known that internal temperatures should also not exceed that temperature limit. Ex. 1003, ¶ 122.
20.0	A system for	See disclosures for [1.0] above.

	Claim Language	Torgerson in view of UL 544
	transferring energy to an implantable medical device, comprising:	
20.1	a primary coil adapted to be transcutaneously coupled to a secondary coil of the implantable medical device to transfer energy to the implantable medical device;	See disclosures for [1.1] above.
20.2	a housing having a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously	See disclosures for [1.2] above.

	Claim Language	Torgerson in view of UL 544
	coupled to the secondary coil;	
20.3	a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing; and	See disclosures for [1.3] above.
20.4	control circuitry adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of	As explained in the disclosure for [1.4], Torgerson teaches "a recharge measurement device monitoring at least one recharge parameter, and a recharge regulation control unit for regulating the recharge energy delivered to the power source in response to the recharge measurement device." Ex. 1005 at 3:16-23; *see also id.* at Claim 36 (claiming a system with "a control unit for regulating the recharge energy delivered to the power source in response to the … temperature sensor."); *see also* Ex. 1003, ¶¶ 111-112, 114. As noted in the disclosures for [1.4] above, Torgerson does not explicitly teach a temperature sensor coupled to the side of the housing of the external device. However, as per the disclosures for [1.3], the addition of such a temperature sensor would have been obvious in view of

	Claim Language	Torgerson in view of UL 544
	energy to the implantable medical device.	UL 544. Further, the control circuitry of Torgerson was disclosed as "increas[ing] or decreas[ing] the energy reaching the power source 315" based on various temperature measurements. *See* Ex. 1005 at 10:19-24. It would have been within the skill of a POSITA to modify the control circuitry of Torgerson to allow for energy transfer to be controlled based on this external temperature parameter of the combination. Ex. 1003, ¶¶ 111-112, 114.

B. Ground 2: Claims 3, 6-8, 13, 16, 17, and 21-24 are unpatentable as obvious over Torgerson in view of UL 544 further in view of Wang

1. Combination of Torgerson, UL 544 and Wang

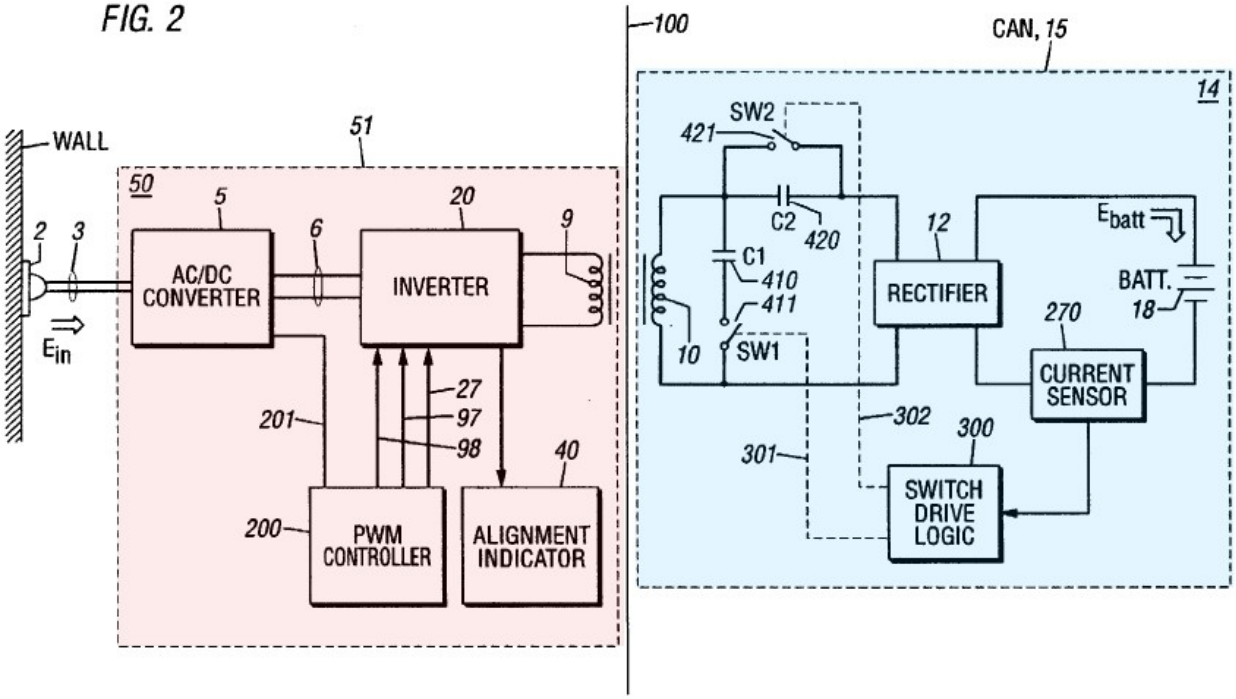
As shown in Section IV.A.4 above, the combination of Torgerson and UL 544 teaches every limitation of claims 1, 2, 4, 9, 11-12, 14-15, 18-20 of the '324 patent. Claims 3, 6-8, 13, 16, 17, and 21-24 introduce limitations relating to controlling the transfer of energy to the implantable medical device.

As the '324 patent explains, much of this claimed functionality was commonplace and well known. *See* Ex. 1001 at 2:33-53 (describing prior art teachings regarding the avoidance of detrimental temperature increases via "switching on and off" voltages, use of "variable duty cycle" and "reduc[ing]

charging current"). The routine nature of these different mechanisms for regulating transcutaneous energy transfer by the priority date of the '324 patent is confirmed by U.S. Patent No. 5,702,431 ("Wang").

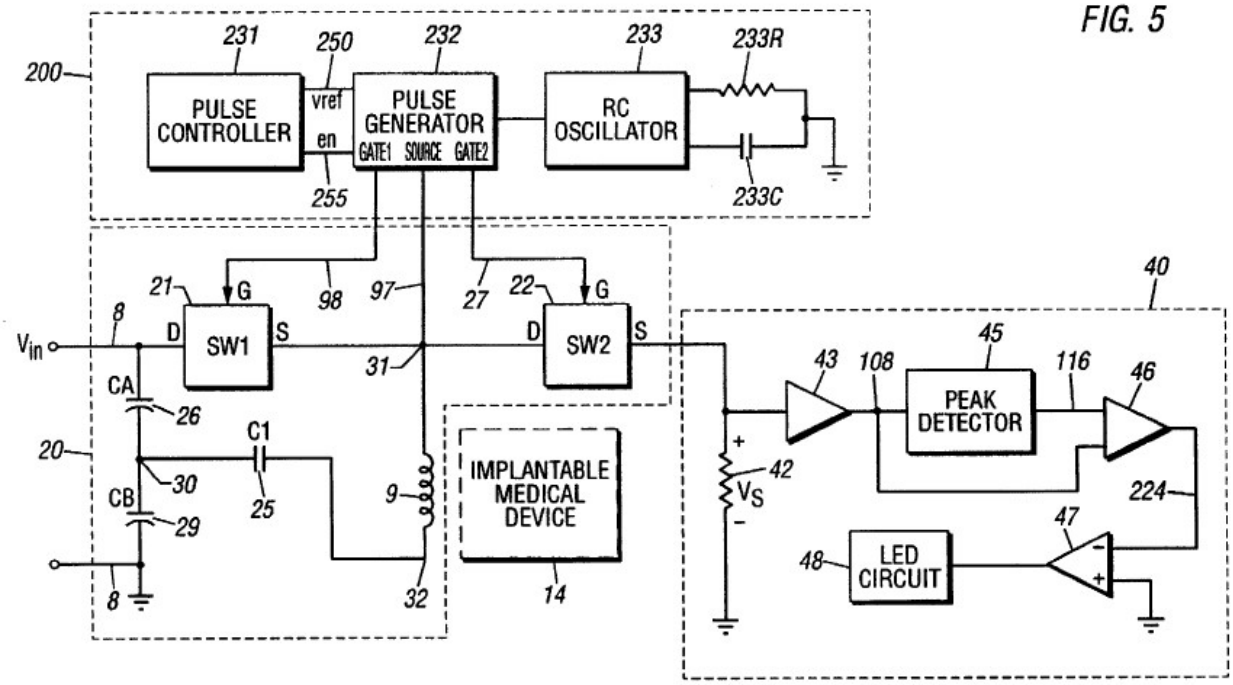
Wang teaches a transcutaneous recharging system that includes "a transcutaneous energy transmission (TET) device 50 and an implanted medical device 14." *See* Ex. 1007 at 6:21-24; *see also* Fig. 2 (reproduced below).

