UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

IPR2020-00713
Patent No. 9,821,112

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 9,821,112

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I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics" or "Petitioner") respectfully petitions for *inter partes* review of claims 1-22 of U.S. Patent No. 9,463,112 ("'112 patent") in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 et seq. ("Petition").

The '112 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 6:4-11. The control circuit is configured to compare the measured temperature to a programmable limit stored within a memory of the external device, then control the temperature generated by the external device based on the comparison. *Id.* at 6:11-17.

The patent explains heat build-up in the tissue of a patient "beyond certain limits, as undesirable and should be limited as acceptable values" set by "current conditions and regulations." Ex. 1001 at 15:61-16:16.

None of this was new as of the ’112 patent’s claimed priority date. The controlled recharging of implantable medical devices using external devices was known as were the safety standards mandating that such devices not exceed defined temperature limits. Thus, the ’112 patent claims should be found unpatentable as obvious.

II. OVERVIEW OF THE ’112 PATENT

A. Background and Summary of the ’112 patent

The ’112 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 6:3-11.

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 2:15-17 (Background of the Invention). 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” and “single cell batteries usually do not supply the lasting power required to perform new therapies in newer implantable medical devices.” *Id*. at 1:57-66. Known transcutaneous recharging systems allowed a battery to be

recharged "from a power source temporarily positioned on the surface of the skin." *Id.* at 2:10-14.

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." *Id*. at 3:64-67.

The '112 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 4:36-50. Torgerson specifically taught that one "recharge parameter" to be monitored was "temperature." *See e.g.*, Ex. 1005, Claim 9.

The '112 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 5:53-54. Like the recharge regulation control unit of Torgerson, which regulates the energy delivered to the power source based on the measured parameter, the '112 patent teaches "[c]ontrol circuitry using the output from temperature sensor" to "limit the energy transfer process." *Id.* at 20:26-29.

Indeed, the '112 patent provides a block diagram (Fig. 3) of the system that shows only familiar components: implantable medical device 16 situated under cutaneous boundary 38 (the patient's skin) above which is external charging device 48, which includes external antenna 52. *See e.g.*, Ex. 1001 at 7:40-43; 9:22-24; 9:53-64.

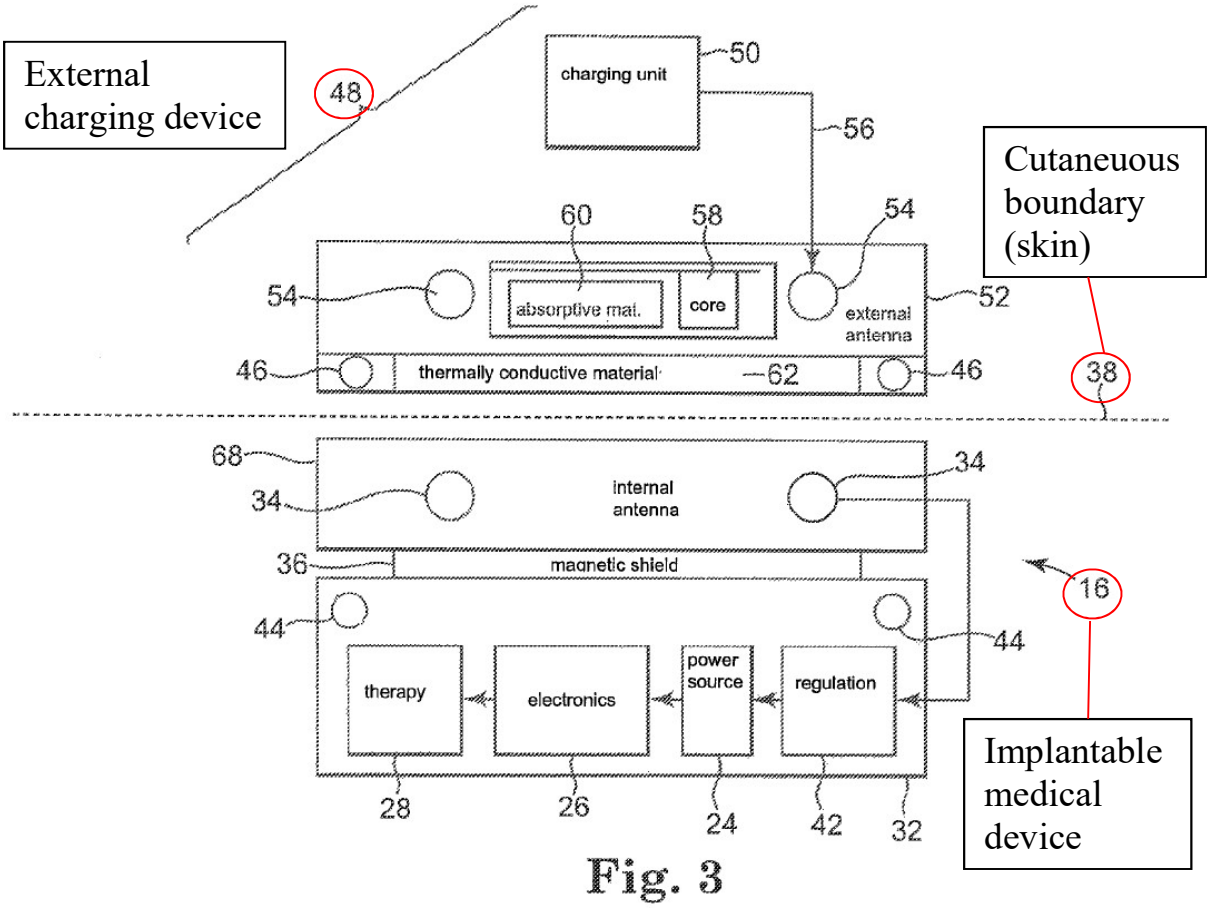


Fig. 3

B. Summary of Relevant Prosecution File History

The application that issued as the '112 patent was filed on September 12, 2016 with 10 claims that were canceled and replaced by claims 11-31 in a

preliminary amendment. In the Non-Final Office Action of February 10, 2017, the Examiner rejected the broadest claims as obvious over U.S. Patent No. 6,275,737 to Mann in view of U.S. Patent No. 5,991,665 ("Wang 665"), alleging Wang 665 taught use of a thermally conductive surface with a temperature sensor and a programmable limit for reducing heat generated from charging. Notably, dependent claims reciting a "memory storing a programmable limit" were only rejected by non-statutory double patenting over U.S. Patent Nos. 7,515,967, 7,225,032, 7,650,192, and 8,725,262. In a Response filed May 9, 2017, Applicant amended base claims to include "a memory configured to store the programmable limit" and filed terminal disclaimers over three of the cited patents as the rejection based on U.S. Patent No. 7,650,192 was withdrawn. All claims were then allowed on July 19, 2017. The relevant portion of the file history can be found at Exhibit 1002.

C. Person of Ordinary Skill in the Art

A 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 electrical or mechanical engineering and at least three years of experience in the industry working with rechargeable medical implantable devices; or a bachelor's of science with at least six years of experience designing, manufacturing, or overseeing rechargeable medical implantable 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, 8, 18, and 19 of the '112 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.

[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, including that the claims conform to the requirements of 35 U.S.C. § 112 and preserves all such arguments.

A. "programmable limit"

Claim 1 requires "a control circuit configured to compare the measured temperature to a programmable limit and to control the transfer of energy based on the comparison; and a memory configured to store the programmable limit." Independent claims 8, 18 and 19 recite "programmable limit" in substantially the same context. Axonics submits that the term "programmable limit" should be interpreted as a variable temperature limit stored on a memory that is able to be changed or modified by a user or software, excluding pre-determined, manufacturer presets.

The specification explains that a sensor may be used to measure a parameter that correlates to a temperature of the system during the transcutaneous coupling of energy and that this measured parameter may then be compared to a programmable limit. The programmable limit may be, for example, under software control so that the temperature occurring during transcutaneous coupling of energy may be modified to fit then-current circumstances. Ex. 1001, Abstract; *see also*, Ex. 1003, ¶ 59. Although the "programmable limit" is not explicitly defined, it is referred to within the context of a maximum allowable temperature:

> "Generally, it is preferable to limit the temperature of external antenna 52 to not more than forty-one degrees Centigrade 65 (41° C.) and to limit the temperature of implanted medical device 16 and the skin of

> patient 18 to thirty-nine degrees Centigrade (39° C.).... While the temperature limits discussed above are preferred under current conditions and regulations, it is recognized and understood that conditions and regulations may change or be different in different circumstances. Accordingly, the actual temperatures and temperature limits may change. In a preferred embodiment, such temperature limits are under software control in charging unit 50 so that any such temperatures or temperature limits can be modified to fit the then current circumstances."

Ex. 1001 at 15:64-16:16 (emphasis added).

Further, Applicant gave additional meaning to what the phrase "programmable limit" is *not* within the related prosecution history of earlier filed U.S. Patent No. 8,725,262. In an Office Action dated January 18, 2013, the Examiner alleged that a "programmable limit" was disclosed by a voltage limit (V_{ref}) that was used as a limit to control temperature in Wang 665, which was also cited in the present application. In a Response filed April 18, 2013, Applicant argued against this same rejection by stating:

> "[T]here is nothing in the cited passage, or in any other passage in [Wang 665], that even suggests that V_{ref} is programmable. At most, the passage describes the maximum value as 'preselected', but this in no way requires that the value be programmable."

Ex. 1014 at 8-9. Applicant further argued "it is quite possible that V_{ref} is a predetermined value set by the system (e.g., at manufacture) and once so set, is not programmable." *Id*. at 9.

Applicant reinforced this interpretation of "programmable limit" in the prosecution history of subsequently filed U.S. Patent No. 9,108,063. In an Office Action dated February 4, 2015, the Examiner alleged that use of a temperature sensor along with a stored programmable limit was disclosed in U.S. Patent No. 7,069,086 to Von Arx, which was also cited in the present application. In a Response filed April 3, 2015, Application argued:

> "The cited portions of Von Arx describe use of predetermined temperature ranges for controlling the radio frequency transmitter rather than a programmable limit... The cited portion of Von Arx states that '[p]rocessor 130C is adapted to execute programming...', and that 'programming instructions provide that for temperatures in a predetermined range, transmitter 180B transmits data at a first output power and for temperatures not in the predetermined range, transmitter 180B transmits data at a second output power'. Applicant does not necessarily acquiesce that this stands for the proposition that in Von Arx, there is a programmable limit."

Ex. 1015 at 14.

In view of the specification, the prosecution history of related cases defining "programmable limit" over the prior art, and the claim language, a POSITA would interpret "programmable limit" as a variable temperature limit stored on a memory

that is able to be changed or modified by a user or software, excluding pre-determined, manufacturer presets.

B. "Means For" Limitations – Claim 18

Claim 18 recites five "means for" limitations, each of which are indicated below along with the corresponding structure in accordance with 37 CFR § 42.104 and the presumption that each is a means-plus-function limitation governed by pre-AIA 35 U.S.C. § 112, sixth paragraph.

1. "means for transcutaneously transferring charging energy to the implantable medical device"

Corresponding structures for this feature are:

- "Transcutaneous energy transfer through the use of inductive coupling involves the placement of two coils positioned in close proximity to each other on opposite sides of the cutaneous boundary. The internal coil, or secondary coil, is part of or otherwise electrically associated with the implanted medical device. The external coil, or primary coil, is associated with the external power source or external charger, or recharger. The primary coil is driven with an alternating current. A current is induced in the secondary coil through inductive coupling. This current can then be used to power the implanted medical device or to charge, or recharge, an internal power source, or a combination of the two." Ex. 1001 at 5:1-13.

- The structures of the primary coil [54] of the external charging device [48], the secondary coil [34] of the implantable device [16] are referenced repeatedly throughout the specification (see Fig. 3 above). Specific examples of such coils are described in Ex. 1001 at 9:22-52.
- Claims 5 and 10 recite "a primary coil" of the external charging device.

Apart from the paired coils described above, there appears no alternative structures for transcutaneous transfer of energy.

Thus, this limitation is interpreted to mean a primary coil configured for transcutaneous energy transfer to the medical device by inductive coupling with the secondary coil.

2. "means for measuring a temperature indicative of heat resulting from the transcutaneous transfer of charging energy to the implantable medical device"

Corresponding structures for this feature are:

- "The external device comprises an alternating current (AC) coil configured for transcutaneously conveying the energy to the implantable medical device, a sensor configured for measuring a parameter correlated to a temperature generated by the external device during the transcutaneous conveyance of the energy to the implantable medical device, and a memory configured for storing a programmable limit." Ex. 1001 at 6:38-45.

- Claims 1 and 19 recite "a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device."

The structure of a "temperature sensor" is referenced throughout the application. Ex. 1001 at 20:6-67. The temperature sensor (87) is shown schematically in Figure 14 below in the external antenna (52).