FIG. 2



Wang teaches charging protocols for reducing "the peak temperature rise" caused by charging of the implantable medical device 14. *Id.* at 7:58-8:24, Figs. 4B and 4C. Figures 5-8 of Wang show the preferred implementation of "the circuity employed to achieve the charging protocols shown in FIGS. 4B and 4C." *See id.* at 8:34-47. As shown in Figure 5 (below) and Figure 2 (above), all of this

circuitry (the PWM Controller 200, inverter 20, alignment indicator 40, pulse controller 231, a pulse generator 232, an RC oscillator 233, resistor 233R, and capacitor 233C) is located within the external charger 50 rather than the implantable device 14. *See id*.



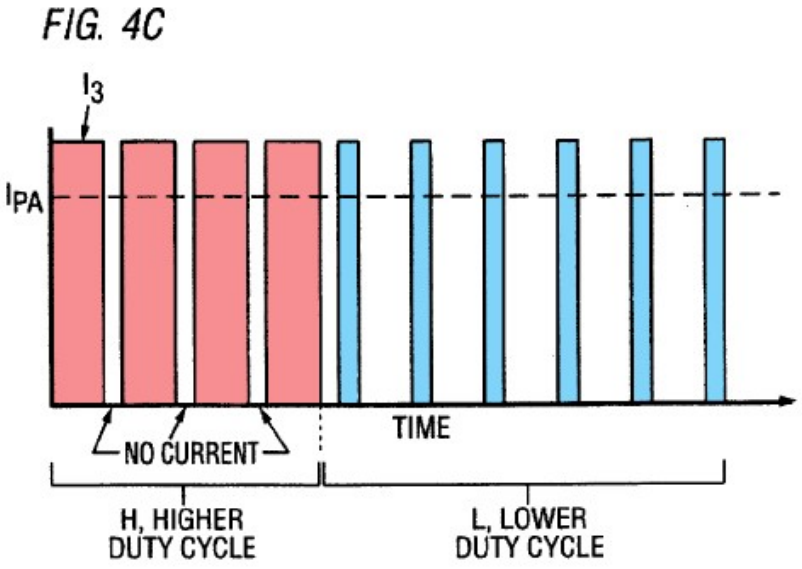
Like Torgerson, Wang recognizes that increased temperatures resulting from transcutaneous recharging of implantable medical devices can have deleterious effects on the patient's tissue and both are directed to limiting such temperature rises. *See* Ex. 1007 at 3:51-62 ("The temperature of the housing increases in response to the eddy currents, and can also increase in response to the elevated temperature of the battery during charging. A rise in temperature of the outer surface of the housing may be detrimental to operation of the medical device and

harmful to surrounding body tissue. Industry standards suggest maximum allowable temperature rises. Limiting a temperature rise (i.e., peak temperature) is desirable to minimize the harmful effects on surrounding body tissues."); *see also* Ex. 1005 at 9:20-23 ("recharge module 310 also serves to maintain INS 14 temperature within acceptable limits so any temperature rise during recharge does not create an unsafe condition for the patient.") UL 544 also recognizes the deleterious effects that heat from medical devices has on human tissue and therefore sets temperature limits for the housing of external medical devices that contact human skin. Ex. 1006 ¶ 36.2 at 62. Because they are directed to solving a common problem, a POSITA would have been motivated to combine Torgerson and UL 544 with Wang.

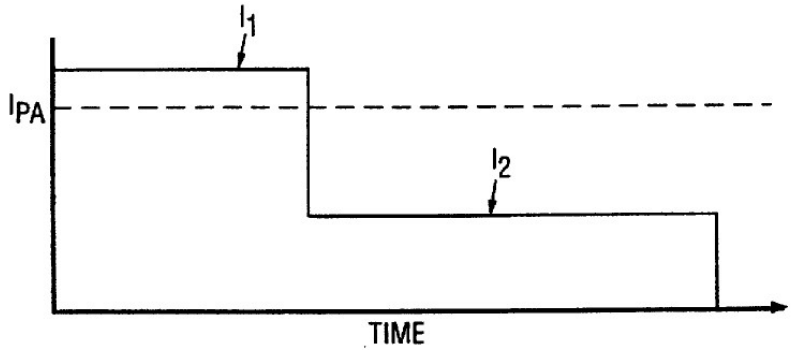
As further shown above, the combination of Torgerson and UL 544 discloses a system in which the transfer of energy to the implantable medical device is controlled based on the output of the temperature sensor to limit a temperature to which a patient is exposed during charging. *See* disclosures for [1.4] in Section IV.A.4 above. Wang discloses circuitry and strategies for manipulating energy transfer to limit temperature rises as described below.

	Claim Language	Wang
3.0	3. The system of claim 1,	Wang teaches that a "controller preferably is constructed as a pulse width modulation device with enable and

	Claim Language	Wang
	wherein the control circuitry is adapted to control a duty cycle of the transfer of energy between the external device and the secondary coil based on the output of the temperature sensor.	reference voltage features to effectuate variable duty cycle control of the current level applied to the primary coil." Ex. 1007, Abstract. While "[t]he transcutaneous energy transmission device produces a relatively high charging current to the battery" it is "periodically interrupted by periods without any charging current." *Id.* at 4:66-5:2. Thus, the "resulting duty cycle of the charging current is adjustable to allow for different levels of average charging current to the battery." *See id.* at 5:1-7 ("An effective current step is thus generated by reducing the duty cycle of the charging current from an initial high level to a lower level."); *see also id.* at 8:17-24 ("The average current, therefore, is higher during the charging period in which a higher duty cycle is used . . . . As the duty cycle is reduced . . . . the result is a lower average charging current.") Wang further teaches a protocol through which lowering the duty cycle during charging results in lower peak temperatures. *See id.* at 4:41-44 ("[t]wo different charging protocols are implemented to minimize the peak temperature produced on the outer surface of the housing"); *see also id.* at 7:41-8:24 (describing the "current step" and "duty cycle" charging protocols). This principle is illustrated in the annotated Figure 4C of Wang below, wherein the red rectangles of the "higher duty cycle" reflect greater energy transfer than the blue