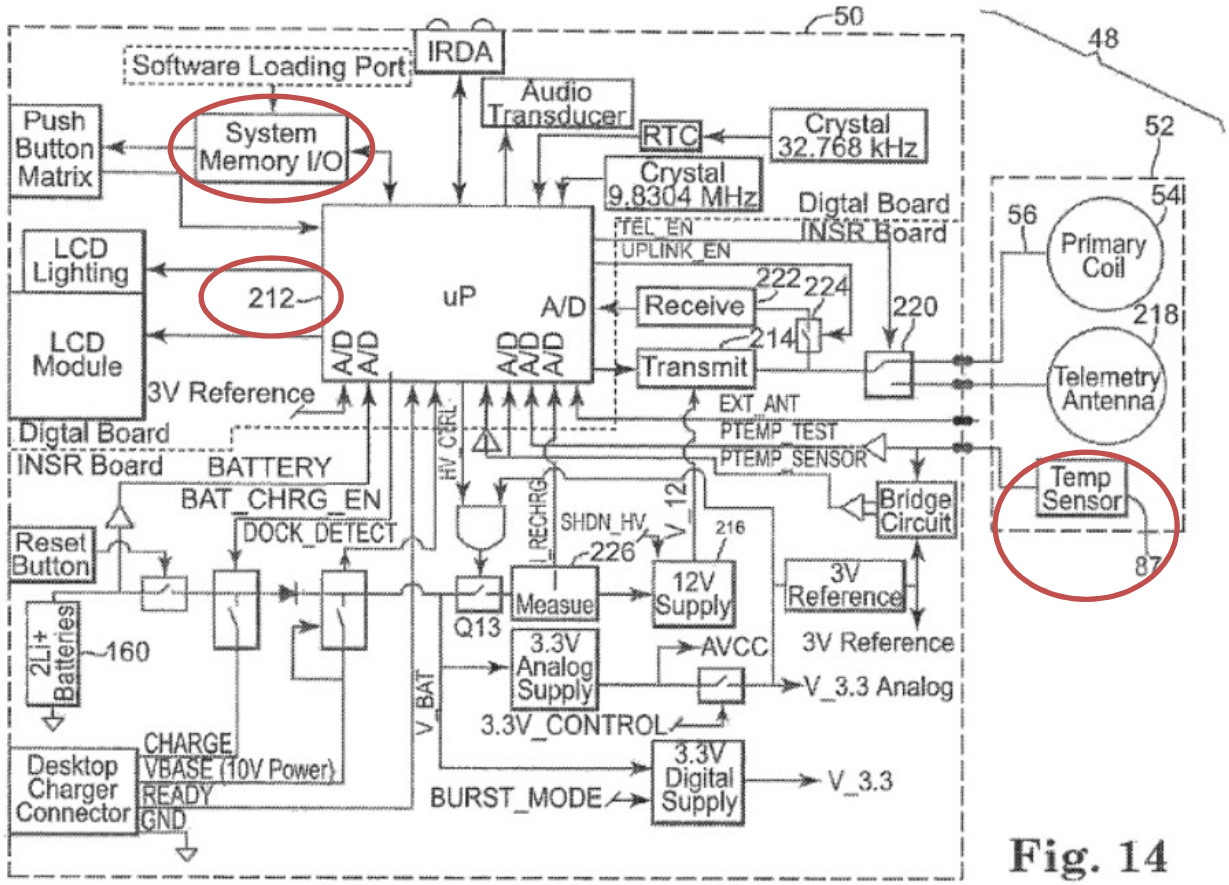


Fig. 14

Apart from the reference to "temperature sensor" noted above, there appears no alternative structure for measuring parameters correlated to temperature.

Thus, this limitation is interpreted to mean "a temperature sensor."

3. "means for comparing the measured temperature to a programmable limit"

Corresponding structures for this feature are:

- "…a control circuit configured to compare the measured temperature to a programmable limit." Ex. 1001 at 6:9-11.
- "A control circuit, which may be a processor." *Id*. at 6:12-16.
- "FIG. 14 is a block diagram of external charging device 48 controlled by microprocessor 212" (see element 212 in Figure 14 above). *Id*. at 13:66-67; *see also id*. at 20:6-11.
- Claims 1 and 19 recite "a control circuit configured to compare the measured temperature to a programmable limit ..."

Apart from the references to a "control circuit", there appears no alternative structures for comparing the measured parameter and maximum temperature limit.

Thus, this limitation is interpreted to mean "a control circuit."

4. "means for controlling the transfer of charging energy based on the comparison"

Corresponding structures for this feature are:

- "A control circuit, which may be a processor, is configured for controlling the temperature based on the measured parameter and the programmable limit." Ex. 1001 at 6:45-48.
- "Control circuitry using the output from temperature sensor 87 can then limit the energy transfer process in order to limit the temperature which external antenna 52 imparts to patient 18. As temperature sensor 87 approaches or reaches preset limits, control circuitry can take appropriate action such as limiting the amount of energy transferred, e.g., by limiting the current driving primary coil 54, or limiting the time during which energy is transferred, e.g., by curtailing energy transfer or by switching energy transfer on and off to provide an energy transfer duty cycle of less than one hundred percent." Ex. 1001 at 20:26-36.
- Specific examples of control circuitry are shown above in Figure 14 and described at Ex. 1001 at 13:66-14:7.
- Claims 1 and 19 recite "a control circuit configured … to control the transfer of energy based on the comparison."

Apart from the "control circuit" electronics noted above and referenced throughout the specification, there appears no alternative structure for controlling transfer of energy based on the comparison.

Thus, this limitation is interpreted to mean a "control circuit."

5. "storage means for storing the programmable limit"

Corresponding structures for this feature are:

- "Such a temperature limit may be stored within a memory of the external device, for instance. The control circuit, which may be a processor, may then control the temperature generated by the external device that is occurring during coupling of the energy. This control of the temperature may be based on the comparison." Ex. 1001 at 6:11-17.
- A "System Memory" is shown in the control circuit in Figure 14 above.
- Claims 1 and 19 recite "a memory configured to store the programmable limit."

Apart from the references to a "memory" integrated within control circuitry noted above, there appears no alternative structure for storing the programmable limit.

Thus, this limitation is interpreted to mean a "memory."

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 1-22 of the '112 patent are invalid in light of the teachings of the following references, alone or in combination with each other:

- PCT Publication No. WO 01/83029 ("Torgerson"), published on November 8, 2001, Ex. 1005.
- UL 544 (1998), Standard for Safety for Medical and Dental Equipment–Ed. 4.0, published on December 30, 1998, Ex. 1006.
- PCT Publication No. WO 00/69012 ("Barreras"), published on November 16, 2000, Ex. 1007.
- U.S. Patent No. 5,702,431 ("Wang"), issued on December 30, 1997, Ex. 1008.
- U.S. Patent No. 5,733,313 ("Barreras '313"), issued on March 31, 1998, Ex. 1010.
- U.S. Patent No. 6,685,638 ("Taylor"), filed on December 23, 2002, Ex. 1011.

Each of the listed references except Taylor were published more than one year before the '112 patent's claimed 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 claimed priority date of the '112 patent and is therefore prior art under pre-AIA section 102(e).

Each of Torgerson, Wang, Barreras, and Barreras '313 were listed on an Information Disclosure Statement—along with over 100 other references—signed by the Examiner on February 2, 2017. However, none were ever mentioned in any office action or response, and therefore were never raised substantively 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).

A POSITA would be motivated to combine these references in ways that would produce the claimed inventions of the '112 patent. The '112 patent is directed generally to a "mechanism for transferring energy from an external power source to an implantable medical device" wherein "[a] sensor may be used to measure a parameter that correlates to a temperature of the system that occurs during the transcutaneous coupling of energy." Ex. 1001, Abstract. Each listed reference similarly addresses transcutaneously transferring energy to implanted medical devices and/or regulating the temperature of rechargeable medical devices.

By the priority date, a POSITA would have been aware of applicable temperature requirements for charging devices and that programmable limits were known by those of skill in the medical field in light of the changing standards at that time.

Petitioner therefore respectfully requests that the Board cancel the challenged claims of the ’112 patent based on the following grounds:

- Ground 1: Claims 1-3, 7, 18, and 22 are unpatentable as obvious over Torgerson in view of UL 544 and Barreras.
- Ground 2: Claims 4-6 are unpatentable as obvious over Torgerson in view of UL 544 and Barreras and further in view of Wang.
- Ground 3: Claims 8, 12, 14-17, and 19-21 are unpatentable as obvious over Torgerson in view of Barreras.
- Ground 4: Claims 9-11, and 13 are unpatentable as obvious over Torgerson in view of Barreras further in view of Wang.
- Ground 5: Claims 1-3, 7, 18, and 22 are unpatentable as obvious over Barreras ’313 in view of Taylor and Barreras.
- Ground 6: Claims 4-6 are unpatentable as obvious over Barreras ’313 in view of Taylor and Barreras and further in view of Wang.
- Ground 7: Claims 8, 12, 14-17, and 19-21 are unpatentable as obvious over Barreras ’313 in view of Barreras.

- Ground 8: Claims 9-11, and 13 are unpatentable as obvious over Barreras ’313 in view of Barreras and further in view of Wang.

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

A. Ground 1: Claims 1-3, 7, 16-18, 22 are unpatentable as obvious over Torgerson in view of UL 544 and Barreras

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 exemplary device, Torgerson describes an implantable neurostimulator (INS). *Id.* at 1:21-22. Figure 1 shows INS medical device 14 (blue) along with other components of the system including an external physician programmer 30 (red), and an external patient programmer 35 (green). *Id.* at 5:1-11.

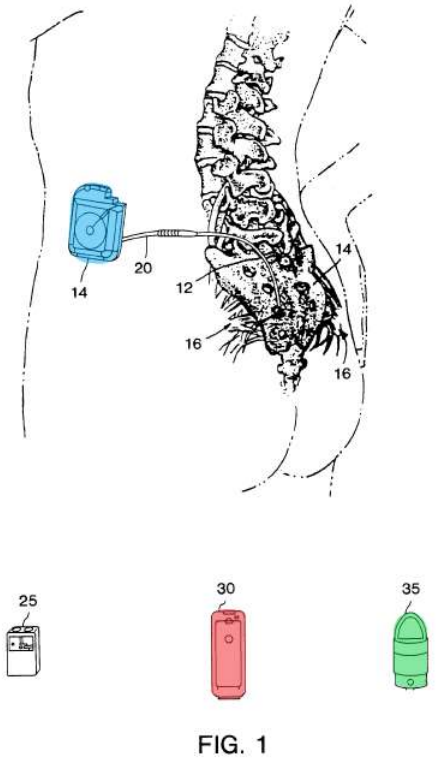


FIG. 1

"[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." Ex. 1005 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 11:17-18.

"[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." Ex. 1005 at 9:21-23. 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." *Id.* at 10:20-22. "Based upon the recharge measurement, the recharge regulation control unit 525 can increase or decrease the energy reaching the power source 315." *Id*. at 10:22-23.

Thus, Torgerson discloses transcutaneous coupling of implantable medical device (14) with a primary coil, and external charging device (30, 35) with a secondary coil, to transfer energy to the implantable medical device, and a temperature sensor (520) and control circuitry (525) adapted to control energy

transfer to the implantable medical device based on temperature output to limit temperature rise during recharge to prevent unsafe conditions for the patient.

Torgerson further discloses an external sensor in an alternative embodiment: "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." Ex. 1005 at 7:20-22. Torgerson does not, however, explicitly disclose a "temperature" sensor located in the external charging device or a "programmable" limit.

2. UL 544

UL 544 (1998), Standard 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 must meet mandated technical standards for safety and performance concerns. *See* Ex. 1003, ¶¶ 74, 109. As of the October 2, 2003 claimed priority date for the '112 patent, the temperature of an external surface of medical device parts contacted by the patient had to meet the UL 544 standard. *See* Ex. 1003, ¶¶ 108–111; Ex. 1006 § 36.2 at 62 ("[T]he temperature on a part that is necessary to be applied to the patient, but not intended to supply heat to patient, shall not exceed 41°C (106°F).").

UL 544 further required testing the temperature of the surface of an applied part with a thermocouple attached to the surface. Ex. 1006 at 71-75. 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." *Id*. § 45.1.9 at 74.

3. Barreras

PCT Publication No. WO 00/69012 ("Barreras") discloses a "method and circuitry for safely regulating the charge and discharge cycles of implantable grade, rechargeable power sources, utilizing inductively coupled radio frequency energy" for patient safety. Ex. 1007 at 1:4-6. As can be seen below in Figure 2, the system in Barreras includes an external charging device (green) connected to a radiofrequency transmitter coil or antenna coil 6 (orange) that transmits energy transcutaneously to the radiofrequency pickup coil 3 (purple) of implanted medical device 4 (blue). Ex. 1007 at 7:14-24; Abstract; 8:17-22; Figs. 1-2.

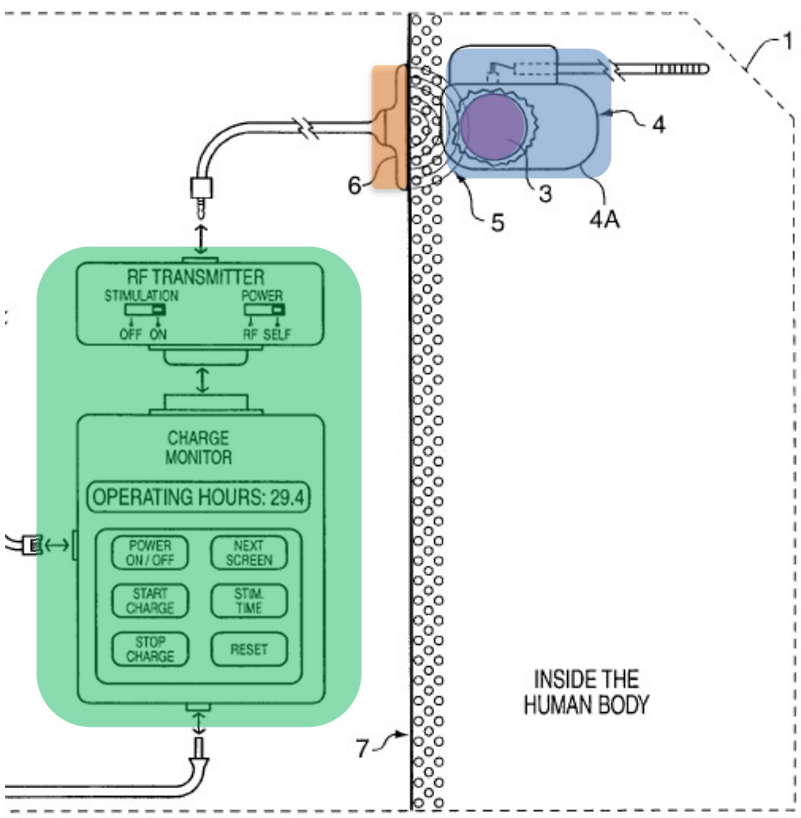
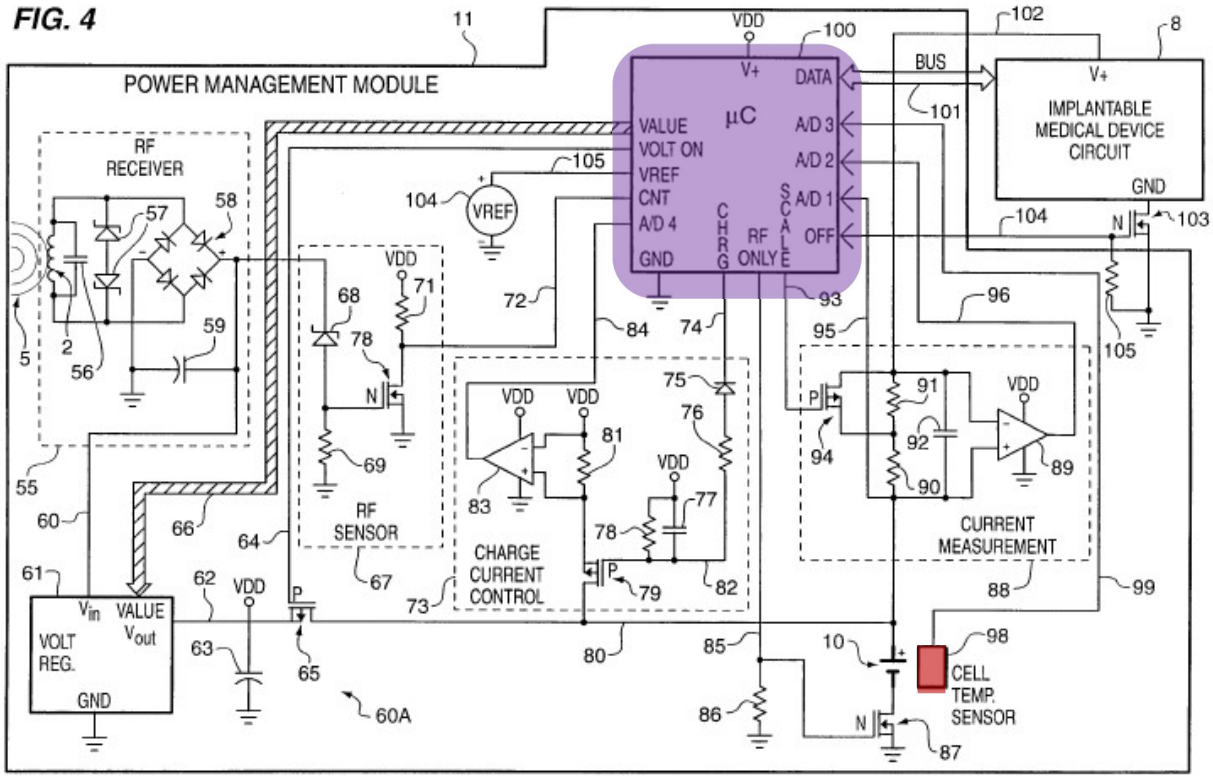


FIG. 2

Barreras teaches methods, software and hardware to "support the correct charge/discharge regimen for different types of power sources" and "the capability of non-invasively up-grading the regimen, by downloading…new software revisions incorporating new improvements." Ex. 1007 at 3:2-7 (emphasis added). Notably, Barreras teaches a circuit configuration with a safety feature that controls charging based on a temperature reading of a temperature sensor that is compared to a software loaded variable of a maximum temperature limit to avoid overheating and ensure safe charging. *Id*. at 13:1-8; Fig. 4; Ex. 1003, ¶ 114.

Shown below in Figure 4, the power management module is controlled by "Controller 100" (purple) based on a sensor output 99 from temperature sensor 98 (red). Ex. 1007 at 10:19-11:27; Ex. 1003, ¶ 115.

Barreras teaches that "[t]his Power Management Module 11 incorporates distinctive circuitry and methods for operating same to:…(g) sense the temperature of the power source,…(j) disconnect a charging circuit 60A from the power source 10 upon sensing a battery temperature exceeding a safe value during charging, (k) reconnect the charging circuit 60A to the power source upon the battery temperature dropping to a safe value during charging…" Ex. 1007 at 7:30-8:12; 5:14-19.



4. The Combination of Torgerson in view of UL 544 and Barreras

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. *See* Ex. 1003, ¶¶ 116–117. Because the housing of the external charging device of Torgerson is applied to the skin of the patient, under UL 544, the temperature of the surface applied to the patient could not exceed the predetermined temperature limit of 41°C during charging. 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 gain regulatory approval for commercial marketing to patients. *See* Ex. 1003, ¶¶ 116–117. Thus, it would have been obvious, for a POSITA to include a temperature sensor in the external charging device of Torgerson applied to the patient, as taught in UL 544, to monitor that temperature and include control circuitry that controls transfer of energy based on the monitored temperature so that the external charging device does not exceed the mandated 41°C to ensure compliance with the UL 544 standard. *Id.*

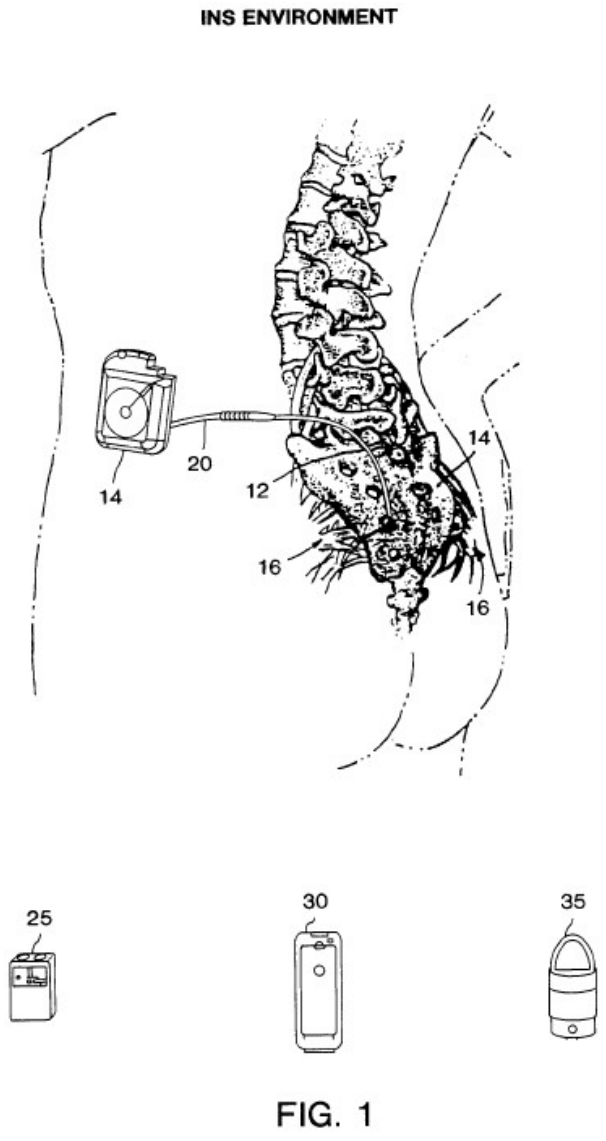
Torgerson disclosed the use of control circuitry to regulate energy transfer from the external charging devices (30, 35) to the implantable medical device (14) based on temperature measurements. *See* Ex. 1005 at 10:20-23. Torgerson itself

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 a temperature of the external surface of the charging device that contacts the patient as another temperature parameter to regulate energy transfer and controlling charging to remain below a maximum temperature limit stored on the control circuity 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.

In view of Barreras, it would further be obvious to utilize a variable temperature limit (i.e., a programmable limit) that is stored on a memory and accessed by the control circuit for regulating charging to ensure that the temperature during charging meets changing safety standards and regulations. A POSITA would have been motivated to combine the programmable limit of Barreras with Togerson and UL 544 because it was known that the precise safety limits could differ by jurisdiction and were subject to change over time. *See* Ex. 1003, ¶¶ 118–120 citing Ex. 1009. Thus, a POSITA would have strong motivation to utilize a software loaded variable as the temperature maximum, as taught in Barreras, since this allows the temperature maximum to be updated to support differing charge regimens or to incorporate new or updated safety standards without any significant manufacturing changes. *See* Ex. 1003, ¶¶ 118–120.

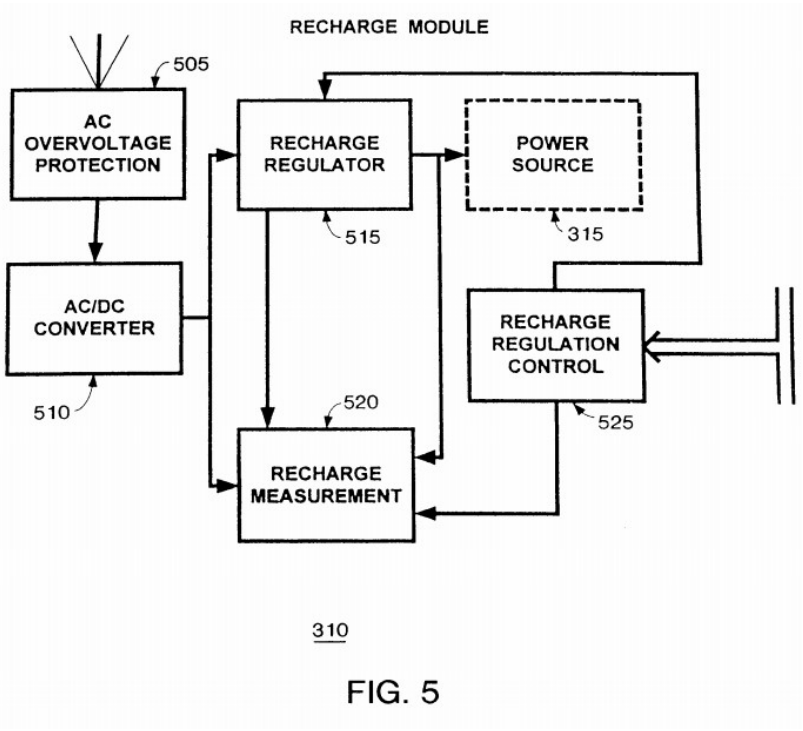
5. Applying Torgerson in view of UL 544 and Barreras to the Claims

The combination of Torgerson and UL 544 teaches every limitation of claims 1-3, 7, 16-18, and 22 of the ’112 patent, as further detailed in the following charts.