	Claim Language	Wang
		rectangles of the "lower duty cycle," and the white space between the rectangles represents periods of "no current" where energy transfer is turned off. Ex. 1003, ¶¶ 142–144.  Wang does not teach controlling a duty cycle or otherwise limiting energy transfer to the implantable medical device based on the output of a temperature sensor, but that is already taught by the combination of Torgerson and UL 544. A POSITA would have understand from Wang how controlling the duty cycle of the energy transfer could be used to limit the energy transfer if the output of the temperature sensor of Torgerson and UL 544 indicated that the side of the housing was too hot. Ex. 1003, ¶¶ 142–144.
6.0	6. The system of claim 1,	As described in the disclosures for [3.0] above, Wang teaches varying the duty cycle of a current to vary the

	Claim Language	Wang
	wherein the control circuit is adapted to limit a time during which energy is transferred from the primary coil to the secondary coil based on the output indicative of a temperature of the side of the housing.	average charging current, and in the combination of Torgerson, UL 544, and Wang the duty cycle of energy transfer is controlled based on the output of the temperature sensor. Varying the duty cycle is accomplished because "PWM controller 200 controls the time when switches 21, 22 (SW1 and SW2), respectively turn on, as well as the time period during which the switches are activated" such that the "enable/disable signal on line 255 is used to define a duty cycle for the current delivered to primary coil 9." *Id.* at 9:52-55, 10:31-34.). In other words, when the duty cycle is lowered in response to a high temperature reading, it also true that the "time during which energy is transferred" is limited. Ex. 1003, ¶¶ 146–147.
7.0	7. The system of claim 6, wherein the control circuit is adapted to switch the energy transfer on and off based on the	See disclosures for [6.0] above. Just as lowering the duty cycle is equivalent to "limiting the time during which energy is transferred," it is also equivalent to switching energy transfer on and off. *See also* Ex. 1007 at 9:52-10:31.

	Claim Language	Wang
	output indicative of a temperature of the side of the housing.	
8.0	8. The system of claim 1, wherein the control circuit is adapted to limit a current driving the primary coil.	As shown in Figure 4B of Wang below, Wang teaches another charging control scheme for reducing peak temperature in which an initial relatively high charging current (generated by an external charging device) is simply lowered to a lower charging current based on feedback from the implanted device. See Ex. 1007 at 7:58-8:8; Ex. 1003, ¶ 151. FIG. 4B 
13.0	13. The method of claim 12, further comprising	*See* disclosures for [3.0] above.

	Claim Language	Wang
	adapting a duty cycle of the transfer of energy between the external device and the secondary coil based on the output of the temperature sensor.	
16.0	16. The method of claim 12, further comprising limiting a time during which energy is transferred from the primary coil to the secondary coil based on	*See* disclosures for [6.0] above.

	Claim Language	Wang
	the output indicative of a temperature of the side of the housing.	
17.0	17. The method of claim 16, further comprising switching the energy transfer on and off based on the output indicative of a temperature of the side of the housing.	*See* disclosures for [7.0] above.
21.0	21. The system of claim 20, wherein the control circuitry is adapted to	*See* disclosures for [3.0] above.

	Claim Language	Wang
	control a duty cycle of the transfer of energy between the external device and the secondary coil based on the output of the temperature sensor.	
22.0	22. The system of claim 20, wherein the control circuit is adapted to limit a time during which energy is transferred from the primary coil to the secondary coil based on	*See* disclosures for [6.0] above.

	Claim Language	Wang
	the output indicative of a temperature of the side of the housing.	
23.0	23. The system of claim 22, wherein the control circuit is adapted to switch the energy transfer on and off based on the output indicative of a temperature of the side of the housing.	*See* disclosures for [7.0] above.
24.0	24. The system of claim 20, wherein the control circuit is adapted to limit a current	*See* disclosures for [8.0] above.

	Claim Language	Wang
	driving the primary coil.	

C. Ground 3: Claims 5 and 10 are unpatentable as obvious over Torgerson in view of UL 544 and Mann

Claim 10 introduces a limitation further requiring the circuit of claim 9 adapted to monitor recharging is further "adapted to provide status of the recharging to a user."

The '324 patent admits that this was a known feature. *See* Ex. 1001 at 3:66-4:2 (explaining that prior art system included a "bidirectional telemetry link" that allowed the system to "inform the patient or clinician regarding the status of the system, including the state of the charge.")

Torgerson teaches the use of a circuit adapted to monitor recharging of a rechargeable power source of the implantable medical device. *See* Ex. 1005 at 10:24-26 ("Advantageously, the recharge method and apparatus of the present invention supplies a regulated voltage and current to the rechargeable power source 315. The regulated voltage and current is continually monitored during recharge." (emphasis added)) *see also id.* at Claim 1 ("a recharge measurement device monitoring at least one recharge parameter").

Similar to Torgerson, U.S. Patent No. 4,082,097 ("Mann") is directed to "controlling the charging of a rechargeable battery in an implanted human tissue stimulator by means of an external power source." Ex. 1008, Abstract. Mann teaches circuitry such that when the charge head 55 is properly aligned for charging and 600ma of charging current flows to the rechargeable battery, a green light is illuminated whereas poor alignment and a lower current causes a yellow light to illuminate and/or flash on and off. *See id.* at 10:24-45. Thus, Mann teaches circuitry that provides status of the recharging to a user.

A POSITA would have been motivated to combine Torgerson and UL 544 with Mann because both Torgerson and Mann teach monitoring of the recharging of the battery of an implantable medical device. The external chargers taught by Torgerson, such as patient programmer 35, already include "an antenna or coil locator that indicates when the telemetry head is aligned closely enough with the implanted INS 14 for adequate telemetry." See Ex. 1005 at 7:16-18. In view of Mann, it would be obvious to include circuitry that further monitors and provides a status of recharging to the user of the external device of Torgerson. Ex. 1003, ¶¶ 154–155.

Thus, the combination of Torgerson in view of UL 544 and Mann renders Claim 10 obvious.

Additionally, Claim 5 introduces a limitation requiring the external device to further comprise "an adjustable assembly adapted to adjust efficiency of energy transfer between the primary coil and the secondary coil."

To hold the external charging device in place during transcutaneous energy transfer, the '324 patent discloses a bracket 84 "adapted to be attached to the body of patient 18 with a belt (not shown)." Ex. 1001 at 10:49-50. The '324 patent states that "bracket 84 of the present invention can be used to roughly find the optimum position for external antenna 52" through a physician or patient moving bracket 84 "around until the bulge caused by implantable medical device 16 is most closely centered on opening 108." *Id.* at 11:57-59. Once roughly aligned, the '324 patent describes a "[m]oveable magnetic core 58" which can be "used to provide a 'fine' adjustment to the lateral positioning of external antenna 52 with respect to secondary coil 34." *Id.* at 12:66-13:1.