	Claim Language	Torgerson in view of UL 544 and Barreras
1.0	1. A medical system, comprising: an implantable medical device; an external charging device configured to transcutaneously transfer energy to the implantable medical device comprising;	 FIG. 1

	Claim Language	Torgerson in view of UL 544 and Barreras
		Torgerson teaches that recharging occurs when the telemetry head of an external patient programmer 35 or physician programmer 30 containing the recharge coil is placed near the INS 14. "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 an external device (30 or 35) with a primary coil that is coupled to the secondary coil of an implanted medical device (14) to transfer energy to the implantable medical device (14) transcutaneously. During coupling, the programmer would typically be placed on the patient so as to position near the secondary coil. *See* Ex. 1003, ¶ 122.
1.1	a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device;	Because the housing of the external device may contact the patient's skin during recharging, a POSITA would have known that the device must comply with the temperature requirements of UL 544 before the device could be safely used on a patient. *See* Ex. 1006 § 36.2 at 62; Ex. 1003, ¶ 123. A POSITA would have known that the device would have only passed the tests for UL 544 certification if the external charging device did not exceed a predetermined temperature limit of 41°C during

	Claim Language	Torgerson in view of UL 544 and Barreras
		charging. *See* Ex. 1006 § 36.2 at 62; Ex. 1003, ¶ 123. To determine the temperature of the device applied to the patient during charging, UL 544 teaches use of a thermocouple in the external device: "[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." *See* Ex. 1006 § 45.1.9 at 74. A POSITA would have known the external device was subject to UL 544 such that it would have been obvious to include a temperature sensor on the external device of Torgerson to measure a temperature of the device applied to the patient during charging to ensure compliance with mandatory safety requirements. *See* Ex. 1003, ¶ 123. This temperature would have been indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device. *Id.*
1.2	a control circuit configured to compare the	Torgerson teaches "a recharge measurement device monitoring at least one recharge parameter, and a recharge regulation control unit for regulating the

	Claim Language	Torgerson in view of UL 544 and Barreras
	measured temperature to a programmable limit and to control the transfer of energy based on the comparison; and	recharge energy delivered to the power source in response to the recharge measurement device." Ex. 1005 at 3:16-23; Claim 36. Figure 5 is a schematic block diagram of recharge module 310 in accordance with a preferred embodiment of Torgerson. Ex. 1005 at 9:17-26.  FIG. 5 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; 13:6-14 ("the INS 14 will communicate to the charging device to lower the supplied energy if

	Claim Language	Torgerson in view of UL 544 and Barreras
		components in the INS 14 are heating up above safe limits for the patient and/or device."); *see also* Ex. 1003, ¶ 125. 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 output of a temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device. See *id*. ¶¶ 124–125. Torgerson also discloses the use of an external sensor to provide closed-loop feedback control to the INS 14. *See* Ex. 1005 at 7:19-22. However, Torgerson does not explicitly teach a temperature sensor located in the external device. As noted in [1.1], the addition of such a temperature sensor would have been obvious in view of UL 544. Torgerson further teaches its control circuitry 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

	Claim Language	Torgerson in view of UL 544 and Barreras
		control circuitry of Torgerson to control energy transfer based on this external temperature parameter of the combination. *See* Ex. 1003, ¶¶ 124–125. 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. *See* Ex. 1003, ¶ 125. Moreover, it would have been obvious to a POSITA to include the control circuitry in the external device in order to reduce the size of the INS. Ex. 1003, ¶ 125. Further, it would be obvious to incorporate the temperature maximum as a software loaded variable (i.e., programmable limit) that can be changed or updated, in view of Barreras. As noted in Section IV.A.3, Barreras teaches a system for transcutaneously charging implanted medical devices that controls charging based on a temperature maximum that is a software loaded variable by which charging is controlled. Ex. 1007 at 13:1-8; Fig. 4. Specifically, Barreras describes that "there is shown

	Claim Language	Torgerson in view of UL 544 and Barreras
		Temperature Sensor 98 whose output line 99 is connected to an A/D Converter channel A/D3. When the temperature of power source 10 is nearing an **unsafe value which is a software loaded variable,** microcontroller 100 will 'float' line 104, switching off transistor 103. This effectively disconnects power source 10 from the circuitry 8 Implantable Medical Device 4. Note that the power source 10 will continue to power the microcontroller 100…in order for the microcontroller 100 to sense when the temperature drops to a safe level by monitoring line 99." Ex. 1007 at 12:34-13:8 (emphasis added). Thus, Barreras describes a control circuit that controls charging based on a comparison of a monitored temperature to a variable temperature maximum (i.e., programmable limit) that is loaded by software of the micro controller to ensure safe charging. *See* Ex. 1003, ¶¶ 124–125. Barreras describes this within the context of a method, including software and hardware to support the correct "charge/discharge regimen for different types of power sources" and "the capability of non-invasively up-grading the regimen, by downloading, via direct telemetry link or telephone link, new

	Claim Language	Torgerson in view of UL 544 and Barreras
		software revisions incorporating new improvements." Ex. 1007 at 3:2-7 (emphasis added). As described above, it would have been obvious for a POSITA to utilize a software loaded variable as the temperature maximum, as taught in Barreras, since this allows the temperature maximum to be updated to support differing charge regimens or to incorporate new or updated safety standards or regulations without a change in hardware. *See* Ex. 1003, ¶ 124.
1.3	a memory configured to store the programmable limit.	As explained in the disclosures for [1.2] above, Barreras teaches "a software loaded variable" that acts as a programmable limit. Ex. 1007 at 12:34-13:8. It is inherent that "a software loaded variable"—having been loaded by a microcontroller controlling charging—would be stored on a memory accessed by the control circuit. *See* Ex. 1003, ¶ 126 (explaining that a POSITA would know that a "loaded" variable is one that has been stored in memory).
2.0	2. The system of claim 1, wherein the external charging device comprises an	*See* [1.1] disclosures above. When attaching a temperature sensor to measure the surface temperature of the external charging device, it would be obvious to secure the sensor to the external

	Claim Language	Torgerson in view of UL 544 and Barreras
	external antenna and wherein the sensor is carried by the external antenna.	component (i.e., the antenna), particularly since this approach is explicitly described in the temperature testing requirements of UL 544. Ex. 1003, ¶ 129.
3.0	3. The system of claim 2, wherein the sensor is thermally-coupled to a surface of the external antenna to measure a temperature to which a patient is being exposed.	In order for the temperature sensor to provide an output indicative of the surface that is applied to the patient, 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.…[I]f a metal surface is involved, brazing or soldering the thermocouple to the metal may be necessary." Ex. 1006 § 45.1.9 at 74; *see also* Ex. 1003, ¶130. Thus, in view of this explicit instruction in UL 544 of thermally-coupling the temperature sensor on the external device to the outer surface of the charging device, it would have been obvious to a POSITA to follow this instruction in order to comply with testing requirements and ensure compliance with UL 544. *See* Ex. 1003, ¶130.
7.0	7. The system of claim 1, wherein	Given the closed-loop control of charging based on temperature measurements described in Torgerson,

	Claim Language	Torgerson in view of UL 544 and Barreras
	the control circuit is configured to alternate between initiating the transcutaneous transfer of energy to the implantable medical device and terminating the transcutaneous transfer of energy to the implantable medical device.	per [1.2], it would be obvious that such closed-loop control would alternate between initiating charging and terminating charging when the monitored temperature exceeds the maximum allowable temperature mandated by UL 544. Barreras more explicitly describes this aspect of its control circuit as: "[t]his Power Management Module 11 incorporates distinctive circuitry and methods for operating same to:…(g) sense the temperature of the power source,…(j) disconnect a charging circuit 60A from the power source 10 upon sensing a battery temperature exceeding a safe value during charging, (k) reconnect the charging circuit 60A to the power source upon the battery temperature dropping to a safe value during charging…" Ex. 1007 at 7:30-8:12. Since Barreras teaches initiating and terminating charging based on temperature, a POSITA would have been strongly motivated to apply the same control scheme to the charging device in Torgerson when implementing the programmable limit of Barreras to provide the same benefits of preventing overheating for safe charging and to ensure compliance with UL 544. Ex. 1003, ¶ 132.

	Claim Language	Torgerson in view of UL 544 and Barreras
16.0	16. The method of claim 8, wherein sensing, via a sensor, a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device comprises sensing, via a sensor, a temperature of the external charging device during the transcutaneous transfer of energy to the implantable medical device.	Regarding claim 8, see disclosures [8.0]-[8.4] in Section IV.C (below). See [1.1] disclosures above.
17.0	17. The method of claim 8, wherein sensing, via a sensor, a temperature	Regarding claim 8, see disclosures [8.0]-[8.4] in Section IV.C (below). *See* [1.1] and [3.0] disclosures above.

	Claim Language	Torgerson in view of UL 544 and Barreras
	indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device comprises sensing, via a sensor, a temperature of a surface of the external device during the transcutaneous transfer of charging energy to the implantable medical device.	It would be obvious to configure the temperature sensor to sense a temperature of a surface of the external device in order to meet the applicable safety standards of UL 544 noted above since this surface is applied to the patient during charging. Ex. 1003, ¶¶ 130–131.
18.0	18. A medical system, comprising: an implantable medical device;	See [1.0] disclosures above.
18.1	means for transcutaneously	See [1.0] disclosures above.

	Claim Language	Torgerson in view of UL 544 and Barreras
	transferring charging energy to the implantable medical device;	
18.2	means for measuring a temperature indicative of heat resulting from the transcutaneous transfer of charging energy to the implantable medical device;	See [1.1] disclosures above.
18.3	means for comparing the measured temperature to a programmable limit;	See [1.2] disclosures above.
18.4	means for controlling the transfer of charging energy based on the	See [1.2] disclosures above.

	Claim Language	Torgerson in view of UL 544 and Barreras
	comparison; and	
18.5	storage means for storing the programmable limit.	See [1.3] disclosures above.
22.0	22. The medical system of claim 1 wherein the programmable limit is under software control.	Barreras teaches that "[w]hen the temperature of power source 10 is nearing an **unsafe value which is a software loaded variable**, microcontroller 100 will 'float' line 104, switching off transistor 103. This effectively disconnects power source 10 from the circuitry 8 Implantable Medical Device 4." Ex. 1007 at 12:34-13:5 (emphasis added) Thus, Barreras teaches a variable temperature maximum that is "software loaded" (i.e., under software control) such that it would be obvious to utilize this software loaded variable in the control scheme in Torgerson to allow the maximum temperature to be updated with software revisions of improvements or updated safety standards. Ex. 1003, ¶ 133.

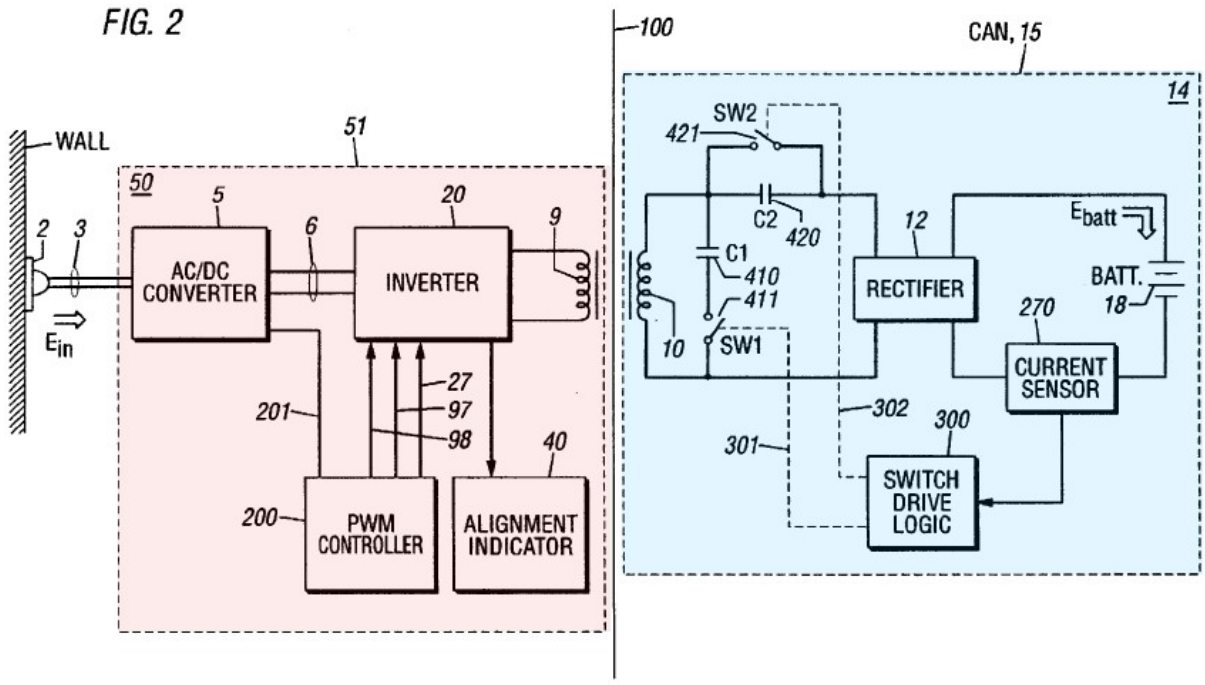
Thus, the combination of Torgerson in view of UL 544 and Barreras renders Claims 1-3, 7, 16-18, and 22 as obvious.