In view of Mann's disclosure of a display that indicates the status of the recharging to the patient based on the alignment of the paired coils, a POSITA would have been further motivated to provide an adjustable assembly that enabled the patient or physician to fine tune the alignment of the coils. Ex. 1003, ¶¶ 153–157. Incorporating a moveable/adjustable antenna component (e.g. coil or magnetic core component) into the combination of Torgerson and UL 544 would have been well within the skill of a POSITA and would have had the predictable

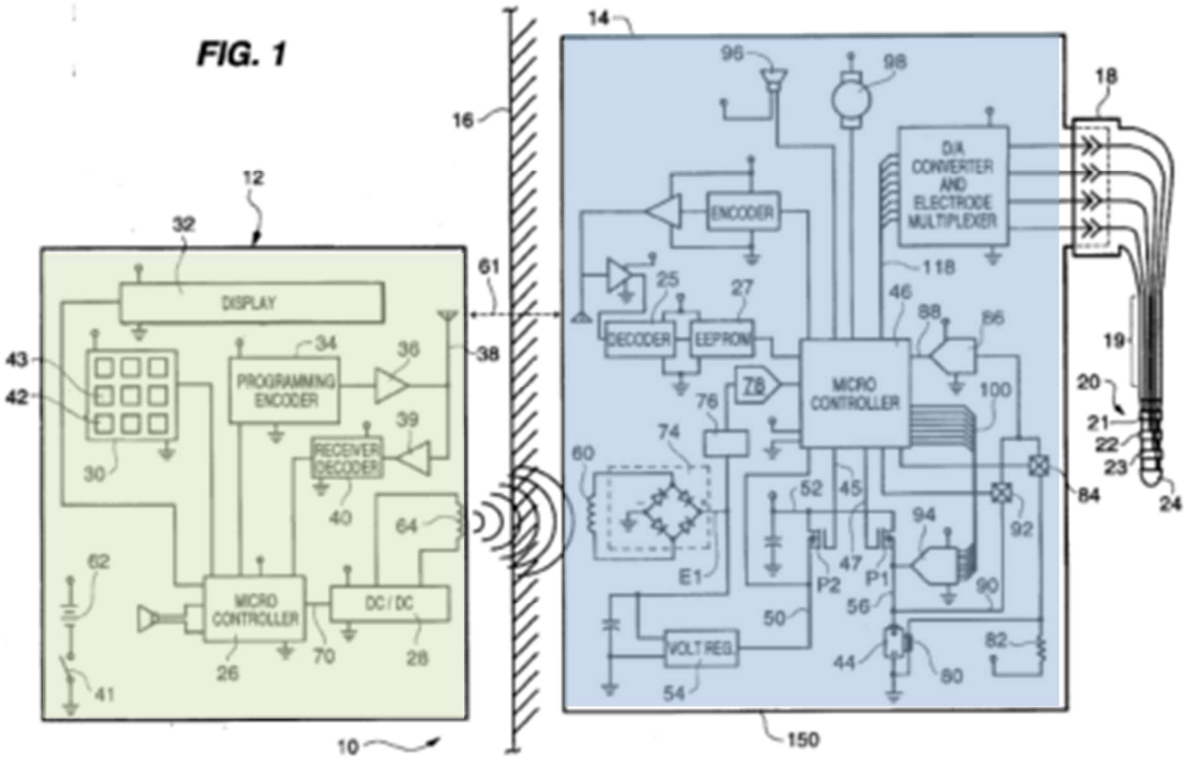
effect of improving positioning and efficiency of charging during actual use of the system by patients or physicians. Ex. 1003, ¶ 157.

Thus, the combination of Torgerson in view of UL 544 and Mann also renders Claim 5 obvious.

D. Ground 4: Claims 1, 2, 4, 9, 11-12, 14-15, 18-20 are unpatentable as obvious over Barreras in view of Taylor

1. Barreras

U.S. Patent No. 5,733,313 ("Barreras") discloses an "an implantable, electrically operated medical device (receiver) capable of obtaining its source of electrical power from … an external battery coupled via low level RF transmissions (transmitter)." Ex. 1009 at 5:3-8. Like the '324 patent, Barreras teaches neural stimulators as one example of an implantable medical device. *Id*. at 1:14-22. Figure 1 of Barreras (reproduced below) shows the implantable medical device (receiver 14, blue) "implanted beneath a patient's skin 16" and receiving energy from an external device, transmitter 12 (green). *See also id.* at 7:35-37. More specifically, the external device 12 transmits RF energy waves via output inductor 64 (a primary coil) to inductor 60 (a secondary coil within the implantable medical device 14) through the patient's skin 16 to recharge the implantable medical device via transcutaneous energy transfer. *See id.* at 8:39-43; Ex. 1003, ¶ 161.



This transcutaneous energy transfer occurs only when the primary coil 64 and secondary coil 60 are in proximity and becomes more efficient as the two coils are brought closer. *See* Ex. 1009 at 8:26-32 ("when RF energy is being coupled into an inductor 60 … the transmitter 12 is proximal to the receiver 14" whereas there is an "absence of RF energy" when "the transmitter 12 is away from the receiver 14"); *see also id.* at 8:53-55 ("[a] close proximity [of primary coil 64 and secondary coil 60] requires much less RF energy to recharge the rechargeable power source 44 than a longer distance would, in the same time."); *see also* Ex. 1003, ¶ 162.

Barreras further discloses circuitry that "restricts the temperature rise of the rechargeable power source" of the implantable medical device by implementing a temperature-controlled feedback loop. *See* Ex. 1009 at 8:56-9:5. More specifically, as shown in Figure 1, there is a micro controller 26 within the external device 12 as well as a second micro controller 46 within the implantable medical device 14 as well as a temperature sensor (thermistor 80). *See id*. at 8:43-9:5. "The actual level of RF energy generated by the inductor 64 is regulated by an output port 70 of the micro controller 26 as a real-time response to data transmitted by the receiver 14 via the micro controller 46." *Id.* at 8:43-49. "[T]he micro controller regulates, as a function of temperature, the current level used to recharge the rechargeable power source 44. The temperature is measured by a thermistor 80 which is adhered to the rechargeable power source 44 during manufacturing. . . . As the voltage rises, the ohmic value of the thermistor 80 drops proportionally to the temperature, thus reducing the voltage at the line conductor 88 to the micro controller 46. This loop forms a temperature-controlled, current-regulated charging system which restricts the temperature rise of the rechargeable power source 44 during recharging . . . ." *Id.* at 8:56–9:5.

By the time of the priority date, a POSITA would have been aware that a housing was a necessity as the transmitter is "worn" by the patient and its components need to be protected as well as not electrocute the patient. Ex. 1003, ¶

164. Although Barreras does not specifically discuss the requirements for such housing in the specification, a POSITA would have understood that the housing of an external charger for an implantable medical device would, at a minimum, have needed to satisfy the requirements of relevant patient safety standards, with which the POSITA would have been familiar. *Id.* Further, a POSITA would have understood the box around external device 12 in Figure 1 indicates that the external device of Barreras includes a housing. *Id.*

Thus, as discussed below, Barreras teaches all limitations of independent Claims 1, 12, and 20 except that Barreras does not explicitly disclose a temperature sensor located on the external charging device to measure a temperature of the external housing of the external charging device that is in contact with the patient during charging. The use of a temperature sensor on the portion of the external device's housing that contacts a patient is explicitly disclosed in Taylor.

2. Taylor

U.S. Patent No. 6,685,638 ("Taylor") discloses a method and system for analyzing signals "generated by any implanted device." Ex. 1010 at 18:59–66. This is accomplished using a monitoring system that includes one or more external transmitters 120, 130 and/or 230 that transcutaneously transfer energy to an implanted valve device. *See id.* at 6:48-7:10 (discussing transmitters 120 and 130), 8:24-9:21 (discussing transmitter 230); Ex. 1003, ¶¶ 166–172. As shown in

Taylor's Figures 2B and 4A (below), each of transmitters 130, 230 is surrounded by housing 136, 236 (formed from, inter alia, plastic or aluminum), which sits on top of base 138, 238. *See* Ex. 1010 at 9:3-7; 7:60-8:5, 11:3-15. Extending from the housing base 138, 238 are feet 158, 258 (formed from stainless steel) "for resting and balancing the housing … against the patient and over the implanted valve." *See id.* at 8:1-5, 9:3-7, 11:3-15.