B. Ground 2: Claims 4-6 are unpatentable as obvious over Torgerson in view of UL 544 and Barreras and further in view of Wang

Claim 4-6 introduce limitations relating to the manner in which charging is controlled.

As the '112 patent explains, much of charging control functionality is commonplace and well known, noting that: "[e]lectronics 26 help provide control of the charging rate of rechargeable power source 24 in a conventional manner." Ex. 1001 at 9:10-12.

The routine nature of controlling charging rate by the claimed priority date of the '112 patent is confirmed by the prior art. U.S. Patent No. 5,702,431 ("Wang"), for example, describes various approaches of controlling transcutaneous charging of an implanted device 14 in order to limit a temperature rise and avoid excess heat caused by eddy currents or temperature rise of the battery during charging as that was "detrimental to operation of the medical device and harmful to surrounding body tissue." Ex. 1008 at 3:51-62. Wang also notes: "[i]ndustry standards suggest maximum allowable temperature rises." *Id*. (emphasis added).



Wang teaches charging protocols for reducing "the peak temperature rise" caused by charging of the implantable medical device 14. Ex. 1008 at 7:58-8:24; Figs. 4B-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." *Id.* at 8:34-47. As shown in 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*.

A POSITA would have been motivated to combine Torgerson and Barrera with Wang because all three references relate to safe charging of an implanted medical device. In light of this common goal, a POSITA would be motivated to

utilize Wang's temperature control scheme in the charging device of Torgerson in order to ensure safe charging and compliance with industry standards as well as applicable safety standards. Ex. 1003, ¶ 153.

Thus, the combination of Torgerson, UL 544, Barrera and Wang renders Claim 4-6 as obvious, as detailed further below.

1. Claim 4: Adjusting a Rate at Which Energy is Transferred

Claim 4 requires "the control circuit is configured to adjust a rate at which energy is transferred to the implantable medical device." Ex. 1001 at 22:15-17.

Wang teaches a first charging protocol that "includes a primary current control circuit that provides control signals to an inverter. Based upon the status of the control signals, the invention produces charging current at either a high or low level to provide efficient charging without an excessive temperature rise in the implanted device." Ex. 1008 at 4:45-53; Fig. 4B.

Wang also teaches that "[i]n a second charging protocol, the transcutaneous energy transmission device produces a relatively high charging current to the battery, but is periodically interrupted by periods without any charging current. The resulting duty cycle of the charging current is adjustable to allow for different levels of average charging current to the battery. 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." Ex. 1008 at 4:66-5:7; Fig. 4C.

In either of the above charging protocols, charging is controlled such that the rate at which energy is transferred to the implantable device is adjusted to limit the temperature rise of the implanted device during charging. *See* Ex. 1003, ¶ 154.

Because Torgerson and Wang both relate to temperature-based charging regulation for safe charging, a POSITA would be motivated to incorporate the control schemes in Wang that regulate charging to limit temperature rise to the device in Torgerson in order to provide safe charging and ensure compliance with industry standards and safety standard UL 544.

Thus, the combination of Torgerson in view of UL 544, Barreras and Wang renders claim 4 as obvious.

2. Claim 5: Limiting a Current Driving Primary Coil

Claim 5 requires that "the control circuit is configured to limit the current driving the primary coil."

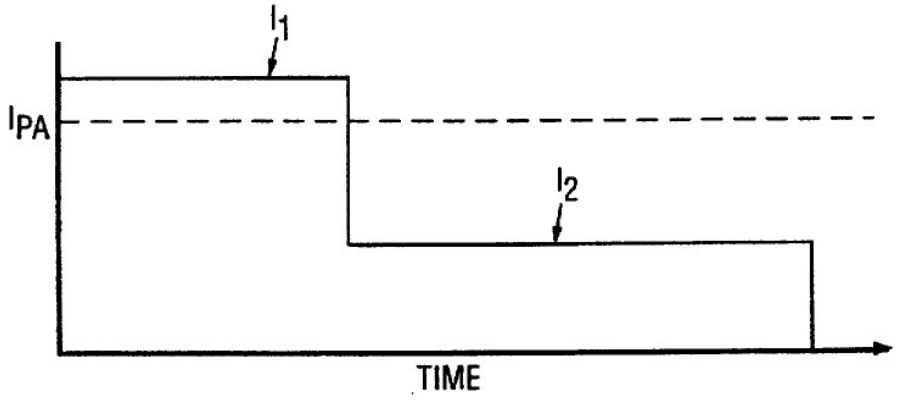
As noted in Section IV.B.1, Wang describes a current-based charging protocol: "the recharging system of the present invention preferably initially delivers to the battery a charging current 14 (which is higher than $I\rho_A$) for a first predetermined period of time, followed by a lower current I_2, which is lower than $I\rho_A$ for the remainder of the charge cycle as shown in FIG. 4B… However, the peak temperature rise of the implantable device can 15 is less using the protocol of

FIG. 4B, referred to in this description as the 'current step' protocol." Ex. 1008 at 7:58-8:8.

Wang describes its approach in the context of a system in which the current in the secondary coil of the implanted medical device corresponds to the electrical current driving the primary coil. Ex. 1008 at 7:1-7.

In contrast to prior art systems that utilized constant current for charging (Fig. 4A), Wang teaches controlling or limiting the current driving the primary coil between two current levels in order to reduce peak temperature rise, shown in Figure 4B. Ex. 1008 at 7:46-8:8.

FIG. 4B



Since each of Torgerson, Barreras, and Wang relate to temperature-based charging control for safe charging, a POSITA would be motivated to incorporate the current-based charging regulation of Wang to the device in Torgerson in order

to limit temperature rise to provide safe charging and ensure compliance with industry standards and safety standard UL 544. Ex. 1003, ¶ 155.

Thus, the combination of Torgerson in view of UL 544, Barreras and Wang renders claim 5 as obvious.

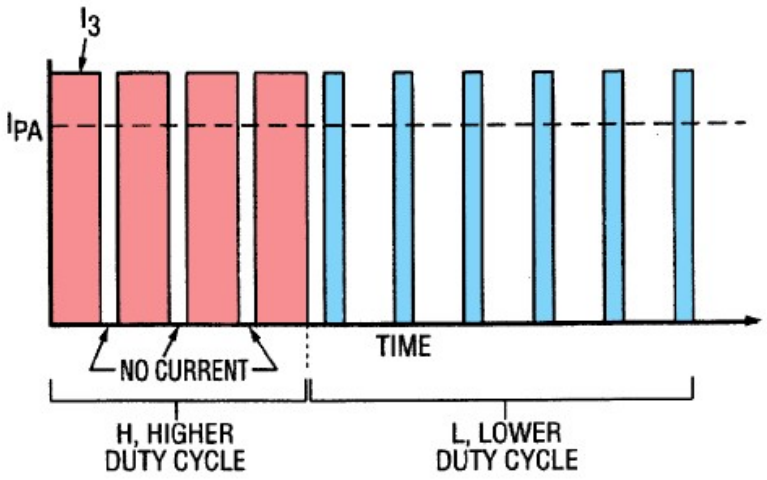
3. Claim 6: Limiting a Time During Which Energy Is Transferred Based on a Temperature Measurement

Claim 6 requires "the control circuit is configured to limit the time during which energy is transferred to the implantable medical device."

As noted in Section IV.B.1, Wang describes a time-based charging protocol that changes a duty cycle: "[i]n a second charging protocol, the transcutaneous energy transmission device produces a relatively high charging current to the battery, but is periodically interrupted by periods without any charging current. The resulting duty cycle of the charging current is adjustable to allow for different levels of average charging current to the battery. 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." Ex. 1008 at 4:66-5:7.

A duty cycle is well understood in the field as operation in a time-based cycle, intermittently rather than continuously. *See* Ex. 1003, ¶¶ 156–157. As shown in Figure 4C, lowering the duty cycle of energy transfer effectively limits the time that energy is delivered to the coil.

FIG. 4C



Thus, a POSITA would be motivated to incorporate the time-based charging regulation of varying duty cycles of Wang to the device in Torgerson in order to limit temperature rise to provide safe charging and ensure compliance with industry standards and safety standard UL 544.

Thus, the combination of Torgerson in view of UL 544, Barreras and Wang renders claim 6 as obvious.

C. Ground 3: Claim 8, 12, 14, 15 and 19-21 are unpatentable as obvious over Torgerson in view of Barreras

As described in Section IV.A.1, Torgerson teaches transcutaneous coupling of implantable medical device (14) with a primary coil, and external charging device (30, 35) with a secondary coil, to transfer energy to the implantable medical device, as well as a temperature sensor (520) and control circuitry (525) adapted to control energy transfer to the implantable medical device based on temperature

output in order to limit temperature rise during recharge to prevent unsafe conditions for the patient. Ex. 1005 at 5:1-11; 10:19-23.

As described in Section IV.A.3, Barreras also teaches a system for recharging implanted medical devices, which includes a circuit configuration with a safety feature that controls charging based on a temperature reading of a temperature sensor. Ex. 1007 at 7:14-24. The control circuitry compares the monitored temperature to a maximum temperature limit to avoid overheating and ensure safe charging. *Id*. at 5:14-19; Fig. 4. The temperature maximum is a software loaded variable, which allows for software revisions incorporating new improvements. *Id*. at 3:2-7.

Barreras teaches methods, software and hardware to "support the correct charge/discharge regimen, for different types of power sources" and "the capability of non-invasively up-grading the regimen by downloading, via a direct telemetry link or telephone link, new software revisions incorporating new improvements." *Id*. at 3:2-7.

As Torgerson already teaches regulating charging based on temperature monitoring from a temperature sensor for safe charging, a POSITA would have been motivated to utilize a software loaded variable stored on a memory of the control circuit as the temperature maximum in order to support the correct charge

regimens and/or to allow software revisions with new improvements in limiting temperature rise and safe charging as taught in Barreras. Ex. 1003, ¶ 160.

The combination of Torgerson and Barreras teaches every limitation of claims 8, 12, 15 and 19-21[2] of the '112 patent, as further detailed in the following charts.

	Claim Language	Torgerson in view of Barreras
8.0	8. A method, comprising: transferring, via an external charging device, energy transcutaneously to an implantable medical device;	*See* disclosures of [1.0] in Section IV.A.
8.1	sensing, via a sensor, a temperature indicative of heat	Torgerson discloses transcutaneous coupling of implantable medical device (14) with a primary coil, and external charging device (30, 35) with a secondary coil, to transfer energy to the implantable

[2] These claims do not require several of the claim limitations to be included on the external device, but rather they merely need to be within the method or system generally.

	Claim Language	Torgerson in view of Barreras
	resulting from the transcutaneous transfer of energy to the implantable medical device;	medical device, as well as a temperature sensor (520) and control circuitry (525) adapted to control energy transfer to the implantable medical device based on temperature output in order to limit temperature rise during recharge to prevent unsafe conditions for the patient. Ex. 1005 at 9:21-23; 10:19-23; Claim 36. Thus, Torgerson teaches a recharge management system that includes a temperature sensor for monitoring the temperature of the medical device. Barreras also teaches a charging control circuit (Power Management Module Controller 100) that controls charging based on an output from a temperature sensor 98. Ex. 1007 at 10:19-11:27; Fig. 4.
8.2	obtaining a programmable limit from a memory;	As described in [1.2] and [1.3] in Section IV.A, Barreras teaches a temperature maximum that is a software loaded variable by which charging is controlled to prevent overheating during charging. Ex. 1007 at 13:1-8; Fig. 4. The software loaded variable allows the control circuitry to be revised to support differing charge regimens or software revisions with new improvements. *Id*. at 3:2-7. As described above, it would have been obvious to a

	Claim Language	Torgerson in view of Barreras
		POSITA to utilize a temperature maximum as a software loaded variable that is loaded from a memory by the charging circuitry as taught in Barreras with the system of Torgerson so that the charge circuitry could readily obtain the required temperature maximum at all times during charging as well as revise or update the temperature maximum to support differing charge regimens or new improvements. Ex. 1003, ¶ 165.
8.3	comparing, via a control circuit, the temperature to the programmable limit; and	As described in [1.2] in Section IV.A, the measured temperature is compared to the maximum temperature variable within the temperature-controlled charging scheme. Thus, utilizing the variable maximum temperature of Barreras in the recharge regulation control would necessarily include comparing the monitored temperature with the temperature maximum in order to control charging based on temperature and prevent charging when the temperature exceeds the maximum temperature, as described in Barreras. Ex. 1003, ¶ 164.
8.4	controlling the transfer of energy based on the comparison.	As described in [1.2] in Section IV.A, Torgerson teaches a recharge management system having a control unit for "regulating the recharge energy delivered to the power source in response to … the

	Claim Language	Torgerson in view of Barreras
		temperature sensor." Ex. 1005, Claim 36. Thus, incorporating the temperature maximum variable of Barreras within the temperature regulation of Torgerson necessitates control of energy transfer based on the comparison of monitored temperature and the programmable limit.
12.0	12. The method of claim 8, wherein controlling the transfer of energy based on the comparison comprises alternating between terminating the transcutaneous transfer of energy to the implantable medical device and initiating the transcutaneous transfer of energy to the implantable	See [7.0] disclosures in Section IV.A.

	Claim Language	Torgerson in view of Barreras
	medical device.	
14.0	14. The method of claim 8, further comprising modifying the programmable limit to fit then-current circumstances associated with the transcutaneous transfer of energy to the implantable medical device.	As described in Section IV.A.3, Barreras teaches use of a variable temperature maximum in the context of supporting differing charge regimens and allowing downloads of new software revisions and improvements. The '112 patent states that temperature limits may change in response to: "conditions and regulations [that] may change or be different in different circumstances." Ex. 1001 at 16:8-12. Thus, a change in "circumstances" refers to either conditions or regulations. A POSITA would have been aware that standards and regulations vary by jurisdiction and over time, and it would have been obvious that one reason for modifying the programmable limit of Barreras would be to tailor it to the then-prevalent (both jurisdiction and temporally) safety standards. Ex. 1003, ¶ 167.
15.0	15. The method of claim 8, wherein the implantable medical device comprises a rechargeable power source, and	See [1.0] disclosures in Section IV.A.
15.1	further comprising	See [1.0] disclosures in Section IV.A.

	Claim Language	Torgerson in view of Barreras
	transcutaneously transferring energy from the external charging device to charge the rechargeable power source.	
19.0	19. A medical system, comprising: an external device configured to transcutaneously transferring charging energy to an implantable medical device;	See [1.0] disclosures in Section IV.A.
19.1	a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous	See [8.1] disclosures in Section IV.C.

	Claim Language	Torgerson in view of Barreras
	transfer of charging energy to the implantable medical device;	
19.2	a control circuit configured to compare the measured temperature to a programmable limit and to control the transfer of charging energy based on the comparison;	See [8.3] and [8.4] disclosures in Section IV. C.
19.3	and a memory configured to store the programmable limit.	See [8.2] disclosures in Section IV. C.
20.0	20. The medical system of claim 19, wherein the control circuit is configured to alternate between	See [7.0] disclosures in Section IV.A.

	Claim Language	Torgerson in view of Barreras
	initiating the transcutaneous transfer of charging energy to the implantable medical device and terminating the transcutaneous transfer of charging energy to the implantable medical device.	
21.0	21. The medical system of claim 19, wherein the programmable limit is under software control.	See disclosures in [22.0] of Section IV.A.

Thus, the combination of Torgerson and Barreras renders claims 8, 12, 14, 15, and 19-21 obvious.

D. Ground 4: Claims 9-11 and 13 are unpatentable as obvious over Torgerson in view of Barreras and further in view of Wang

Claims 9-11 and 13 introduce limitations relating to controlling charging based on temperature. Claim 9 introduces limitations relating to adjusting a rate of energy transfer. Claim 10 introduces limitations relating to limiting the current driving the primary coil. Claims 11 and 13 introduce limitations relating to limiting the time during which energy is transferred.[3]

These limitations are disclosed in Wang as described in Sections IV.B. A POSITA would have been motivated to combine Torgerson and Barreras with Wang because all three references related to transcutaneous charging of implanted medical devices.

In light of their common goal of limiting heating during charging, a POSITA would be motivated to utilize Wang's approach of reducing peak temperature by adjusting a rate of energy transfer (claim 9) as discussed in Section IV.B.1, or by limiting the current driving the primary coil (claim 10) as discussed in Section IV.B.2, or by limiting the time during which energy is transferred (claims 11 and 13) as discussed in Section IV.B.3, in order to ensure compliance with industry standards of temperature rise, as described in Wang.

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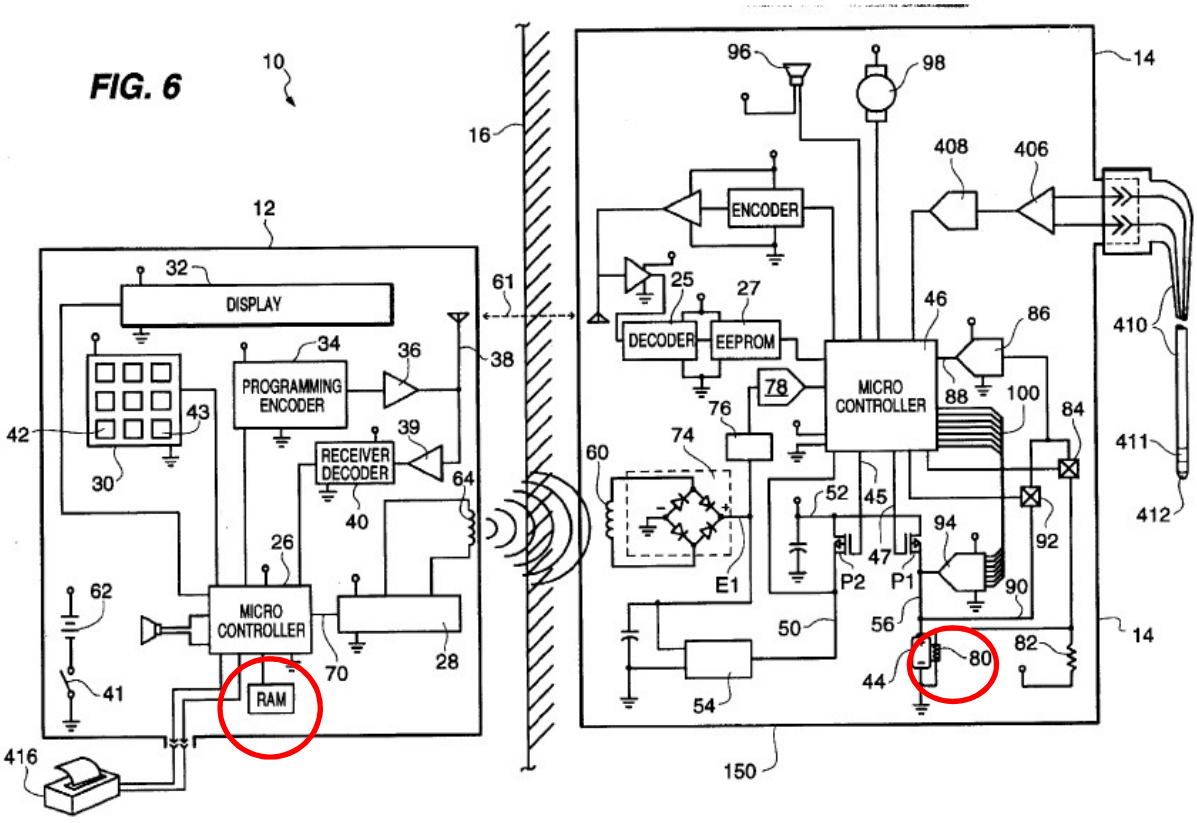
[3] Claims 11 and 13 appear almost identical apart from repeating recitations from claim 8 from which each depends; thus, these claims appear substantially identical in claim scope, likely a claim drafting error.

Thus, the combination of Torgerson in view of Barreras and Wang renders claims 9-11 and 13 obvious.

E. Ground 5: Claims 1-3, 7, 16-18 and 22 are unpatentable as obvious over Barreras '313 in view of Taylor further in view of Barreras

1. Barreras '313

U.S. Patent No. 5,733,313 to Barreras ("Barreras '313") teaches an external charging device held in close proximity to the patient for transcutaneous charging of a medical device implanted beneath the patient's skin. Ex. 1010 at 8:33-9:5. As shown below in Figure 6, Barreras '313 teaches an implantable, rechargeable tissue stimulation system 10, which includes an external transmitter 12 (charging device) and an implanted receiver 14 (medical device), the latter being surgically implanted beneath a patient's skin 16. *Id*. at 12:6-9 and 7:33-38. The external transmitter 12 transfers energy transcutaneously from the output inductor 64 to the receiving inductor 60 of the implanted device 14. *See id.* at 8:39-43; Ex. 1003, ¶ 180.



Barreras '313 further teaches "a method for regulating the rate of recharging the back-up power source contained within the implanted receiver as a function of temperature of the back-up power source..." Ex. 1010 at 5:42-50. "The temperature is measured by a thermistor 80 which is adhered to the rechargeable power source 44 during manufacturing." *Id.* at 8:58-60. The external transmitter 12 includes a micro controller 26, which is coupled to random-access memory (RAM), that is used to regulate the RF energy coupled into the receiver 14. *Id.* at 7:48-59. "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.

2. Taylor

Taylor teaches controlled transcutaneous energy delivery based on a temperature measurement from a temperature sensor located on the external transmitter device to ensure compliance with applicable safety standards (e.g., EN60601[4]) for medical devices applied to the patient. Specifically, Taylor teaches a system that includes transmitters 120, 130 and/or 230 that transcutaneously transfer energy to the implanted device. *See* Ex. 1011 at 6:48-7:10 (discussing transmitters 120 and 130), 8:24-9:21 (discussing transmitter 230); *see also* Ex. 1003, ¶ 186. As shown below in Figures 2B and 4A, each of transmitters 130, 230 is surrounded by housing 136, 236, which sits on top of base 138, 238. Ex. 1011 at 9:3-7, 7:60-8:5, 11:3-15. Extending from the housing base 138, 238 are feet 158,

[4] A POSITA would understand Taylor's references to "EN60601" refers to BS EN 60601-1:1990, the British Standard (BS) for Medical electrical equipment—Part 1: General requirements for safety. Ex. 1003, ¶ 191. This is the Great Britain version of the International Electrotechnical Commission (IEC) 60601 standard. IEC standards are published international technical standards for safety and essential performance of medical electrical equipment. Ex. 1003, ¶ 191.

258 (formed from stainless steel) "for resting and balancing the housing … against the patient and over the implanted valve." *Id.* at 8:1-5, 9:3-7, 11:3-15.

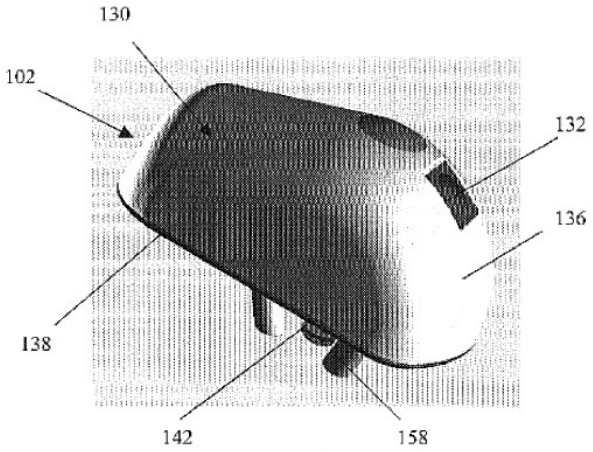


FIG. 2B

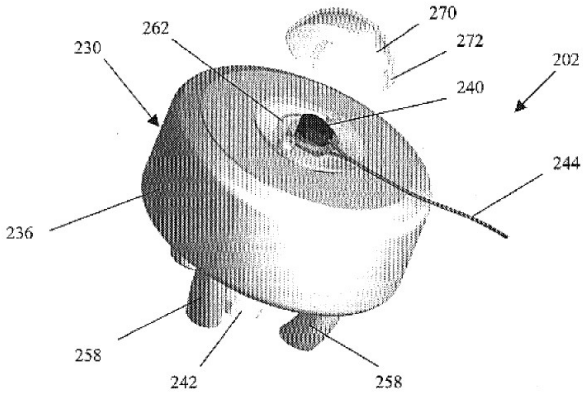


FIG. 4A

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 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. 1011 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 16:23-26; *see also* Ex. 1012, § 42.3 at 74–76 (setting 41°C temperature limit); *see also id.* § 2.1.5 at 18 (defining APPLIED PARTS).

setting ("[T]he temperature on a part that is necessary to be applied to the patient…shall not exceed 41°C (106°F).").. To this end, Taylor further teaches

control circuitry that "monitors transmitter temperature, which should be below 41° C." and controls energy transfer based on the monitored temperature. Ex. 1011 at 14:31-33.

3. Barreras

As described in Section IV.A.3, Barreras '313 teaches an external charging device to be applied to the patient for transcutaneous charging of an implanted medical device and further teaches regulating charging based on temperature monitoring to reduce temperature rise during recharging for safety purposes. Ex. 1010, 5:42-50; 8:33-9:5. Barreras further teaches a circuit configuration with a safety feature that controls charging based on monitoring a temperature of a sensor that is compared to a maximum temperature variable, which is loaded by software of the charging circuitry, in order to avoid overheating and ensure safe charging. Ex. 1007, Abstract; p. 8, li. 17-22; p. 13, li. 8; Figs. 1-2.