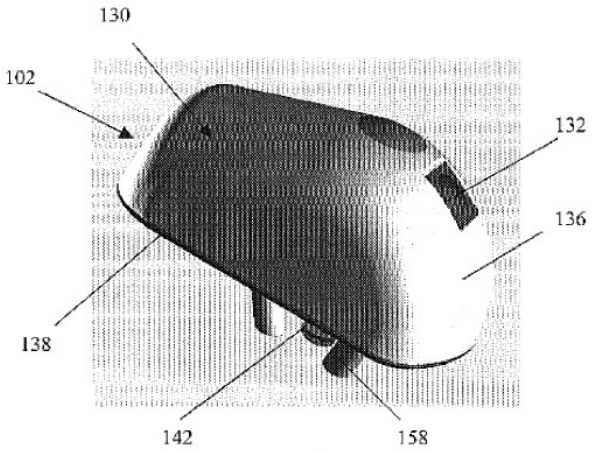


FIG. 2B

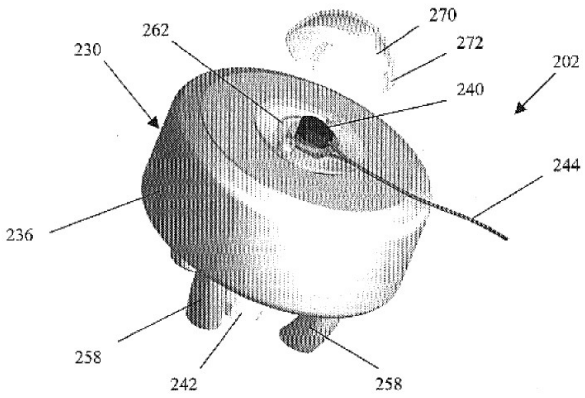


FIG. 4A

Because the feet of the transmitter are in contact with the patient during operation, Taylor teaches that "[p]referably, a thermistor can be incorporated into the [sic] any of the various transmitters 120, 130, 230 to assure that the temperature of the feet 258 does not exceed a particular temperature during patient or clinician contact." Ex. 1010 at 9:16-21. Similarly, Taylor explains that the temperature sensor in the transmitter is used to "assure that the temperature of the legs 158 does not exceed the requirements for brief patient contact as defined in EN60601." *See id.* at 16:23-27. To this end, Taylor further teaches control

circuitry that "monitors transmitter temperature, which should be below 41° C." *Id.* at 14:31-33.

3. The Combination of Barreras in view of Taylor

As shown above, both Barreras and Taylor teach the use of external transmitters applied to the skin of a patient to transmit energy transcutaneously to an implanted device. While Barreras teaches control circuitry that utilizes the output of a temperature sensor to restrict temperature rise during recharging by regulating the energy transfer to the implantable medical device from an external transmitter, it does not disclose any details of the external transmitter housing or a temperature sensor directly coupled to such housing. Taylor, in contrast, focuses on the housing of an external transmitter and explains the need for a temperature sensor that monitors the external surface temperature of the housing portions that are contact with the patient so as to ensure that this temperature "does not exceed the requirements for brief patient contact as defined in EN60601." Ex. 1010 at 16:23-27.

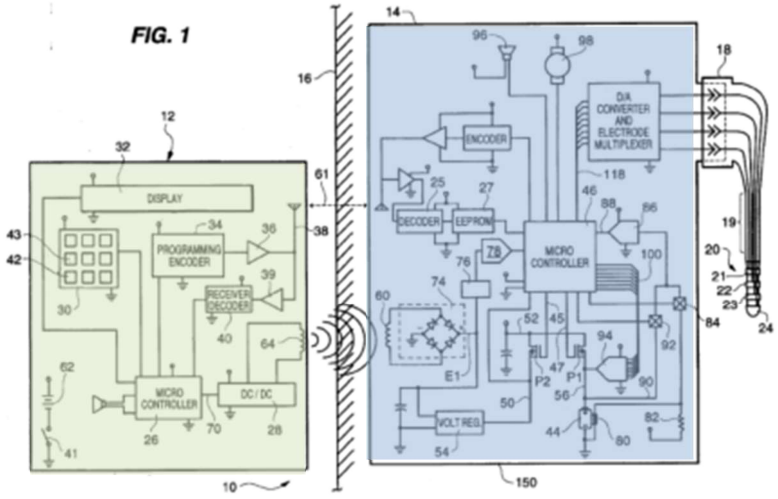
In order to ensure patient safety and regulatory approval for commercial marketing of a medical device, it would have been obvious to a POSITA to modify the external device of Barreras to incorporate the housing and temperature sensor of Taylor. Ex. 1003, ¶ 173. Further, it would have been obvious to modify the control circuitry of Barreras to regulate the energy transfer from the external

device to the implantable medical device based on the output of the temperature sensor of Taylor in order to ensure that the temperature limits set by relevant safety standards were not exceeded during operation because exceeding such safety limits would have prevented pre-market approval and/or exposed marketers of the device to civil liability if a patient was harmed by overheating devices. *Id.*

4. Applying Barreras in view of Taylor to the Claims

The combination of Barreras and Taylor teaches every limitation of claims 1, 2, 4, 9-12, 14-15, 18-20 of the '324 patent, as set forth in greater detail in the following charts.

	Claim Language	Barreras in view of Taylor
1.0	1. A system, comprising: an implantable medical device comprising a secondary coil; and an external device comprising:	Barreras teaches a system comprising an implantable medical device with a secondary coil (or receiving inductor) as well as an external device (external transmitter / recharging unit). *See, e.g.*, Ex. 1009 at 4:8-20 ("an implantable, electronically operated medical device comprising an implanted radio frequency (RF) receiver incorporating a rechargeable back-up power source and an external RF transmitter"); 5:34-41 ("electrical energy . . . is transferred into the rechargeable power source within the receiver utilizing an inductive RF power link between the external transmitter (recharging unit) and the implanted receiver (unit being recharged)").

	Claim Language	Barreras in view of Taylor
		Figure 1 of Barreras (reproduced below) shows "[t]he system 10 includ[ing] a transmitter 12 [green] and a receiver 14 [blue], the latter being surgically implanted beneath a patient's skin 16." *Id.* at 7:35-37. The external device (transmitter 12) generates via "an output inductor 64, high energy RF waves which are coupled into the inductor 60 [i.e., a secondary coil] contained within the receiver 14." *Id.* at 8:39-43. 
1.1	a primary coil adapted to be transcutaneously coupled to the secondary coil to transfer energy to the	Barreras teaches that the "receiver 14 will transmit, via a RF communication link 61, a 'recharge' command to the transmitter 12. This will cause the transmitter 12 to generate, via the battery 62, the DC/DC converter 28 and an output inductor 64, high energy RF waves which are coupled into the inductor 60 contained within the receiver 14," which is "surgically implanted