4. The Combination of Barreras '313 in view of Taylor and Barreras

Barreras '313 and Taylor pertain to transcutaneous energy delivery to an implanted device by an external device applied to the patient and controlling energy delivery based on temperature for safety. Thus, a POSITA would have been motivated to incorporate the temperature sensor of Taylor into the system of Barreras '313 to provide more efficient charging while ensuring the heat from charging of the implanted medical device when the external device is applied to the

patient complies with applicable safety standards, including EN60601, as taught in Taylor.

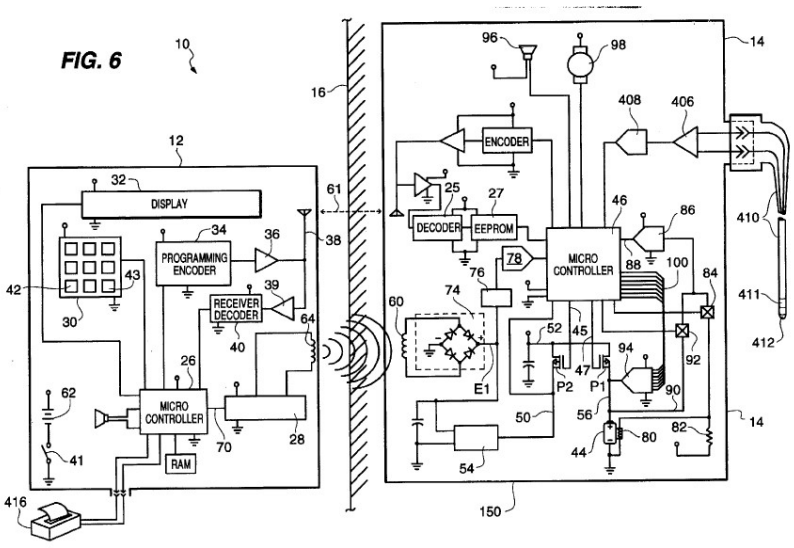
By the priority date of the ’112 patent, it was effectively mandatory for the external charging transmitter of Barreras ’313 to meet application safety requirements—as explained in Taylor. Ex. 1011 at 16:23-26; 15:43-45 (describing EN60601 as a safety standard with which the EU medical industry “must comply”); *see also* Ex. 1003, ¶¶ 191–192, 195–196. Because the external charging device of Barreras ’313 may contact the patient, then, under EN60601, the Barreras ‘313 external transmitter device—like the external transmitter of Taylor—must remain below 41 ºC during charging. Ex. 1003, ¶¶ 195–196. If the external charging device exceeded these temperature limits, it would not be in compliance with applicable safety requirements and would not gain regulatory approval for commercial marketing to patients. Ex. 1003, ¶¶ 191–192, 195–196. Thus, it would have been obvious, for a POSITA to include a temperature sensor in the external charging device in Barreras ’313, as taught in Taylor, to monitor the temperature and include control circuitry that controls transfer of energy based on the monitored temperature so that the external charging device does not exceed the mandated 41 °C to ensure compliance with the applicable safety standard. Ex. 1003, ¶¶ 195–196.

Further, in view of Barreras, it would be obvious to utilize a variable temperature limit (e.g., a programmable limit) that is stored on a memory and accessed by the control circuit for regulating charging to ensure that the temperature rises during charging meet safety regulations. A POSITA would have been motivated to combine the programmable limit of Barreras with Barreras '313 and Taylor because it was known that the precise safety limits could differ by jurisdiction and environment conditions, and are also subject to change over time. Ex. 1003, ¶¶ 197–198 citing Ex. 1009. Thus, a POSITA would have strong motivation to utilize a software loaded variable as the temperature maximum, as taught in Barreras, since this allows the temperature maximum to be updated to support differing charge regimens or to incorporate new or updated safety standards without any significant manufacturing changes. Ex. 1003, ¶¶ 197–198.

5. Applying Barreras '313 in view of Taylor and Barreras to the Claims

The combination of Barreras '313, Taylor and Barreras teaches every limitation of claims 1-3, 7, 16-18 and 22 of the '112 patent, as further detailed in the following charts.

	Claim Language	Barreras '313 in view of Taylor and Barreras
1.0	*See* claim 1.0 in Section IV.A	Barreras '313 teaches an implantable, rechargeable stimulator system 10 that includes an external transmitter device 12 and an implanted receiver 14

	Claim Language	Barreras ’313 in view of Taylor and Barreras
		implanted beneath the patient’s skin 16, as shown below in Figure 6. Ex. 1010 at 12:6-9. The external transmitter 12 transfers energy transcutaneously from the output inductor 64 to the receiving inductor 60 of the implanted device 14. *Id*. at 8:39-60. 
1.1	*See* claim 1.1 in Section IV.A	Barreras ’313 teaches a thermistor 80 in the implanted device such that “[t]he temperature is measured by a thermistor 80 which is adhered to the rechargeable power source 44 during manufacturing.” Ex. 1010 at 8:58-60. Further as shown in Figure 6 above, Barreras ’313 teaches a control circuit that regulates charging based on a temperature reading of a temperature sensor (80) to restrict temperature rise. *See id.* at 8:56-9:5.

	Claim Language	Barreras ’313 in view of Taylor and Barreras
		Barreras ‘313 does not, however, explicitly disclose a temperature sensor located in the external transmitter. Taylor teaches a system that includes an external transmitter having legs that are applied to the patient during transcutaneous energy delivery to an implanted device. Ex. 1011 at 9:16-21. Notably, Taylor teaches that “[a] thermistor such as a PT100 can be incorporated in the transmitter to assure that the temperature of the legs 158 does not exceed the requirements for brief patient contact as defined in EN60601.” *Id.* at 16:23-27. As discussed, it would have been obvious to incorporate the temperature sensor of Taylor into the external transmitter of Barreras ’313 to ensure compliance with EN60601. In light of Taylors’s disclosure of (1) applicable safety standards, (2) temperature sensor in external transmitter, and (3) concern to limit overheating of skin by the transmitter feet for patient comfort and safe charging, a POSITA would have strong motivation as a medical device manufacturer to modify Barreras ‘313 based on Taylor to include a temperature sensor in the transmitter to determine the temperature of the surface applied to the

	Claim Language	Barreras ’313 in view of Taylor and Barreras
		patient during recharging met applicable safety standards. Ex. 1003, ¶ 201.
1.2	*See* claim 1.2 in Section IV.A	Barreras ‘313 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. 1010 at 7:48-52. There is also a micro controller 46 within the implanted receiver as shown in Figure 6 above. “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. 1010 at 8:43-49. Barreras ‘313 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

	Claim Language	Barreras ’313 in view of Taylor and Barreras
		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; *see also id.* at 5:57-63 and Claim 4. Thus, Barreras ‘313 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, ¶ 202. Barreras ‘313 does not, however, explicitly disclose a programmable limit. As described in Section IV.A.3, Barreras describes a system for transcutaneously recharging an implanted device that includes a temperature sensor for temperature monitoring during charging. Barreras further teaches a control circuit having a microcontroller that compares the monitored temperature to a maximum temperature variable loaded by software: “[w]hen the temperature of power source 10 is nearing an **unsafe value which is a software**

	Claim Language	Barreras '313 in view of Taylor and Barreras
		loaded variable, microcontroller 100 will 'float' line 104, switching off transistor 103. This effectively disconnects power source 10 from the circuitry 8 Implantable Medical Device 4." Ex. 1007 at 13:1-5 (emphasis added). This feature is taught within the context of a method, software and hardware to support the "the capability of non-invasively up-grading the regimen, by downloading …new software revisions incorporating new improvements." *Id.* at 3:2-7 (emphasis added). As explained in [1.1] above, it would have been obvious for a POSITA to modify the control circuity of Barreras '313 to control the transfer of energy based on the temperature of the external transmitter based on Taylor. Further, because each of Barreras '313, Taylor and Barreras pertain to thermal management of transcutaneous energy transmitting system, a POSITA would also have strong motivation to use the variable temperature maximum described in Barreras to allow software revisions incorporating new improvements and ensure applicable safety standards are met. Ex. 1003, ¶ 202.
1.3	*See* claim 1.3 in	Barreras teaches a programmable limit that is a

	Claim Language	Barreras ’313 in view of Taylor and Barreras
	Section IV.A	“software loaded variable.” Ex. 1007 at 13:1-5. It is inherent that “a software loaded variable” that is loaded by a microcontroller controlling charging would utilize a memory on which the variable is stored. *See* Ex. 1003, Ex. 1003, ¶ 203 (explaining that a software “loaded” variable would necessarily be stored in memory). As shown in Figure 6 of Barreras ’313, external transmitter 12 includes microcontroller, which is connected to random-access memory (RAM), that regulates charging based on temperature. Thus, it would be obvious for the variable maximum temperature that informs charging regulation by the microcontroller to be stored on the RAM of Barreras ’313.
2.0	*See* claim 2.0 in Section IV.A	As shown in Figure 6, Barreras ’313 describes an external transmitter 12 that includes an antenna 38. Ex. 1010 at 7:58. Upon incorporating a temperature sensor in the external transmitter per Taylor, as discussed above, it would be obvious for a POSITA to secure the sensor to the “antenna 38” since the antenna is near the portion of the external transmitter that contacts the patient’s skin, to ensure compliance with the applicable safety

	Claim Language	Barreras ’313 in view of Taylor and Barreras
		standard for devices applied to the patient. Ex. 1003, ¶ 206.
3.0	*See* claim 3.0 in Section IV.A	It would have been obvious to include the temperature sensor as described in Taylor on the external transmitter of Barreras ’313. *See* disclosures for [1.1] above. Taylor teaches incorporating a thermistor in the transmitter to monitor the temperature of the legs (Ex. 1011 at 16:23-26), and further teaches that the housing and feet that are applied to the patient can be made from stainless steel. *Id.* at 7:62-8:1. A thermistor coupled to stainless steel legs applied to the patient would necessarily measure the temperature to which the patient is exposed. Ex. 1003 ¶ 207.
7.0	*See* claim 7.0 in Section IV.A	Given the temperature based regulation described in Barreras ’313, such charge control circuitry would necessarily be capable of initiating energy transfer and terminating transfer of energy when temperature monitoring exceeds the maximum temperature requirements. Barreras explicitly describes this aspect. *See* disclosures of [7.0] in Section IV.A. Thus, a POSITA would have been motivated to apply the same temperature based control scheme described

	Claim Language	Barreras ’313 in view of Taylor and Barreras
		in Barreras ‘313 in order provide more efficient and safe charging while ensuring the applicable safety standard is met.
16.0	*See* claim 1.0 in Section IV.A	Regarding claim 8, see disclosures [8.0]-[8.3] in Section IV.G. See [1.1] disclosures above.
17.0	*See* claim 17.0 in Section IV.A	Regarding claim 8, see disclosures [8.0]-[8.3] in Section IV.G. See [1.1] and [3.0] disclosures above. It would be obvious to configure the temperature sensor to measure temperature of a <u>surface</u> of the external device, since the surface contacts patient during charging, in order to meet applicable safety standard EN60601. Ex. 1003, ¶¶ 207–208.
18.0	*See* claim 18.0 in Section IV.A	See [1.0] disclosures above.
18.1	*See* claim 18.1 in Section IV.A	See [1.0] disclosures above.
18.2	*See* claim 18.2 in Section IV.A	See [1.1] disclosures above.
18.3	*See* claim 18.3	See [1.2] disclosures above.

	Claim Language	Barreras ’313 in view of Taylor and Barreras
	in Section IV.A	
18.4	*See* claim 18.4 in Section IV.A	See [1.2] disclosures above.
18.5	*See* claim 18.5 in Section IV.A	See [1.3] disclosures above.
22.0	*See* claim 22.0 in Section IV.A	See [22.0] in Section IV.A for Barreras disclosures.

Thus, the combination of Barreras ’313 in view of Taylor and Barreras renders each of claims 1-3, 7, 16-18 and 22 obvious.

F. Ground 6: Claims 4-6 are unpatentable as obvious over Barreras ’313 in view of Taylor and Barreras and further in view of Wang

Claims 4-6 introduce limitations relating to controlling charging based on temperature. Claim 4 pertains to adjusting a rate at which energy is transferred. Claim 5 pertains to limiting a current driving the primary coil. Claim 6 pertains to limiting the time during which energy is transferred.

As described in Section IV.B, the routine nature of controlling charging rate by the claimed priority date of the ’112 patent is confirmed by the prior art. Wang describes various approaches of controlling transcutaneous charging of an implanted device in order to limit a temperature rise and avoid excess heat caused by eddy currents or temperature rise of the battery during charging. Ex. 1008 at

3:51-62. Wang also notes: "Industry standards suggest maximum allowable temperature rises." *Id*.