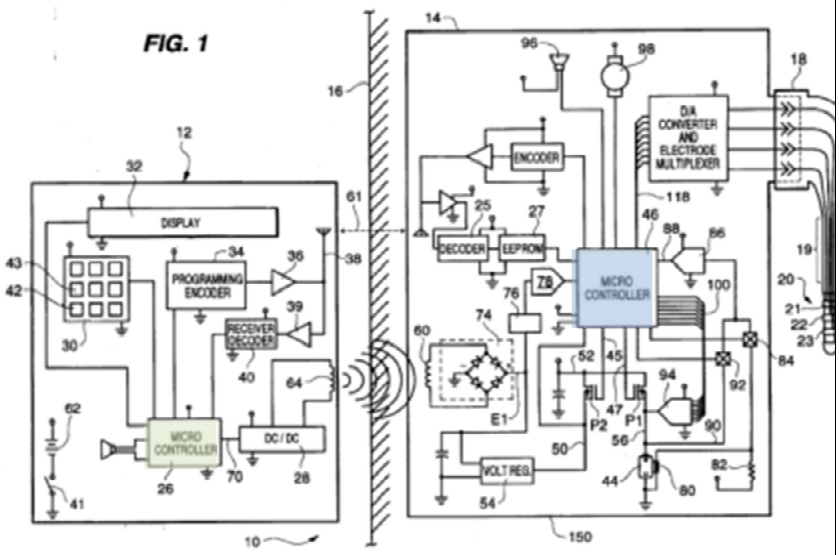
	Claim Language	Barreras in view of Taylor
	implantable medical device;	beneath a patient's skin 16." *Id.* at 8:35-43; 7:36-38. Barreras also teaches that the "transmitter incorporates a transmitting antenna [inductor 64] which generates RF wave-fronts which are coupled into an inductor within the implanted receiver." *Id.* at 4:62-64; *see also* Ex. 1003, ¶ 175. Thus, Barreras teaches an external device (transmitter 12)—which is outside the patient—with a primary coil (output inductor 64) that is coupled to the secondary coil (inductor 60) of the implantable medical device (receiver 14)—which is inside the patient—to transfer energy to the implantable medical device (receiver 14) through the patient's skin. *See* Ex. 1003, ¶ 175.
1.2	a housing having a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously coupled to the secondary coil;	Barreras teaches that "the transmitter is worn externally by the patient." Ex. 1009 at 4:17-18. A POSITA would have understood that this external transmitter necessarily includes a housing for its circuitry. *See* Ex. 1003, ¶ 164, 173. Barreras also teaches "the implanted receiver will only operate when the transmitter unit is proximate to the implanted receiver, and the transmitter will generate low level RF energy." Ex. 1009 at 5:67-6:3; *see also id.* at 8:21-32. Thus, a POSITA also would have understood that a side of the housing of the external charger of Barreras would be in contact with

	Claim Language	Barreras in view of Taylor
		the patient during recharging. Ex. 1003, ¶ 173. This is evidenced by Taylor which teaches a transmitter wherein "[s]urrounding the second transmitter 230 is a housing 236" with feet 258 for resting against the patient. Ex. 1010 at 9:3-7; see also Ex. 1003, ¶¶ 173, 176. Thus, it would have been, at a minimum, obvious to modify Barreras to include housing as taught in Taylor where a side of the housing of external transmitter 12 would be in proximity to the secondary coil (inductor 60) when the primary coil and secondary coil are coupled. Ex. 1003, ¶¶ 173, 175–176, 179.
1.3	a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing; and	Barreras teaches a temperature sensor mounted adjacent to the rechargeable battery and coupled to the circuitry of the external device. *See, e.g.*, Ex. 1009 at 8:58-60; *see also id.* at Claim 4 ("a temperature sensor which is mounted closely adjacent" to the rechargeable battery and "coupled via said RF signal transmitting means to said first control means of said transmitting unit…"). Barreras does not explicitly teach a temperature sensor to measure a temperature of the external surface portion of the housing that is placed against the patient during recharging. Taylor, however, teaches that "[a] thermistor such as a PT100 can be incorporated in the transmitter to assure that the temperature of the legs

	Claim Language	Barreras in view of Taylor
		158 does not exceed the requirements for brief patient contact as defined in EN60601." Ex. 1010 at 16:23-27.[2]; see also *id.* at 9:17-21 and 6:54-59. Thus, Taylor teaches a temperature sensor that provides an output indicative of the temperature of the part of the device that is placed in contact with the patient during energy transfer (the feet 258). Upon modifying the Barreras transmitter to include housing as taught in

[2] EN60601 refers to BS EN 60601-1:1990, the British Standard (BS) European Norm (EN) version of the International Electrotechnical Commission (IEC) 60601-1 standard that describes safety and essential performance requirements that must be adhered to for medical electrical equipment and systems. *See* Ex. 1003 at ¶ 171. EN60601 is a widely accepted benchmark, like UL standards, for medical electrical equipment and compliance with this standard has become a requirement for the commercialization of electrical medical equipment in many countries. Ex. 1003 at ¶ 171. In the U.S., UL 60601 (a version of IEC 60601-1) eventually superseded the UL2601 standard, which, after the priority date for the '324 patent, had superseded the UL 544 standard that was previously adhered to in the U.S. market, and included many of the same technical standards. *See* Ex. 1003 at ¶ 171.

	Claim Language	Barreras in view of Taylor
		Taylor (as described above), a POSITA would have included the temperature sensor adapted to provide an output indicative of a temperature of the side of the housing as taught in Taylor to obtain an accurate measurement of the temperature of the external surface of the housing portion that is placed against the patient during recharging to ensure that the temperature of the housing does not exceed mandated safety standards. Ex. 1003, ¶¶ 173, 176.
1.4	control circuitry adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the	Barreras teaches control circuitry for limiting temperatures in both the external transmitter 12 and the implantable medical device. External "transmitter 12" comprises "a micro controller 26 which is used, via software, to: 1) control the output of a programmable DC to DC converter 28 in order to regulate the amount of RF energy to be coupled into the receiver . . . ." Ex. 1009 at 7:48-52. There is also a micro controller 46 within the implanted receiver as shown in Figure 1 below.

	Claim Language	Barreras in view of Taylor
	implantable medical device.	 "The actual level of RF energy generated by the inductor 64 is regulated by an output port 70 of the micro controller 26 as a real-time response to data transmitted by the receiver 14 via the micro controller 46." Ex. 1009 at 8:43-49. Barreras teaches "the micro controller regulates, as a function of temperature, the current level used to recharge the rechargeable power source 44. The temperature is measured by a thermistor 80 which is adhered to the rechargeable power source 44 during manufacturing. . . . As the voltage rises, the ohmic value of the thermistor 80 drops proportionally to the temperature, thus reducing the voltage at the line conductor 88 to the micro controller 46. This loop forms a temperature-controlled, current-regulated charging system which restricts the temperature rise of the rechargeable power

	Claim Language	Barreras in view of Taylor
		source 44 during recharging . . . ." *Id.* at 8:56–9:5; *see also id.* at 5:57-63 and Claim 4. Thus, Barreras teaches control circuity (micro controller 26) adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor (transmitted wirelessly through micro controller 46) adjacent to a rechargeable power source 44 to limit a temperature of the rechargeable power source 44 during the transfer of energy to the implantable medical device. Ex. 1003, ¶ 163. As explained in the disclosures for [1.3] above, Barreras does not explicitly teach a temperature sensor to measure a temperature of the external surface portion of the housing that is placed against the patient during recharging, however, the addition of a temperature sensor coupled to the side of the housing of the external device to which a patient is exposed would have been obvious in vew of Taylor. *See* Ex. 1003, ¶ 176–177. It would have been obvious for a POSITA to modify the control circuity of Barreras (which enables "a temperature-controlled, current-regulated charging system which restricts the temperature rise of the rechargeable power source 44 during recharging") (Ex. 1009 at 8:67–9:2) to control the transfer of energy to the implantable medical device

	Claim Language	Barreras in view of Taylor
		based on the additional temperature parameter of the side of the housing to which the patient is exposed. Ex. 1003, ¶ 177.
2.0	*See* claim 2.0 in Section IV.A.4	See disclosures for [1.4] above. Barreras teaches control circuity (micro controller 26) adapted to control the transfer of energy to the implantable medical device, including by lowering the amount of RF energy transmitted. Ex. 1009 at 8:43–9:5; *see also id.* at 4:27-29; *see also id.* at Claim 4 ("…control means of said transmitting unit whereby the level of transmitted RF energy can be reduced…").
4.0	*See* claim 4.0 in Section IV.A.4	Taylor teaches a temperature sensor incorporated into the external device to "assure that the temperature of the feet 258 does not exceed a particular temperature during patient or clinician contact." Ex. 1010 at 9:16-21; *see also id.* at 16:23-26 (teaching a temperature sensor to ensure the side of the housing that contacts the patient "does not exceed the requirements for brief patient contact as defined in EN60601.") Taylor further teaches that the controller board "monitors transmitter temperature, which should be below 41° C." *Id.* at 14:31-33. As noted in the disclosures for [1.3] and [1.4] above, Barreras teaches circuity that "forms a temperature-controlled, current-regulated charging system which

	Claim Language	Barreras in view of Taylor
		restricts the temperature rise of the rechargeable power source 44 during recharging . . . ." Ex. 1009 at 8:56–9:5. It would have been obvious to utilize the circuitry of Barreras and the temperature sensor of Taylor to ensure that side of the housing in contact with the patient was limited to no higher than a respective predetermined temperature, such as 41° C. Ex. 1003, ¶ 181.
9.0	*See* claim 9.0 in Section IV.A.4	Barreras teaches that "during recharging of the power source 44, the micro controller 46 will monitor the voltage level of the power source 44 . . . . Upon sensing a fully charged state, the micro controller 46 will telemeter to transmitter 12, via the RF communications link 61, a 'stop' recharging command." Ex. 1009 at 9:7-16. Thus, Barreras teaches the external device (transmitter 12) with a circuit adapted to monitor the recharging of the rechargeable power source of the implantable medical device. However, the circuit identified in Barreras is predominantly on the implantable medical device and not the external device. Taylor teaches a controller board that "monitors transmitter temperature, which should be below 41° C" and also that "the current through the coils is monitored so that they are kept within operating limits." Ex. 1010 at 14:31-40. Taylor further teaches that the controller board is housed outside of the patient on external

	Claim Language	Barreras in view of Taylor
		programmer 110. *Id.* at 12:4-7. Thus, it would have been an obvious design choice to include the circuit to monitor recharging, as taught in Barreras, within the external device rather than the implantable medical device. Ex. 1003, ¶ 183.
11.0	*See* claim 11.0 in Section IV.A.4	Barreras does not explicitly teach a side housing. But, as discussed in [1.2] above, it would have been within the skill of a POSITA to modify the transmitter of Barreras to have a housing as taught in Taylor for placement against the patient. Taylor teaches that the housing 236 can be made from aluminum and that feet 158, 258 "for resting and balancing the housing … against the patient and over the implanted valve" are formed from stainless steel. *See* Ex. 1010 at 8:1-5, 9:3-7, 11:3-15. Stainless steel has very high thermal conductivity. Ex. 1003, ¶ 185. Thus, it would have been within the skill of a POSITA to modify the housing of the transmitter to have a portion of the side that is thermally conductive. *Id.*
12.0	*See* claim 12.0 in Section IV.A.4	As noted in the discussion for [1.1] above, Barreras teaches an external device (transmitter 12) with a primary coil (output inductor 64) that is coupled to the secondary coil (inductor 60) of the implantable medical device (receiver 14) to transfer energy to the implantable medical device (receiver 14) through the

	Claim Language	Barreras in view of Taylor
		patient's skin. *See* Ex. 1003, ¶¶ 173, 178. Barreras also teaches in "one aspect of the present invention, there is provided a method of supplying power, on an exclusive basis, from externally low energy RF coupled power (transmitter), to an implanted receiver during continual delivery of medical therapy." Ex. 1009 at 5:9-13.
12.1	*See* claim 12.1 in Section IV.A.4	Barreras teaches "the implanted receiver will only operate when the transmitter unit is proximate to the implanted receiver, and the transmitter will generate low level RF energy." Ex. 1009 at 5:67-6:3. As explained in the discussion of [1.2] above, it would have been obvious for a POSITA to modify the transmitter of Barreras to have a housing as taught in Taylor for placement against the patient. *See* Ex. 1003, ¶¶ 173, 175–176, 178. When Barreras is modified to include the housing of Taylor, a side of the housing of external transmitter 12 would be in proximity to the secondary coil (inductor 60) when the primary coil and secondary coil are coupled to transfer energy to the implantable medical device. *See id*.
12.2	*See* claim 12.2 in Section IV.A.4	See disclosures for [1.3] above.

	Claim Language	Barreras in view of Taylor
12.3	*See* claim 12.3 in Section IV.A.4	See disclosures for [1.4] above.
14.0	*See* claim 14.0 in Section IV.A.4	*See* disclosures for [4.0] above.
15.0	*See* claim 15.0 in Section IV.A.4	Barreras teaches both "regulating the RF energy generated by the external RF transmitter as a function of distance between the transmitting and receiving inductors" (Ex. 1009 at 5:51-55) as well as "regulating the rate of recharging…as a function of temperature." *Id.* at 5:42-50. It would have been obvious for a POSITA to further utilize the output of the external temperature sensor of the Barreras combination with Taylor when adjusting efficiency of the energy transfer as taught in Barreras. Ex. 1003, ¶ 186.
18.0	*See* claim 18.0 in Section IV.A.4	In view of Taylor's disclosure that the temperature of the portion of the external device's housing that contacts the patient during energy transfer should "not exceed the requirements for brief patient contact as defined in EN60601" (Ex. 1010 at 16:23-27) and that

	Claim Language	Barreras in view of Taylor
		the transmitter temperature "should be below 41° C" (*id*. at at 14:31-33), the exercise of routine skill would have made it obvious to use a method of charging that limited the temperature of the patient's skin to 39º C. Ex. 1003, ¶ 187.
19.0	*See* claim 19.0 in Section IV.A.4	Barreras does not explicitly teach limiting the temperature of the side of the implantable medical device to not more than 41°C. As noted in the disclosure for [4.0] above, Taylor teaches that "[d]uring the adjustment cycle, the controller board also monitors transmitter temperature, which should be below 41° C." Ex. 1010 at 14:31-33. It would have been obvious to a POSITA to also limit the temperature of the side of the implantable medical device that contacts the patient to ensure the temperature of that surface does not exceed 41° C. Ex. 1003, ¶ 188.
20.0	*See* claim 20.0 in Section IV.A.4	See disclosures for [1.0] above.
20.1	*See* claim 20.1 in Section IV.A.4	As discussed in the disclosure for [1.1] above, Barreras teaches an external transmitter, containing the primary coil, that must be positioned in proximity to the implanted receiver, containing the secondary coil, in order to generate RF energy when the primary coil is transcutaneously coupled to the secondary coil. *See*