These limitations in claims 4, 5 and 6 are disclosed in Wang as discussed in Sections IV.B.1, IV.B.2 and IV.B.3, respectively. A POSITA would have been motivated to combine Barreras, Taylor, and Barreras '313 with Wang because all three references related to transcutaneous energy transfer to an implanted medical device.

In light of their common goal of avoiding overheating during charging, a POSITA would be motivated to utilize Wang's control scheme of reducing peak temperature by adjusting a rate of energy transfer (claim 4) as discussed in Section IV.B.1, or by limiting current driving the primary coil (claim 5) as discussed in Section IV.B.2, or by limiting the time during which energy is transferred (claim 6) as discussed in Section IV.C.3. Such modification would reduce peak temperature in order to ensure compliance with industry standards of temperature rise, as taught in Wang, and applicable safety standards, such as EN60601, as taught in Taylor.

Thus, the combination of Barreras '313 in view of Taylor and Barreras and Wang renders claims 4-6 obvious.

G. Ground 7: Claims 8, 12, 14, 15 and 19-21 are unpatentable as obvious over Barreras '313 in view of Barreras

As described in Section IV.E.1, Barreras '313 teaches an external charging device held in close proximity to the patient for transcutaneous charging of a medical device implanted beneath the patient's skin. Ex. 1010 at 5:42-50; 8:33-9:5. Barreras '313 further teaches regulating charging based on temperature monitoring to reduce temperature rise during recharging. *Id*.

As described in Section IV.A.3, Barreras teaches an external charging device to be applied to the patient for transcutaneous charging of an implanted medical device and further teaches regulating charging based on temperature monitoring to reduce temperature rise during recharging for safety purposes. Ex. 1007 [needs cite]. Barreras further teaches a circuit configuration with a safety feature that controls charging based on monitoring a temperature of a sensor that is compared to a maximum temperature variable, which is loaded by software of the charging circuitry, in order to avoid overheating and ensure safe charging. Ex. 1007 at Abstract; 8:17-22; 13:1-8; Figs. 1-2.

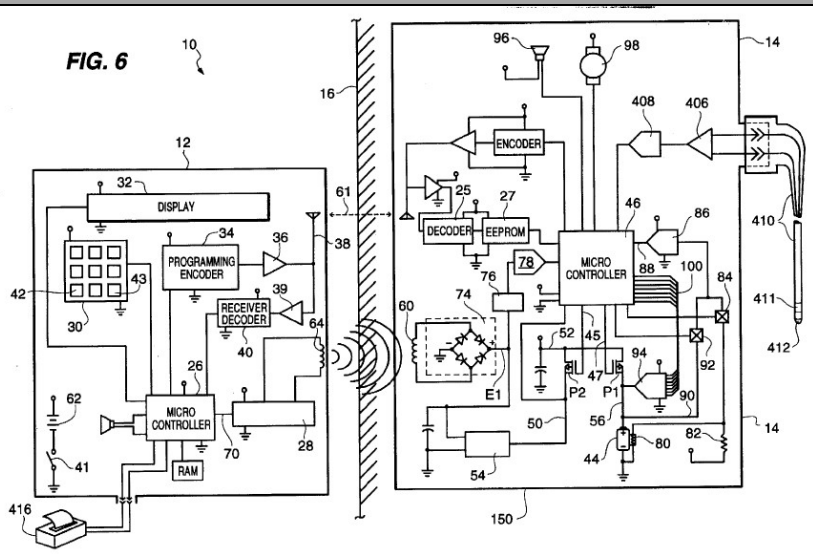
It would have obvious to combine Barreras '313 with Barreras because both references relate to safe charging of an implanted medical device by temperature based charging control.

A POSITA would be motivated to utilize the maximum temperature limit variable in Barreras within the temperature based control circuitry in Barreras '313

to ensure the temperature of the external charging devices meets applicable safety standards while allowing software revisions incorporating new improvements or changing standards. Ex. 1003, ¶ 210; Ex. 1007 at 3:2-7.

The combination of Barreras and Barreras '313 teaches every limitation of claims 8, 12, 15 and 19-21[2] of the '112 patent, as further detailed in the following charts.

	Claim Language	Barreras '313 in view of Barreras
8.0	*See* claim 8.0 in Section IV.C	Barreras '313 teaches an implantable, rechargeable stimulator system 10 that includes an external transmitter device 12 and an implanted receiver 14 implanted beneath the patient's skin 16, as shown below in Figure 6. Ex. 1010 at 12:6-9. The external transmitter 12 transfers energy transcutaneously from the output inductor 64 to the receiving inductor 60 of the implanted device 14. *Id*. at 8:39-60.

	Claim Language	Barreras ’313 in view of Barreras
		
8.1	*See* claim 8.1 in Section IV.C	Barreras ’313 teaches a thermistor 80 in the implanted device (see above in Fig. 6) such that “[t]he temperature is measured by a thermistor 80 which is adhered to the rechargeable power source 44 during manufacturing.” Ex. 1010 at 8:58-60. Further as shown in Figure 6 above, Barreras ’313 teaches a control circuit that regulates charging based on a temperature reading of a temperature sensor (80) to restrict temperature rise. *See id.* at 8:56-9:5.
8.2	*See* claim 8.2 in Section IV.C	As described in [1.2] and [1.3] in Section IV.E.3, Barreras describes a system for transcutaneously recharging an implanted device that includes a temperature sensor for temperature monitoring during charging, and further describes a method, software and hardware to support the “the capability of non-invasively up-grading the regimen, by downloading …new

	Claim Language	Barreras ’313 in view of Barreras
		software revisions incorporating new improvements.” Ex. 1007 at 3:2-7 (emphasis added). Along these lines, Barreras teaches a control circuit having a microcontroller that compares the monitored temperature to a maximum temperature, which is a “software loaded variable.” Ex. 1007 at 13:1-5. Specifically, Barreras teaches that “[w]hen the temperature of power source 10 is nearing an **unsafe value which is a software loaded variable**, microcontroller 100 will ‘float’ line 104, switching off transistor 103. This effectively disconnects power source 10 from the circuitry 8 Implantable Medical Device 4.” *Id*. (emphasis added). Because each of Barreras ’313 and Barreras pertain to thermal management of transcutaneous energy transmitting system, a POSITA would have been motivated to use the programmable temperature limit described in Barreras to ensure applicable safety standards are met and allow revisions incorporating new improvements and ensure applicable safety standards are met. Ex. 1003, ¶¶ 219–220, 223–224.
8.3	*See* claim 8.3 in Section IV.C	As disclosed in [8.2] above and described in [1.2] in Section IV.E, Barreras compares the monitored temperature output with the maximum temperature

	Claim Language	Barreras ’313 in view of Barreras
		variable loaded by software. Thus, utilizing the variable temperature maximum of Barreras in the controlled charging scheme of Barreras ‘313 would necessarily include comparing the monitored temperature with the maximum temperature variable in order to control charging based on temperature and prevent charging when the temperature exceeds the maximum temperature, as described in Barreras. Ex. 1003, ¶¶ 223–224.
8.4	*See* claim 8.4 in Section IV.C	As described in [1.2] in Section IV.E, Barreras ’313 teaches regulating transfer of energy based on temperature monitoring. “[T]here is provided a method for <u>regulating the rate of recharging the back-up power source contained within the implanted receiver as a function of temperature</u> of the back-up power source, in order to inhibit the power source from generating harmful gases and to prevent electrolyte loss, thereby enhancing the service life of the back-up power source and increasing the possible number of recharge cycles.” Ex. 1010 at 5:42-50 (emphasis added). Because Barreras ’313 already teaches a control circuit that regulates charging based on temperature, incorporating the maximum temperature variable from

	Claim Language	Barreras ’313 in view of Barreras
		Barreras would necessarily control the transfer of energy based on the comparison with the programmable limit. Ex. 1003, ¶¶ 223–224.
12.0	*See* claim 12.0 in Section IV.C	See [7.0] disclosures in Section IV.E.
14.0	*See* claim 14.0 in Section IV.C	As described in Section IV.A.3, Barreras teaches use of a variable temperature maximum in the context of supporting differing charge regimens and allowing downloads of new software revisions and improvements. The ’112 patent states that temperature limits may change in response to: “conditions and regulations [that] may change or be different in different circumstances.” Ex. 1001 at 16:8-12. Thus, a change in “circumstances” refers to either conditions or regulations. A POSITA would have been aware that standards and regulations vary by jurisdiction and over time, and it would have been obvious that one reason for modifying the programmable limit of Barreras would be to tailor it to the then-prevalent (both jurisdiction and temporally) safety standards. Ex. 1003, ¶ 227.
15.0	*See* claim 15.0 in Section IV.C	See [1.0] disclosures in Section IV.E.
15.1	*See* claim 15.1 in Section IV.C	See [1.0] disclosures in Section IV.E.

	Claim Language	Barreras ’313 in view of Barreras
19.0	*See* claim 19.0 in Section IV.C	See [1.0] disclosures in Section IV.E.
19.1	*See* claim 19.1 in Section IV.C	See [8.1] disclosures in Section IV.G.
19.2	*See* claim 19.2 in Section IV.C	See [8.3] and [8.4] disclosures in Section IV.G.
19.3	*See* claim 19.3 in Section IV.C	See [8.2] disclosures in Section IV.G.
20.0	*See* claim 20.0 in Section IV.C	See [7.0] disclosures in Section IV.E.
21.0	*See* claim 21.0 in Section IV.C	See disclosures for [22.0] in Section IV.E.

Thus, the combination of Barreras ’313 in view of Barreras renders claims 8, 12, 14, 15 and 19-21 obvious.

H. Ground 8: Claims 9-11 and 13 are unpatentable as obvious over Barreras ’313 in view of Barreras and further in view of Wang

Claims 9-11 and 13 introduce limitations relating to controlling charging based on temperature. Claim 9 introduces limitations relating to adjusting a rate of energy transfer. Claim 10 introduces limitations relating to limiting the current driving the primary coil. Claims 11 and 13 introduce limitations relating to limiting the time during which energy is transferred.

These limitations are disclosed in Wang as shown in Sections IV.B.1, IV.B.2 and IV.B.3, respectively. A POSITA would have been motivated to combine Barreras '313 and Barreras with Wang because all three references related to transcutaneous charging of an implanted medical device.

In light of their common goal of avoiding overheating during charging, a POSITA would be motivated to utilize Wang's approach of adjusting a rate of energy transfer (claim 9) as discussed in Section IV. B.1, or by limiting the current driving the primary coil (claim 10) as discussed in Section IV.B.2, or by limiting the time during which energy is transferred (claims 11 and 13) as discussed in Section IV.3, in order to ensure compliance with industry standards of temperature rise, as described in Wang.

Thus, the combination of Barreras '313 in view of Barreras and further in view of Wang renders claims 9-11 and 13 obvious.

V. MANDATORY REQUIREMENTS

A. Ground for Standing

Axonics certifies that the '112 patent is available for IPR and Axonics is not barred or estopped from requesting an IPR of the challenged claims. This petition is timely filed within one year of the service of Medtronic's complaint alleging infringement of the '112 patent. Ex. 1016.

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

1. Real Parties in Interest

Axonics is the real party in interest for this Petition.

2. Related Matters

The '112 Patent is at issue in *Medtronic, Inc. v. Axonics Modulation Techs., Inc.*, No. 8:19-cv-02115-DOC-JDE (C.D. Cal.).

The '112 Patent is related to U.S. Patent No. 9,463,324, against which Axonics is filing a separate petition for IPR concurrently with this Petition.

3. Fees

Petitioner requests review of 22 claims of the '112 patent. This Petition is accompanied by a payment of $34,700.00, which includes the $15,500.00 inter partes review request fee, and the $19,200.00 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).

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

Axonics serves this Petition and all exhibits to the correspondence address of record for the '112 Patent pursuant to 37 C.F.R. § 42.105(a) and the Certificate of Service. Axonics consents to be served via lead and back-up counsel identified below at the mailing and e-mail addresses below.

Respectfully submitted,

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

Lead Counsel	Back-Up Counsel
A. James Isbester Registration No. 36,315 jisbester@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	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 13,990 words according to the word-processing program used to prepare this paper (Microsoft Word). Petitioner certifies that this Petition for *Inter Partes* Review does not exceed the applicable type-volume limit of 37 C.F.R. § 42.24(a).

Dated: March 16, 2020 /s/ *A. James Isbester*

Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,463,112, including its supporting Exhibits (1001-1016) has been served via USPS Priority Express Mail on March 16, 2020 upon Patent Owner's correspondence address of record for U.S. Patent 9,463,112:

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
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[Additional counsel identified on next page]

Vivek V. Krishnan: vkrishnan@winston.com
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Respectfully,

Dated: March 16, 2020

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