	Claim Language	Barreras in view of Taylor
		Ex. 1003, ¶¶ 175, 179.
20.2	*See* claim 20.2 in Section IV.A.4	See disclosure for [1.2] above. The combination of Barreras and Taylor would be configured so that the housing included a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously coupled to the secondary coil. Ex. 1003, ¶¶ 173, 175–176, 179.
20.3	*See* claim 20.3 in Section IV.A.4	See disclosures for [1.3] above.
20.4	*See* claim 20.4 in Section IV.A.4	As explained in the disclosure for [1.4], Barreras teaches control circuity (micro controller 26) adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor adjacent to a rechargeable power source 44 to limit a temperature of the rechargeable power source 44 during the transfer of energy to the implantable medical device. Ex. 1009 at 8:56-9:5, 7:48-52. Further, as discussed in disclosure [1.3] above, the addition of a temperature sensor coupled to the side of the housing of the external device to which a patient is exposed would have been obvious in view of Taylor. *See* Ex. 1003, ¶¶ 176, 179. The control circuitry of Barreras disclosed "a temperature-controlled, current-regulated charging system which restricts the

	Claim Language	Barreras in view of Taylor
		temperature rise of the rechargeable power source 44 during recharging." Ex. 1009 at 8:67-9:5. It would have been within the skill of a POSITA to modify the control circuity of Barreras to also control the transfer of energy to the implantable medical device based on this additional temperature parameter of the combination. *See* Ex. 1003, ¶¶ 177, 179.

E. Ground 5: Claims 3, 6-8, 13, 16, 17, and 21-24 are unpatentable as obvious over Barreras in view of Taylor further in view of Wang

As described in Section IV.B. above, Wang teaches charging protocols for reducing temperature rises caused by charging of an implantable medical device via transcutaneous energy transfer and discloses the limitations of dependent claims 3, 6-8, 13, 16, 17, and 21-24.

A POSITA would have been motivated to combine Barreras, Taylor and Wang because all three references are directed to transcutaneous energy transfer systems in which control circuitry is utilized to limit the temperature rises that result from such energy transfers. Ex. 1003, ¶ 191.

As explained in Section IV.B above, Wang does not teach controlling a duty cycle or otherwise limiting energy transfer to the implantable medical device based on the output of a temperature sensor, but that is already taught by the combination of Barreras and Taylor. A POSITA would have understood from Wang how

controlling the duty cycle of the energy transfer could be used to limit the energy transfer (including limiting the time during which energy is transferred, switching energy transfer, and limiting the current driving the primary coil) if the output of the temperature sensor of Barreas and Taylor indicated that the side of the housing was too hot. Ex. 1003, ¶¶ 142–143, 193.

F. Ground 6: Claims 5 and 10 are unpatentable as obvious over Barreras in view of Taylor and Mann

As described in Section IV.C above, Claim 10 introduces a limitation further requiring the circuit of claim 9 adapted to monitor recharging is further "adapted to provide status of the recharging to a user" that is taught by Mann. A POSITA would have been motivated to combine Barreras and Taylor with Mann because both Barreras and Mann teach monitoring of the recharging of the battery of an implantable medical device. In view of Mann, it would be obvious to include circuitry that further monitors and provides a status of recharging to the user of the external device of Barreras. Ex. 1003, ¶¶ 192–194. Thus, the combination of Torgerson in view of UL 544 and Mann renders Claim 10 obvious.

Claim 5 introduces a limitation requiring an adjustable assembly for adjusting efficiency of energy transfer. Barreras teaches "regulating the RF energy generated by the external RF transmitter as a function of distance between the transmitting and receiving inductors." Ex. 1009 at 5:51-55. Barreras further

discloses a display 32 within the transmitter that can provide status information to the user regarding the recharging such as the recharging mode. *Id.* at 8:7-35; *see also id.* at Claim 12 ("said transmitting unit includes a visual display coupled to said first control means.").

As explained in Section IV.C above, Mann teaches circuitry that provides status of the recharging to a user that indicates whether the paired coils are in proper alignment for efficient energy transfer. Ex. 1008 at 10:24-45. In view of Barreras' teachings regarding the relationship of coil distance, temperature, and efficiency, and the Mann's teaching of a display that alerts the user regarding the status of the coil alignment, a POSITA would have been motivated to modify the transmitter of Barreras and Taylor to include an adjustable assembly that enabled the user to make fine adjustments to the coil alignment. Ex. 1003, ¶ 196. Thus, the combination of Barreras in view of Taylor and Mann renders Claim 5 obvious.

V. MANDATORY REQUIREMENTS

A. Grounds for Standing

Axonics certifies that the '324 Patent is available for IPR and Axonics is not barred or estopped from requesting an IPR of the challenged. This petition is timely filed within one year of the service of Medtronic's complaint alleging infringement of the '324 Patent. Ex. [1013].

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

1. Real Parties in Interest

Axonics is the real party in interest for this Petition.

2. Related Matters

The ’324 Patent is at issue in *Medtronic, Inc. v. Axonics Modulation Technologies., Inc.*, No. 8:19-cv-02115-DOC-JDE (C.D. Cal.).

The ’324 Patent is related to U.S. Patent No. 9,821,112, against which Axonics is filing separate petition for IPR concurrently with this Petition.

3. Fees

This Petition requests review of twenty-four (24) claims of the ’324 Patent and is accompanied by a payment of $36,100.00, which includes the $15,500.00 inter partes review request fee, and the $20,600 post-institution fee. See 37 C.F.R. § 42.15(a). Thus, this Petition meets the fee requirements under 35 U.S.C. § 312(a)(1). The Board is hereby authorized to charge any additional fees required by this action to Deposit Account No. 20-1430..

4. Power of Attorney

Powers of attorney are filed herewith in accordance with 37 C.F.R. § 42.10(b).

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

Axonics serves this Petition and exhibits to the correspondence address of record for the '324 Patent pursuant to 37 C.F. R. § 42.105(a) and the Certificate of Service. Axonics consents to service via lead and back-up counsel identified below at the mailing and e-mail addresses below.

Respectfully submitted,

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

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

CERTIFICATE OF WORD COUNT

The undersigned certifies pursuant to 37 C.F.R. § 42.24(d) that the foregoing Petition for *Inter partes* Review excluding any table of contents, table of authorities, certificates of service or word count, or appendix of exhibits or claim listing, contains 13,875 words according to the word-processing program used to prepare this paper (Microsoft Word). Petitioner certifies that this Petition for *Inter partes* Review does not exceed the applicable type-volume limit of 37 C.F.R. § 42.24(a).

Dated: March 13, 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. 9,463,324, including its supporting Exhibits (1001-1013) 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. 9,463,324:

Medtronic Inc. (Neuro)
710 Medtronic Parkway NE
MS: LC340 Legal Patents
Minneapolis, MN 55432

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

George C. Lombardi
glombard@winston.com
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601-9703

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

Nimalka Wickramasekera: nwickramasekera@winston.com
Samantha M. Lerner: slerner@winston.com
J.R. McNair: jmcnair@winston.com

[Additional counsel identified on next page]

Vivek V. Krishnan: vkrishnan@winston.com
Joe S. Netikosol: jnetikosol@winston.com

Respectfully,

Dated: March 16, 2020

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

73021981V.1